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A clinical study to evaluate the efficacy of *Khaakhasadi Lepa* in *Padadari* (Crack Heel)

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ABSTRACT

Padadari = Pada + Dari. *Padadari* is one among *Kshudra Rogas*. *Sushruta*, *Madhavnidana* and *Bhavprakasha* has explained *Padadari* as distinct disease. In modern, it is termed as crack heel. *Padadari* is a *Vatapradhana Vyadhi. Vataprakopa* leads to the symptoms as *Padasputana*, *Vedana*, *Rukshata* and *Daha*. *Atichankramana* and *Vataprakopaka Ahara* and *Vihara* are the main cause for *Padadari*. *Khaakhasadi Lepa* has *Vatahara, Vranashodhaka, Vranaropaka, Twagdoshahara*, *Kandughna* properties which helps in *Samprapti Vighatana* of *Padadari*. The study is attempt to clinically analyze the efficacy of *Khakhasadi Lepa* indendently and compare with Moisturex cream in *Padadari*. This study is a randomized single blind standared control clinical study conducted on 60 subjects divided randomly in two groups. Group A (Trial group) and Group B (Control group) were formed with 30 patients in each group. Group A was treated with *Khaakhasadi Lepa* for one month. Group B was treated with Moisturex cream for one month. Lepa was adviced to apply in night on affected area of sole in quantity sufficient. Cleaning of sole and after proper drying, application of lepa was advised.The patients were assessed with severity of symptoms subjectively before and after treatment. Data from each group is statistically analyzed and compared. Both the group showed marked results but *Khaakhasadi Lepa* showed statistically highly significant result in subjective parameter like *Vedana* and *Rukshata*. *Khakhasadi Lepa* is not that much significant in *Padasputana* as compare to Moisturex cream. The study shows that *Khaakhasadi Lepa* and Moisturex cream had got equally significant relief in *Vedana* and *Rukshata*. Both drugs were insignificant in reducing *Daha*. *Khakhasadi Lepa* was not more effective in *Padasputana*.

Key words: *Padadari, Khaakhasadi Lepa, Moisturex Cream.*

INTRODUCTION

Ayurveda is termed as the science of life where in are laid down the good and bad of life, the happy and unhappy life and what is wholesome and unwholesome in relation to life. Ayurveda always emphasizes on maintenance of healthy body, in fact its first aim itself, is preservation and protection of normal health i.e. maintain the health of *Swastha Purusha* and cure the *Vyadhi* of *Atura Purusha*.[1] Ayurveda has explained many protective measures in certain regimens such as *Dinacharya*[2] and *Rutucharya*.[3]

Now a day, in developing countries like India, man has to compete for good economical status. In order to get such desired life, one has to live continuous busy and stressful life. Such lifestyle contributes poor hygiene and irregular dietary habits also. All these factors lead to disturbance of healthy aspect of *Dinacharya* and causes common problems of skin. *Padadari* is one of them. *Pada* is foot. *Dari* means crack. *Padadari* is one among the *Kshudra Rogas*.

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In modern science, *Padadari* is called crack heel. Crack heel is commonest and most negligible disease. In India 80% of population live in rural area. Most of them work in farms in wet soil and water. So the incidence of cracking the skin of foot is very common. Also due to hurried life, peoples are unable to spare time for foot protection. This negligence leads to crack heel. Most of people ignore this problem due to lack of consciousness about foot care or may be due to costly drugs. Common causes for crack foot include use of inappropriate foot wear, hot and dry weather that removes moisture from exposed skin, overweight, excessive walking etc. In Ayurveda, *Padadari* is described as *Kshudraroga* by *Sushruta*,[4] *Madhavnidana*,[5] *Bhavprakasha*,[6] *Yogratnakara*[7] etc. *Padadari* involves *Vruddha Vata Dosha*. It is characterized by mild to severe forms of the cracks which are seen on foot, more common on heels. It leads to signs and symptoms of *Vedana, Daha, Rookshata,* sometimes *Raktasrava* in severe cases.[5],[6] Ayurveda has mentioned *Trividha Aushadha* as *Antahaparimarjana*, *Bahiparmarjana* and *Shastra Paridhana. Antahaparimarjana* includes *Samshodhana* and *Sanshamana*. And *Bahiparimarjan* includes *Abhyanga, Pradeha, Sweda, Pralepa* etc.[8] As the *Padadari* involves *Vrudhha Vata Dosha*, the line of treatment is controlling *Vata*, overwhelming dryness and heeling the cracks, which is possible by cleaning, drying and applying *Sneha Dravyas* (lubricants) to affected area. Modern science also tells to treat the crack feet with proper moisturizers. In *Padadari* local treatment is more effective than systemic in short duration. Many *Bahya* (local) *Lepas* are mentioned in *Padadari Chikitsa* in Ayurvedic *Samhita*. In *Vangasen Samhita, Khaakhasadi Lepa* is prescribed for *Padadari*.[9] It contains *Khuskhusbeeja, Dhamargav, Musta* and *Go-ghruta*. In the study an attempt is made to evaluate the efficacy of *Khakhasadi Lepa* on *Padadari* and It's efficacy is compared with Moisturex cream.

Objectives of the Study

A clinical study to evaluate the efficacy of *Khakhasadi Lepa* in *Padadari* (Crack Heel).

Materials and Methods

60 Patients of *Padadari* within the age group of 20-60yrs were selected randomly from OPD of BLDEA's AVS Ayurveda Mahavidyalaya Hospital and Research centre, Vijayapura and Camps conducted in the city (Vijayapura) by the institute, irrespective of sex, occupation and socio-econimic status.

Diagnostic criteria

Diagnosis was made on the basis of *Lakshanas* of *Padadari*.

Inclusion criteria

- Irrespective of sex and occupation.
- Age 20yrs to 60 yrs.
- Having good orientation and ability to communicate orally.
- Patients having *Samanya Lakshanas* (*Padasputana*, *Vedana, Rookshata, Daha*) of *Padadari*.

Exclusion criteria

- Suffering from any systemic and dreadful diseases.
- Suffering from Diabetes, Psoriasis, Athletes foot and Thyroid disease.

Intervention

While making group simple random sampling procedure was adopted.

Group A:

30 patients were treated with *Khakhasadi Lepa*. *Lepa* was adviced to apply in night on affected area of sole in quantity sufficient. Cleaning of sole and after proper drying, application of *Lepa* was advised.

Group B:

30 patients were treated with Moisturex cream. Cream was adviced to apply in night on affected area of sole in quantity sufficient. Cleaning of sole and after proper drying, application of cream was advised.

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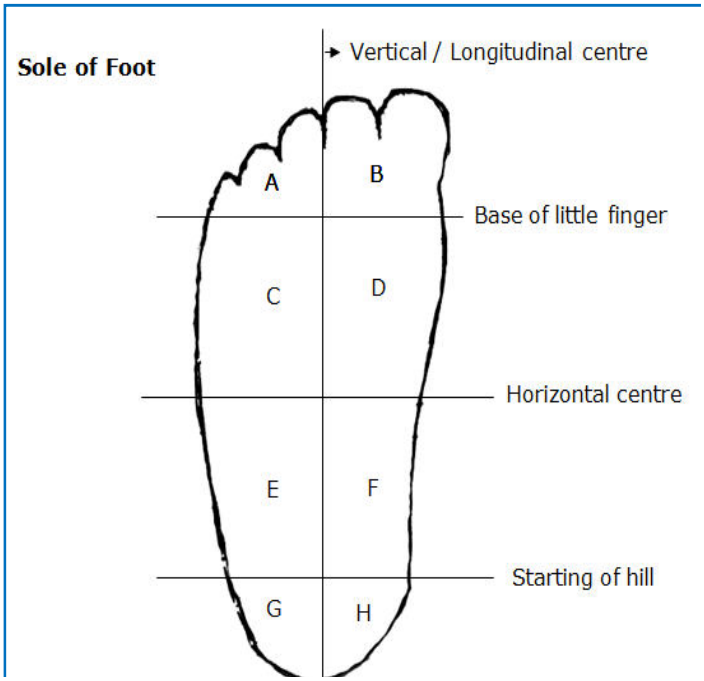
Assessment criteria

A detailed proforma was prepared for the assessment of subjective and objective parameters by grading them. The data obtained was recorded statistically.

Subjective criteria

1. *Padasputana*

Quadrant	A	B	C	D	E	F	G	H
No. of cracks								



2. *Vedana*

- *Rookshata*
- *Daha*

Objective criteria

- Haemoglobin percentage.
- Random blood sugar.
- Tridot test.
- Thyroid function test.

Observations and Results

As grading used for assessment parameters were ordinal in nature, "Wilcoxon Signed Rank test" is used for intra-group comparison. (i.e. before and after treatment of a group) while for inter-group comparison, (i.e. for comparing two groups with each other) "Mann-Whitney U test" is used.

Padasputana

Right Leg

Table 1: Showing effect in *Padasputana* at quadrant-A of right sole.

Group	B.T.	A.T.	diff	Median diff.	n	Wilcoxon signed rank test	P - value
Group A	1.00	0.67	0.33	0.00	3	1.00	0.500
Group B	1.00	0.50	0.50	0.50	4	3.00	0.173

In group A, the reduction in *Padasputan* score for quadrant A of right sole after treatment is not significant (P-value = 0.500) at 5% level of significance. i.e. It can be said that there is no significant reduction in *Padasputana* for Group A at quadrant-A of right sole. For group B, the median reduction in *Padasputana* score after treatment is not significant (P-value = 0.173) at 5% level of significance. i.e. in Group B too, there is no significant reduction in *Padasputana* at quadrant-A of right sole.

Table 2: Showing effect in *Padasputana* at quadrant-B of right sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann-Whitney U test	P - value
Group A	1.00	0.60	0.55	14.00	0.913
Group B	1.00	0.67	0.52		

Reduction in *Padasputana* score for Group A and Group B were not significantly different (P - value = 0.913) at 5% level of significance. Thus, although, group B has significant reduction in *Padasputana* and group A has not, there was no significant difference between efficacy of treatment A and treatment B. Thus, both treatments can be considered as equally

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effective with *Padasputana* at quadrant-B of right sole.

Table 3: Showing effect in *Padasputana* at quadrant-C of right sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann-Whitney U test	P - value
Group A	0.00	0.42	0.51	44.00	0.754
Group B	0.50	0.50	0.53		

Reduction in *Padasputana* score for group A and group B were not significantly different (P-value = 0.754) at 5% level of significance. Thus, both treatments A and treatment B can be considered as equally effective in reducing *Padasputana* at quadrant-C of right sole.

Table 4: Showing effect in *Padasputana* at quadrant-D of right sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann Whitney U test	P - value
Group A	0.50	0.50	0.51	229.50	0.727
Group B	1.00	0.56	0.51		

Reduction in *Padasputana* score for Group A and Group B were not significantly different (P-value = 0.727) at 5% level of significance. Thus, both treatments A and treatment B can be considered as equally effective in reducing *Padasputana* at quadrant-D of right sole.

Table 5: Showing effect in *Padasputana* at quadrant-E of right sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann-Whitney U test	P - value
Group A	0.50	0.50	0.52	72.00	0.490
Group B	1.00	0.64	0.50		

Reduction in *Padasputana* score for group A and group B were not significantly different (P-value = 0.490) at 5% level of significance. Thus, both treatments A and treatment B can be considered as equally effective in reducing *Padasputana* at quadrant-E of right sole.

Table 6: Showing effect in *Padasputana* at quadrant-F of right sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann-Whitney U test	P - value
Group A	1.00	0.57	0.53	7.50	1.000
Group B	0.50	0.50	0.71		

Reduction in *Padasputana* score for group A and group B were not significantly different (P-value = 1) at 5% level of significance. Thus; Although, the reduction in group A was significant and group B was insignificant, there was no significant difference in efficacy of treatment A and treatment B. Thus, both treatments A and treatment B can be considered as equally effective in reducing *Padasputana* at quadrant-F of right sole.

Table 7: Showing effect in *Padasputana* at quadrant-G of right sole.

Group	B.T	A.T	diff	Median diff.	sample size	Wilcoxon signed rank test	P-value
Group A	1.83	1.30	0.53	1.00	30	136.00	0.000
Group B	2.17	1.23	0.93	1.00	30	276.00	0.000

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Reduction in *Padasputana* score for group B was significantly higher (P-value = 0.015) than that in group A at 5% level of significance. Thus, treatment B can be considered as more effective than treatment A in reducing *Padasputana* at quadrant-G of right sole.

Table 8: Showing effect in *Padasputana* at quadrant-H of right sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann-Whitney U test	P - value
Group A	0.00	0.47	0.51	294.00	0.008
Group B	1.00	0.87	0.57		

Reduction in *Padasputana* score for Group B was significantly higher (P-value = 0.008) at 5% level of significance. Thus, treatment B can be considered as more effective than treatment A in reducing *Padasputana* at quadrant-H of right sole.

Left Leg

Table 9: Showing effect in *Padasputana* at quadrant-A of left sole.

Group	B.T	A.T	diff	Median diff.	sample size	Wilcoxon signed rank test	P-value
Group A	1.00	0.50	0.50	0.50	2	1.00	0.500
Group B	1.00	0.50	0.50	0.50	2	1.00	0.500

In group A, the reduction in *Padasputana* score for quadrant A of left sole after treatment is not significant (P-value = 0.500) at 5% level of significance. i.e. it can be said that there is no significant reduction in *Padasputana* for Group A at quadrant-A of left sole. For group B, the median reduction in *Padasputana* score after treatment is not significant (P-value = 0.500) at 5% level of significance. i.e. in group B too, there is no significant reduction in *Padasputana* at quadrant-A of left sole.

Table 10: Showing effect in *Padasputana* at quadrant-B of left sole.

Group	B.T.	A.T.	diff	Median diff.	n	Wilcoxon signed rank test	P-value
Group A	1.00	0.50	0.50	0.50	4	3.00	0.173
Group B	1.00	0.62	0.38	0.00	8	6.00	0.074

In group A, the reduction in *Padasputana* score for quadrant B of left sole after treatment is not significant (P-value = 0.173) at 5% level of significance. i.e. it can be said that there is no significant reduction in *Padasputana* for Group A at quadrant-B of left sole. For group B, the median reduction in *Padasputana* score after treatment is not significant (P-value = 0.074) at 5% level of significance. i.e. in group B too, there is no significant reduction in *Padasputana* at quadrant-B of left sole.

Table 11: Showing effect in *Padasputana* at quadrant-C of left sole.

Group	B.T	A.T	diff	Median diff.	sample size	Wilcoxon signed rank test	P-value
Group A	1.00	0.70	0.30	0.00	10	6.00	0.074
Group B	1.00	0.67	0.33	0.00	3	1.00	0.500

In group A, the reduction in *Padasputana* score for quadrant C of left sole after treatment is not significant (P-value = 0.074) at 5% level of significance. i.e. it can be said that there is no significant reduction in *Padasputana* for Group A at quadrant-C of left sole.

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For group B, the median reduction in *Padasputana* score after treatment is not significant (P-value = 0.500) at 5% level of significance. i.e. in Group B too, there is no significant reduction in *Padasputana* at quadrant-C of left sole.

Table 12: Showing effect in *Padasputana* at quadrant-D of left sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann-Whitney U test	P-value
Group A	0.00	0.33	0.49	130.00	0.216
Group B	1.00	0.55	0.51		

Reduction in *Padasputana* score for group A and group B were not significantly different (P-value = 0.216) at 5% level of significance. Thus, both treatments A and treatment B can be considered as equally effective in reducing *Padasputana* at quadrant-D of left sole.

Table 13: Showing effect in *Padasputana* at quadrant-E of left sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann-Whitney U test	P-value
Group A	0.00	0.45	0.52	49.50	0.425
Group B	1.00	0.64	0.50		

Reduction in *Padasputana* score for Group A and Group B were not significantly different (P-value = 0.425) at 5% level of significance. Thus, both treatments A and treatment B can be considered as equally effective in reducing *Padasputana* at quadrant-E of left sole.

Table 14: Showing effect in *Padasputana* at quadrant-F of left sole.

Group	B.T.	A.T.	diff	Median diff.	n	Wilcoxon signed rank test	P-value
Group A	1.33	1.00	0.33	0.00	6	3.00	0.173
Group B	1.00	0.50	0.50	0.50	2	1.00	0.500

In Group A, the reduction in *Padasputana* score for quadrant F of left sole after treatment is not significant (P-value = 0.173) at 5% level of significance. i.e. it can be said that there is no significant reduction in *Padasputana* for Group A at quadrant-F of left sole. For Group B, the median reduction in *Padasputana* score after treatment is not significant (P-value = 0.500) at 5% level of significance. i.e. in Group B too, there is no significant reduction in *Padasputana* at quadrant-F of left sole.

Table 15: Showing effect in *Padasputana* at quadrant-G of left sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann-Whitney U test	P-value
Group A	0.00	0.48	0.51	297.50	0.016
Group B	1.00	0.83	0.53		

Reduction in *Padasputana* score for Group B was significantly higher (P-value = 0.016) than that in Group A at 5% level of significance. Thus, treatment B can be considered as more effective than treatment A in reducing *Padasputana* at quadrant-G of left sole.

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Table 16: Showing effect in *Padasputana* at quadrant-H of left sole.

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann Whitney U test	P-value
Group A	0.00	0.41	0.50	286.50	0.012
Group B	1.00	0.83	0.65		

Reduction in *Padasputana* score for Group B was significantly higher (P-value = 0.012) than Group A at 5% level of significance. Thus, treatment B can be considered as more effective than treatment A in reducing *Padasputana* at quadrant-H of left sole.

Vedana

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann Whitney U test	P-value
Group A	1.00	0.83	0.39	299.00	0.528
Group B	1.00	0.75	0.53		

Reduction in *Vedana* score for Group A and Group B were not significantly different (P-value = 0.528) at 5% level of significance. Thus, both treatments A and treatment B can be considered as equally effective in reducing *Vedana*.

Rukshata

Group	Median diff (BT-AT)	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Mann Whitney U test	P-value
Group A	1.00	0.90	0.55	475.50	0.646
Group B	1.00	0.83	0.53		

Reduction in *Rukshata* score for group A and group B were not significantly different (P-value = 0.646) at 5% level of significance. Thus, both treatments A and treatment B can be considered as equally effective in reducing *Rukshata*.

Daha

Group	B.T.	A.T	diff	Median diff.	n	Wilcoxon signed rank test	P-value
Group A	1.30	1.00	0.30	0.00	10	6.00	0.074
Group B	1.00	0.67	0.33	0.00	9	6.00	0.074

In Group A, the reduction in *Daha* score after treatment is not significant (P-value = 0.074) at 5% level of significance. i.e. it can be said that there is no significant reduction in *Daha* for Group A. For group B, the median reduction in *Daha* score after treatment is not significant (P-value = 0.074) at 5% level of significance. i.e. in Group B too, there is no significant reduction in *Daha*.

Overall assessment of therapy

Variables	Group A	Group B	Comparative efficacy
Padasputana			
Right leg - Quadrant A	Insignificant	Insignificant	-
Right leg - Quadrant B	Insignificant	Significant	Equally effective
Right leg - Quadrant C	Significant	Significant	Equally effective
Right leg - Quadrant D	Significant	Significant	Equally effective
Right leg - Quadrant E	Significant	Significant	Equally effective

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Right leg - Quadrant F	Significant	Insignificant	Equally effective
Right leg - Quadrant G	Significant	Significant	Group B
Right leg - Quadrant H	Significant	Significant	Group B
Left leg - Quadrant A	Insignificant	Insignificant	-
Left leg - Quadrant B	Insignificant	Insignificant	-
Left leg - Quadrant C	Insignificant	Insignificant	-
Left leg - Quadrant D	Significant	Significant	Equally effective
Left leg - Quadrant E	Significant	Significant	Equally effective
Left leg - Quadrant F	Insignificant	Insignificant	-
Left leg - Quadrant G	Significant	Significant	Treatment B
Left leg - Quadrant H	Significant	Significant	Treatment B
Vedana	Significant	Significant	Equally effective
Rukshata	Significant	Significant	Equally effective
Daha	Insignificant	Insignificant	-

Overall effect of therapy

Overall Effect (patient wise)	**No. of patients**			
	Group A		**Group B**	
	Count	**%**	**Count**	**%**
Excellent	07	23.33%	13	43.33%
improvement				
Good improvement	10	33.33%	09	30.00%
Moderate improvement	03	10.00%	01	03.33%
Mild improvement	10	33.33%	07	23.33%
Total	**30**	**100.00%**	**30**	**100.00%**

Group A - 7 patients (23%) were observed with excellent improvement 10 patients (33%) were with good improvement, 3 patients (10%) were with moderate improvement while 10 patients (33%) were found with mild improvement.

Group B - 13 patients (43%) realized marked improvement 9 patients (30%) were with good improvement, 1 patient (3%) was with moderate improvement while 7 patients (23%) were observed with mild improvement.

DISCUSSION

The disease '*Padadari*' has been explained under *Kshudra Roga* by *Sushruta*, *Bhavaprakasha* and *Yogaratnakara*. In one who does excessive walking on foot, the *Vata* located in sole gets vitiated brings in dryness of the area by absorbing all the moisture and *Kleda* thus produces painful cracks in excessively dry feet. It is known as *Padadari*. Habit of excess walking is the foremost causative factor for the disease. No pre monitory symptoms have been explained for *Kshudra Roga,* hence not even to *Padadari*. *Dari* on dorsum of foot which will shows signs and symptoms as *Vedana* and *Rookshata*. Due to continuous indulgence into *Vatakara Vihara* such as excessive walking *Vata* gets vitiated leading to *Twak* and *Mamsadarana* and *Rasakshaya* manifesting the *Vyadhi Padadari.*

Among 60 patients, Maximum patients were belonging to age group 40-44 years and then 20-24 years. It may be due to *Atichankarma* of this age group. In 60 patients, 46 patients were female

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patients and 14 were male patients. This indicates that females are more prone to *Padadari*. It is due to etiological factor like exposure to cold (i.e. water, cold). Among 60 patients, 27 patients were workers and 14 patients were females. Workers which are in contact with water, dust are prone to *Padadari*. Among 60 patients, 58 pateints are hindu by religion and 2 were muslims. According to Socioeconomic status - In 60 patients, 32 were from middle class and 28 from lower class. Due to hurried life, unhygienic food intake, standing jobs and ignorance of foot care, middle class peoples more prone to *Padadari*. In 60 patients, 26 pateints were of *Vatapitta Prakriti*, 19 patients were of *Vatakapha Prakriti* and 15 patients were of *Pittakapha Prakriti*. None of *Vata, Pitta* or *Sannipataja Prakriti* was found. As *Vata* and *Pitta* predominance in etiopathogenesis of *Padadari*, *Vata* and *Pitta Pradhana Prakriti* peoples are prone to *Padadari*.

Padasputana were observed more in Quadrant G and H than any other quadrant because the posterior part of foot is the main load bearing part of body. Percentage of relief is more seen in Group B than Group A. Among 60 patients maximum patients having moderate symptoms while minimum having severe symptoms. According to statistics percentage of relief was 52.17 % in Gr. A and 54.86 % in Gr. B. Patient in both the group had got nearby same and significant relief from *Vedana*. Among 60 patients, according to statastics percentage of relief was 56.17 % in Gr. A and 60.00 % in Gr. B. Patient in both group had got nearby same and significant relief from *Rukshata*. Among 60 patients, according to statastics percentage of relief was 25.00 % in Gr. A and 33.33 % in Gr. B. Patient in both group had got insignificant relief from *Daha*.

CONCLUSION

Patient having *Padadari* were mainly from the middle age and working class. It was due to Poor hygiene of foot and doing work or *Atichankraman* especially foot wear. *Padadari* was more prevalent in those who had frequent exposure to mud or soil, those who were not using foot wears, exposure to cold weather, detergents etc. *Padasputan* was observed more in Quadrant G & H as compared with other quadrant because the posterior part of foot is the main load bearing part of body. After analyzing all the data and the observations, application of both the *Lepa* i.e. *Khakhasadi Lepa* (Group A) and Moisturex cream (Group B) is effective in *Padadari*. But we have seen that Control drug, moisture cream is more effective than *Khakhasadi Lepa*. *Khakhasadi Lepa* was not more effective in *Padasputana* as compared with Moisturex cream, but has nearby same result in *Vedana* and *Rukshata*. *Khakhasadi Lepa* was effective in *Vedana* and *Rukshata* as compared with Moisturex cream.

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