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The efficacy of Vidanga Triphaladi Lepa and Chandanadi Lepa in the management of Padukavisha (footwear dermatitis) - A comparative clinical trial

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Introduction: Footwear dermatitis is a CD4-T-lymphocyte mediated type-IV hypersensitivity reaction representing a distinct group among the common types of contact dermatitis reported in India with an overall prevalence of 11.7%. It is often misdiagnosed and if left untreated or mismanaged, may exacerbate causing permanent disfigurement of the skin leading to physiological, psychological and social impacts. This type of dermatitis can be correlated to Padukavisha in Ayurveda. **Methods:** The study was a comparative clinical trial involving 90 participants diagnosed with footwear dermatitis, randomly allocated into trial and control groups. Patch test was done for both groups to test the antigen sensitivity. Trial group received Vidangatriphaladi Lepa and control group received Chandanadi Lepa. Both groups received Dushivishari Agada as internal medicine. Clinical data was collected Before Treatment, 8th day, 15th day and on the 22nd day (follow-up). **Results:** Results concluded that the trial drug was more effective than the control in managing 4 of the 5 symptoms of Paduka Visha ($p<0.001$). The symptom Swapa had better result with the control drug. **Discussion and conclusion:** Vidangatriphaladi Lepa which is effective in poisoning and skin disorders, is found to be more effective than Chandanadi Lepa in managing Padukavisha.

Keywords: Footwear dermatitis, Padukavisha, Vidangatriphaladi Lepa, Agadatantra, Ayurveda

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Introduction

Footwear dermatitis (shoe-contact dermatitis) occurs when the skin over the feet reacts with certain antigens found in footwear, thus leading to a CD4-T-lymphocyte mediated type-IV hypersensitivity reaction culminating cutaneous inflammatory changes.[1] It represents a distinct group among the common types of contact dermatitis reported in India with an overall prevalence of 11.7%.[2],[3] Footwear dermatitis is often misdiagnosed as several other lower extremity dermatitis such as psoriasis, atopic dermatitis, cellulitis etc. If left untreated or mismanaged, the symptoms may exacerbate resulting in permanent disfigurement of the skin often leading to physiological, psychological and social impacts.[4]

Patch test is a method used to determine whether a specific substance causes allergic inflammation on skin. Patch testing is a well-established method of diagnosing contact allergy, a delayed type of hypersensitivity (Type IV reaction).[5] Patients with contact dermatitis are re-exposed to the suspected allergens under controlled conditions to confirm the diagnosis.[6]

Gara, as per *Agada Tantra* (a sub branch of Ayurveda) is a type of *Kritrima Visha* (artificial poison), considered as a mixture of poisonous and non-poisonous substances which can result in infirmities when ingested or when kept in close contact. The possible modes through which *Gara* can enter the body are enumerated in principal Ayurveda literatures.[7-10] *Paduka Visha* is a common condition among these modes, often misdiagnosed or mismanaged. It is clinically presented with *Sopha* (swelling*), Srava* (exudation*), Swapa* (loss of sensation) and *Sphoṭa* (blistering).[9] Previous studies observed *Kaṇḍu* (itching) also as a prodromal symptom of *Paduka Visha.*[11] This symptomatology goes hand in hand with the presentation of Allergic footwear dermatitis described in conventional medicine.

Chandanadi choorna is a type of *Lepa* (external application) mentioned in the treatment of *Paduka Visha,*[9] and is commonly prescribed by Ayurveda practitioners. But on continuous usage it was observed to inflict adverse effects, possibly due to one of its mineral ingredient *Sasyaka* (copper sulphate).[11] *Vidangatriphaladi Choorna* is another *Lepa,* mentioned for the treatment of *Viṣhaja Sopha*, an inflammatory swelling Developed as a result of contact with poisonous substances.[10] Hence, it can be used in *Paduka Visha,* a condition arising due to repetitive contact with possible allergens present in footwear. The present paper discusses the efficacy of *Vidangatriphaladi Lepa* over *Chandanadi Lepa* in the management of *Paduka Visha* (footwear dermatitis).

Aims and Objectives

01. To assess the efficacy of *Vidangatriphaladi Lepa* in the management of *Paduka Visha* (footwear dermatitis).
02. To compare the efficacy of *Chandanadi Lepa* with *Vidangatriphaladi Lepa* in the management of *Paduka Visha* (footwear dermatitis).

Materials and Methods

Study Design

The study was a comparative clinical trial on 90 patients diagnosed with *Paduka Visha* (footwear dermatitis).

Source of data

Primary data was collected from 90 Subjects who satisfied the inclusion criteria, attending the *Agadatantra* Out-Patient Department of Vaidyaratnam PS Varier Ayurveda College Hospital, Kottakkal.

Study Setting

Agadatantra Out-Patient Department of VPSV Ayurveda College Hospital, Kottakkal, Kerala.

Study Period

The study was completed during a period of 9 months (March 2018 to December 2018)

Sampling

90 subjects who satisfied the inclusion criteria and tested positive for patch test for footwear dermatitis were selected for the trial from the patients who attended the *Agadatantra* OPD during the study period. The participants were allocated into two groups by simple random sampling using random number table method. Group I (Trial) received *Vidangatriphaladi Lepa* and Group II (control) received *Chandanadi Lepa.* Both groups received *Dushivishari Agada* as internal medicine.

Inclusion criteria

- *Sopha, Srava, Swapa, Sphoṭa*

- Subjects who presented with and *Kaṇḍu* in foot.
- Subjects of any gender aged 18-70 years.
- Positive Patch test.
- Participants ready to give an informed consent.

Exclusion criteria

- Participants with a history of Atopic dermatitis.
- Patients with serious systemic disorders including Diabetes Mellitus or Hypertension.
- Lactating and pregnant women.
- Subjects on concomitant dermatological medications.
- Subjects with any substance abuse or insanity.
- Subjects with Immuno-deficiencies.

Method of collection of data

The participants who satisfied the inclusion criteria were selected. Clinical data was collected on the 0th day (Before Treatment), 8th day (D8), 15th day (D15) and on the 22nd day (D22) after follow-up. Patch test was initially done for the participants and the data was recorded.

Patch test

Patch test was done using Indian Standard Footwear Series (ISFS) approved by Contact and Occupational Dermatoses Forum of India (CODFI). Patch test kit was purchased from Systopic Laboratories Private limited, 305, Pragati chambers, commercial complex, Ranjit Nagar, New-Delhi110008. Each kit contained 20 antigen strips and 60 finn chamber strips. A written consent was obtained from each participant after detailing the procedure and instructions of the test.

Procedure

The strip was fixed on the upper back of the patient using standard techniques.**[12]** Patients were strictly instructed to avoid bath and any strenuous work that can induce sweating. On return after 48 hours, the strips were removed and the sensitivity to the allergens were identified according to the grading (Table. 1). On any adverse reactions, the participants were instructed to report to the OPD.

Table 1: Grading of patch test

SN	Grade	Criteria	Significance
1.	0	Mild erythema, no oedema	Doubtful
2.	1+	Erythema, oedema and induration	Positive
3.	2+	Erythema, oedema isolated vesicles	Positive
4.	3+	Erythema, oedema and confluent vesicles	Positive

Study tool

A self-designed case record form was used for the assessment of clinical signs and symptoms of the disease. The symptoms were graded according to the severity on 0th day, 8th day, 15th day and 22nd day (Table. 2).

Grading of the Symptoms

Grading of Swelling

No swelling - 0

Mild swelling not well appreciable - 1

Well appreciable swelling causing no discomfort in wearing foot wear - 2

Well appreciable swelling causing discomfort in wearing foot wear - 3

Swelling spread to areas of no contact - 4

Grading of Discharge

No discharge - 0

Moistens the lesion - 1

Mild discharge occasionally on scratching - 2

Profuse discharge on scratch - 3

Discharge without any intervention disturbing routine and sleep - 4

Grading of Numbness

No numbness - 0

Numbness present - 1

Grading of Vesicles

Absence - 0

Erythema - 1

Confined to area of contact - 2

Spread beyond area of contact - 3

Generalized lesion - 4

Grading of Itching

No itching - 0

Mild itching occasionally - 1

Mild itching persists whole day - 2

Severe itching causing discomfort always and with scratch mark - 3

Source and authentication of drugs

The Trial and control drugs (Table 3) were prepared at Arya Vaidya Sala Factory, Kottakkal and were authenticated by experts at Vaidyaratnam PS Varier Ayurveda College, Kottakkal. The drug that was administered internally was procured from Vaidyaratnam Oushadhasala, Thaikkattussery, Ollur.

Table 2: Ingredients of *Chandanadi Lepa* (control)

SN	Sanskrit Name	Binomial Name	Part Used	Ratio
1.	Chandana	Pterocarpus santalinus linn	Heart wood	1 part
2.	Tagara	Valeriana wallichi DC	Root	1 part
3.	Kushta	Sausuurea lappa C B Clarke	Root	1 part
4.	Usira	Vetiveria zizanoides[Linn]	Root	1 part
5.	Venu	Bambusa arundinacea[Retz]Wild	Leaf	1 part
6.	Somavalli	Tinospora cordifolia	Stem	1 part
7.	Amruthasanga	Coppper sulphate		1 part
8.	Sveta	Clitoria ternate Linn	Root	1 part
9.	Padma	Nelumbo nucifera Gaertn	Whole plant	1 part
10	kaliyaka	Coscinium fenestratum [Gaertn] Colebr	Root/stem	1 part
11	Twacha	Cinnamomum zeylanicum	Bark	1 part

Table 3: Ingredients of *Vidangatriphaladi Churna* (trial)

SN	Sanskrit Name	Binomial Name	Part Used	Ratio
1.	Vidanga	Embelia ribes Burm.f	Seed	1 part
2.	Haritaki	Terminalia chebula Retz	Fruit	1/3
3.	Vibhithaki	Terminalia bellerica Roxb.	Fruit	1/3
4.	Amalaka	Emblica officianalis	Fruit	1/3
5.	Maricha	Piper nigrum Linn	Fruit	1/3
6.	Pippali	Piper longum Linn	Fruit	1/3
7.	Sunti	Zingiber officianalis Rose	Rhizome	1 part
8.	Devadaru	Cedrus deodara [Roxb]	Stem bark	1 part
9.	Usira	Vetiveria zizanoides[Linn]	Root	1 part
10	Padmaka	Prunus puddum Roxb.Ex Wall	Heart wood	part

Intervention

Table 4: Details of Intervention

Particulars	Group 1 (trial)	Group 2 (control)
Sample size	45	45
Intervention done	Vidangatriphaladi Lepa	Chandanadi Lepa
Dispensing form	Powder	Powder
Mode of use	External application - local	External application - local
Medium of application	Water	Water
Dosage	Q.S	Q.S
Duration	2 weeks	2 weeks
Internal medication	Dooshivishari Agada	Dooshivishari Agada
Dosage	1gm tablet with plain water taken twice daily for 2 weeks	1gm tablet with plain water taken twice daily for 2 weeks

Statistical tests used

Non-parametric statistical tests were used for the analysis as the data obtained were ordinal.

- Within the group comparison was done with Freidman's test
- Pair wise comparison within the group was done by Wilcoxon signed rank test.
- Mann-Whitney-u test used for in between the group comparison.
- Chi-square test was used to find out any association in between the variables and total score.

Ethical considerations

Ethical committee approval was obtained from Institutional Ethical Committee of Vaidyaratnam P S Varier Ayurveda college, Kottakkal with Approval No. IEC / CL / 03 / 17 dated 27/04/2018.

Observation and Results

Demographic data

Out of 90 participants, 50% were from the age group of 18-23 years. 72.2% were females and the rest 27.8% males. Graduates accounted 48.9% of the participants. 75.6% were from Muslim community and 64% were from middle economic class. 51.1% of the participants were home makers and 22.2% were students.

Appetite and diet

84.4% of the participants had normal appetite while 15.6% of the participants had the reduced appetite.95.6% of the participants were on mixed diet i.e, they consumed both non-vegetarian and vegetarian type of the diet and 4.4% were vegetarians. The bowel was normal for 81.1% of

The participants but constipated type of bowel movement was observed in 18.9% of the participants.

Properties of the drugs

The properties of the trial and control drug are summarized in Table.5, In trial group the participants recieved Vidangatriphaladi Lepa and in control group the participants recieved Chandanadi Lepa. The attributes of both the drugs has been mentioned in the below table.

Table 5: Comparison of attributes of trial and control drugs.

Attributes	Vidangatriphaladi Lepa	Chandanadi Lepa
Rasa (Taste)	Kaṭu Tiktha (Pungent-Bitter)	Kashaya Tiktha Madhura (Astringent-Bitter-Sweet)
Guna (Properties)	Laghu Ruksha Tikshna (Light-Dry-Sharp)	Ruksha Tikshna
Veerya (Potency)	Ushna (Hot)	Ushna
Vipaka (Metabolic effect)	Katu	Madhura
Doshasamanatwa (Function on Dosha)	Pacifies Tridosha	Pacifies Kapha and Pitta

Adverse drug reaction (ADR)

Chandanadi Lepa produced adverse reactions in one participant. Increased burning sensation, superficial ulceration, exudation in the region of the foot (*Srava*) and itching sensation at the region of the foot (*Kandu*) were reported after the application of the medicine.

ADR was managed by the following internal medication.

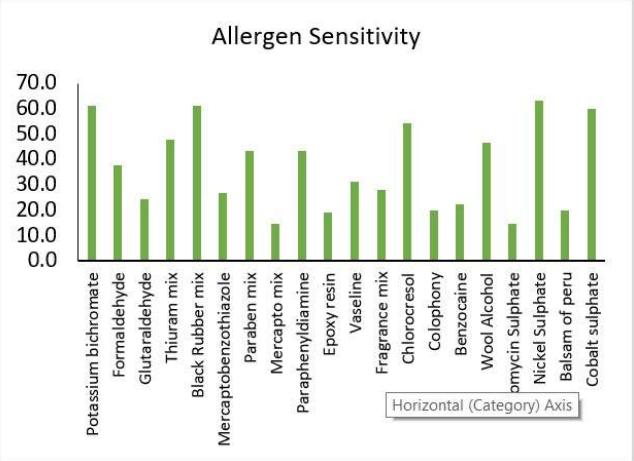
- *Drakshadi Kashaya* - 60 ml twice daily before food
- *Triphala Guggulu* - 1 each after food
- Rinsing the site of the exudation and burning sensation with the decoction of *Triphala*.

The symptoms subsided within 1 week.

Patch test

Majority of the patients showed grade 1 and grade 2 of allergic inflammation on patch test. No adverse reactions were reported. Itching and vesicles at the site of application of patch test strip was noted in few participants. Maximum sensitivity was observed for Nickel sulphate, Black rubber, cobalt sulphate, Paraphenyl diamine and chlorocresol. The percentage of allergen sensitivity is shown in figure

Fig 1: Allergen sensitivity



Results of Intervention

The results are summarised in tables 7 & 8 and figure 2.

Table 7: Summary of Results

Symptoms	Group	Mean BT	Mean D22	Mean rank	Reduction %	P
Sopha	Gp 1	2.35	0.11	57.33	93.1	<0.001
	Gp 2	2.42	1.31	33.67	42.95	<0.001
Srava	Gp 1	1.70	0.06	57.33	94.96	<0.001
	Gp 2	2.33	1.28	33.67	41.48	<0.001
Sphota	Gp 1	2.46	0.22	51.67	92.22	<0.001
	Gp 2	2.42	1.15	39.33	49.44	<0.001
Swapa	Gp 1	1.68	0.08	36.37	98.81	<0.001
	Gp 2	1.80	0.57	54.63	60.44	<0.001
Kandu	Gp 1	3.46	0.64	62.88	80.77	<0.001
	Gp 2	3.46	2.35	28.12	82.11	<0.001
P <0.001 = HS						

Fig 2: Overall effect of trial and control drugs

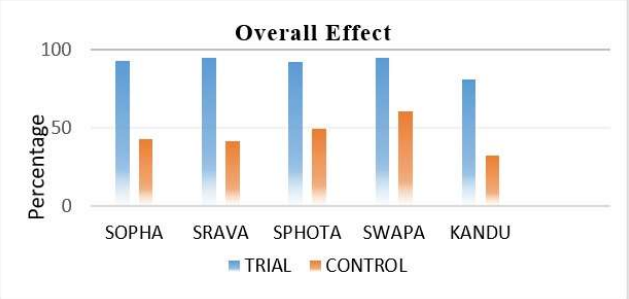


Table 8: Comparison of trial and control group

Symptom		Trial Mean	Trial SD	Control Mean	Control SD
Sopha	BT	2.35	0.77	2.42	0.89
	D8	1.42	0.69	1.68	0.87
	D15	0.11	0.38	1.26	0.96
	D22	0.11	0.38	1.31	2.04
Srava	BT	1.70	0.70	2.33	0.73
	D8	0.50	0.59	1.48	0.92

D15	0.06	0.27	1.17	0.98	
D22	0.06	0.25	1.28	0.96	
Sphota	BT	2.46	0.72	2.42	0.81
	D8	1.04	0.95	1.57	0.91
	D15	0.17	0.64	1.08	1.04
	D22	0.22	0.67	1.15	1.04
Swapa	BT	1.68	0.70	1.80	0.99
	D8	0.48	0.58	1.22	0.92
	D15	0.06	0.25	0.57	0.75
	D22	0.08	0.28	0.57	0.75
Kandu	BT	3.46	0.75	3.46	0.81
	D8	1.91	0.87	2.68	1.08
	D15	0.64	0.48	2.31	1.08
	D22	0.64	0.48	2.35	1.09

Discussion

Footwear dermatitis is a very common diagnostic and therapeutic challenge in dermatological practice in India.**[13]** It is a common disorder with an overall prevalence of 3–11%. Factors like high temperature, humidity, lack of quality control and habitual avoidance of socks are the contributing factors for the upsurge of the incidence of footwear dermatitis in India.**[3],[14],[15]**

Shoe-contact Dermatitis may result from materials like leather, rubber, adhesives, dye, nickel, stockings, topical medicaments, antiseptics, and antiperspirants. The common chemical sensitizers that cause allergic inflammation are Potassium dichromate, Black rubber, Nickel sulphate, Cobalt sulphate, Colophony, and rubber accelerators.**[16]** The impermeability of the footwear maintains the skin contact with the chemicals. The accumulation of sweat increases the hydration of stratum corneum, the outer layer of the skin and percutaneous absorption is increased. Researchers have proved that sweat leaches out chrome from the leather and it is possible that other chemicals are also released in the same manner. The other factors which induce sensitivity are heat, pressure and friction.**[15]**

Paduka or footwear is one among the *Gara Adhishtana* explained in Ayurveda. *Gara Visha* has Acute, sub-acute or chronic toxicity depending on the dose, frequency and duration of exposure.**[7], [9]** So *Gara Visha* can be considered as a combination of chemicals used in the manufacture of substandard footwear. These chemicals can cause allergic inflammation due to repeated and prolonged contact with the skin. It is a T-Lymphocyte mediated type 4 hypersensitivity Reaction which triggers allergic manifestations, especially over skin in contact with the allergen. The diagnosis is done on the basis of the clinical features of *Paduka Visha*. The etiopathogenesis of *Vishaja Sopha* has been considered for better understanding of the disease.**[10]** The clinical features of *Paduka Visha* are *Sopha, Srava, Swapa and Sphota*.**[9]** A few studies have observed *Kandu* also as one of the prominent features. With this observation in the background, the current study has taken these 5 symptoms of *Paduka Visha* into consideration.

Patch test is a method used to determine whether a specific substance causes allergic inflammation on patient's skin. A patch test is a diagnostic method used to determine which specific substances cause allergic inflammation of a patient's skin. Patch testing helps identify which substances may be causing a delayed-type allergic reaction in a patient, and may identify allergens not identified by blood testing or skin prick testing. The common allergens and the percentage of reaction produced in the patch test were Nickel sulphate (80%), Cobalt sulphate (68.85%), Black rubber (64.4%), Chlorocresol (60%), Paraphenyl diamine (57.7%) and wool alcohol (51.1%). Nickel is the most common allergen found in Patch test**[16]** and Nickel is commonly found in buckles and zip of footwears. The current study also revealed similar results with a high share of Nickel sulphate allergy in Patch tests (80%). Majority of participants came under the age group of 18-23 years, and they used fancy shoes and sandals with high nickel content in buckles and zips. Dry itchy skin lesions on areas in contact with the footwear are conclusive of nickel allergy.

50% of the participants were from the age group of 18 to 23 years & 22.2% of the participants were students. This is due to the fact that this age group includes the active phase of one's life where chances of exposure to allergens are high.**[15,17]**

The present study showed more of female participants (72.2%) This may be because of the fact that women use a variety of footwear more than men. The majority of participants were home makers (51.1%) & they are more likely to be exposed to external allergens like cleansing agents, detergents etc. that may cause irritation to the foot & impair epidermal barrier functioning, resulting in an increased penetration of shoe allergens.**[2,18]**

75.6% of the participants were from Muslim community which was obvious as majority of the inhabitants of the district belonged to this community.**[19]**

On evaluating the overall action of the trial drug, it is *Katu-Tikta Rasa* predominant. This property aids to subside itching, poison and skin disorders. It also enhances drying up of mucous and excessive moisture and promotes wound healing.**[20]**

The elemental constitution (*Panchabhauthikatwa*) of these tastes are *Vayu-Agni* and *Akasa-Agni* respectively,**[21]** which imparts *Laghu-Rooksha-Teekshna Guna* in these drugs, enabling fast action and easy penetration. The drug as a combination pacifies *Kapha* and *Pitta Dosha*. The properties of individuals drugs were evaluated in which *Vidanga* has anti-microbial and antifungal effect.**[22]** *Triphala* has high contents of anti-oxidants which protects the cells from free radicals. It also has therapeutic effects on skin diseases, discharges and wounds.**[23,24]** The other components of the drug collectively have anti-oxidant, antimicrobial, anti-bacterial, antifungal, anti-allergic, immuno-modulatory, & wound healing properties.**[25-27]**

The control drug (*Chandanadi Lepa*) is *Kashaya-Tikta-Madhura* in taste and pacifies *Kapha* and *Pitta Dosha*. The *Kashaya* and *Katu Rasa* having *Vruna Sodhana* and *Ropana* property which helps in quick healing of the lesions.**[20]**

*Lepa*is a form of *Sthaanika Chikitsa / Bahiparimarjana Chikitsa* (local treatment/external application), wherein the drugs used come directly in contact with the skin (of the body part) where a response is anticipated. The drugs may be wet or dry, is made into a paste and employed as local application.**[28]**

According to Pallavi *et. al*, 2015; The rationale of the mode of action is postulated in 3 different ways. First, when the *Lepa* is applied on a specific site, it comes in contact with the skin and hair follicles both of which is connected to the peripheral circulation (*Tiryak Gata Dhamani*) which has the function of producing sweat (*Swedavahana*). The active principles of the drug enter the sweat ducts (*Swedavaha Srotas*) and hair follicles to bring about specific therapeutic actions. Thus, topically applied substances can penetrate into the hair follicles, they do not necessarily penetrate through the skin barrier into the living tissue.

Second, After the application of *Lepa*, the active principles of the drug initiate a reaction on the skin, which is due to the *Ushna Guna* of *Bhrajaka Pitta* and *Rasa Dhatwagni*. These two steps correspond to the pathway across stratum corneum and normal tissue.

Finally, these steps lead to *Rasa Tarpana* (nourishment of the *Rasa Dhatu*) achieved by action of *Udana* and *Vyana Vata* that nourishes the integumentary system.**[29]**

The reduction in *Sopha* and *Srava* in the trial group throughout the treatment and follow up period was found to be statistically significant (p value<0.001), while the results became insignificant for the control group in the follow up period. The trial drug, which is mentioned in the management of *Vishaja Sopha* was thus found to be effective in reducing the symptoms of *Paduka Visha*.

Srava, a *Pitta Kapha* dominant condition, which represents the underlying inflammation, was significantly reduced by the trial drug. Its ingredients like *Triphala, Trikatu, Devadaru* and *Usira* having anti-infective and anti-bacterial property must have brought about this remarkable change.**[30]** The control drug was *Kashaya Tikta Madhura* in taste, which may have triggered an increase in *Kapha Dosha,* thereby increasing *Srava* in the follow up period.

Significant reduction in *Sphota* was observed in the trial drug Vidangatriphaladi Lepa and control group drug Chandanadi Lepa at (p<0.001) during the treatment period, but the changes became insignificant during the follow up. The anti-ulcerogenic, anti-inflammatory and anti-infective properties of the both the drugs might have been responsible for the reduction in symptoms of the disease, which eventually dropped with the withdrawal of the medicine and hence a longer duration of the medicine may be suggested for the future studies.

Significant reduction in *Swapa* was observed in the trial group (p<0.001) during the treatment period, but the changes became insignificant during the follow up. But, in the control group, this effect was statistically significant (p< 0.05) even after the follow up. Hence, the control drug was more effective than the trial, with respect to *Swapa* in *Paduka Visha.*

Reduction in *Kandu* was found to be statistically significant in the trial group throughout the treatment period and follow up (p value<0.001), while in the control group the results on sopha became insignificant in the follow up period. The trial drug has a predominance of *Katu Tikta* and it helps in *Kapha Samana.* It is also *Vishahara.* These properties might have collectively reduced the symptom.

Conclusion

Footwear dermatitis is often a misdiagnosed type of contact dermatitis caused by the repetitive contact of certain antigens in the footwear. It can be correlated to a condition called *Paduka Visha* explained in Ayurveda. The study was a comparative clinical trial involving 90 participants to test the efficacy of *Vidangathriphaladi Lepa* over commonly used *Chandanadi Lepa*. Patch test and a self-designed case record form were used to assess the allergens and symptoms. Nickel sulphate, Cobalt sulphate, Black rubber, Leather processing chemicals, Metal buckles adhesives were the most detected allergens. Results concluded that the trial drug was more effective than the control in managing 4 of the 5 symptoms of *Paduka Visha* ($p<0.001$). Avoidance is the mainstay treatment and participants were advised to replace any form of footwear with the identified allergens and also to improve the general immunity through Ayurveda lifestyle guidelines. A robust clinical trial involving the trial drug in a modified form like emollients should be done to affirm the findings of the study.

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