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Research Article

RANDOMIZED CONTROLLED TRIAL ON CANDANAADI LEPA VERSUS TRIPHALA LEPA IN PAADUKA VISHA (FOOTWEAR DERMATITIS) W.S.R. TO ALLERGIC CONTACT DERMATITIS

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Abstract:
Paaduka visha (Footwear dermatitis) represents a distinct and common group among the types of contact dermatitis cases seen in India. This ailment, however, often remains undiagnosed, misdiagnosed or empirically diagnosed without pinpointing the contributory allergens. The main objective of the present study was to evaluate the comparative effect of Candanaadi lepa with Triphala lepa in reducing the cardinal signs and symptoms due to Paaduka Visha viz. swelling, vesicles, oozing and numbness with itching as an associated symptom. A total number of 30 cases with footwear dermatitis were selected and divided randomly into two groups. Criteria for selection were those having exclusively feet dermatitis and positive patch test reactions to standard footwear allergens with significant clinico-allergological correlation. Both the drugs Candanaadi lepa and Triphala lepa were significant in reducing swelling ($P<0.001$) and ($P<0.01$) respectively. Both the drugs were significant in relieving discharge, vesicles and itching ($P<0.001$). Though both the drugs were highly significant, on account of percentage of relief obtained, it was found that Candanaadi lepa was more effective in the management of footwear dermatitis as compared to Triphala lepa.

Keywords: Paaduka visha; Agadatantra; Allergic Contact Dermatitis; Footwear dermatitis; Patch test.

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INTRODUCTION

Ayurveda, being the most ancient system of medicine, believes and visualizes each individual as unique. Based on this, in the present times there is the emergence and development of personalized medicine or the branch of pharmacogenomics. Uniqueness in subjects is attributed to variations in many factors from individual to individual. Among the various individual variations, the term satmya (compatibility) is one and is vital in understanding allergic reactions. Asatmyendriyarta samyoga (Incompatible union of sense organs with its objects), pradnyaparadha (wrongful actions due to deranged intellect) and parinama (time represents the change such as day / night, seasons etc) being the prime causes of diseases,[1] further emphasizes this fact that changes in the macrocosm are observed in the microcosm as well.[2] The subject matter of

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paaduka visha (footwear dermatitis) can be understood under the purview of asatmyendriyarta samyoga (incompatible contact) with respect to Skin (twak indriya).

Paaduka visha represents a frequently occurring skin ailment in dermatological practice. However, these dermatoses often remain undiagnosed and designated as other skin dermatoses such as eczema, psoriasis or dermatomycosis.[3] It is often empirically diagnosed without pinpointing the contributory allergens by allergic patch testing.

Allergic contact dermatitis is a type IV, delayed, cell-mediated response of hypersensitivity reaction to the allergen present in the contact substance (footwear, cloth, anklet, bangle, watch strap etc) with the skin.[4] Thus, the integrity of skin is overcome by allergens on contact, which results in dermatitis. Here an attempt has been made to compare the efficacy of Candanaadi lepa and Triphala lepa along with oral administration of Dushivishari agada in reducing the signs and symptoms of paaduka visha. Candanaadi lepa is mentioned in the context of paaduka visha and hence was taken as the trial drug.

MATERIALS AND METHOD

Collection of the drug:

The ingredients of the formulations were collected from the local market, authenticated and the lepa prepared in the Agadatantra Department (OPD) of Vaidyaratnam P.S. Varier Ayurveda College, Kotttakal. The composition of the trial drugs are given in the Table 1.

Table 1: Formulation of the trial drug - Candanaadi lepa (Susruta Samhita, Kalpasthana, 1/53)

Sr. No.	Sanskrit name	Botanical / scientific name	Part used	Proposition used
1	Candana	*Pterocarpus santalinus* Linn.f,	Heartwood	1 Part
2	Tagara	*Valeriana wallichi* DC.	Root	1 Part
3	Kusta	*Saussurea lappa* CBClarke.	Root	1 Part
4	Usira	*Vetiveria zizaniodes* (Linn.) Nash.	Root	1 Part
5	Venu	*Bambusa arundinacea* (Retz.) Willd	Leaf	1 Part
6	Somavalli	*Tinospora cordifolia* Willd.	Stem	1 Part
7	Amruta sanga	Copper sulphate	-	1 Part
8	Sveta	*Clitoria ternatea* Linn.	Root	1 Part
9	Padmam	*Nelumbo nucifera* Gaertn.	Whole plant	1 Part
10	Kaliyakam	*Coscinium fenestratum* (Gaertn.) Colebr.	Root / Stem	1 Part
11	Tvacam	*Cinnamomum zeylanicum* Beryn.	Bark	1 Part

Table 2: Formulation composition of the Control drug – Triphala lepa

Sr. No.	Sanskrit name	Botanical name	Part used	Proportion used
1.	Amalaki	*Emblica officinalis* Gaertn.	Fruit rind	1 Part
2	Haritaki	*Terminalia chebula* Retz.	Fruit rind	1 Part
3	Vibhitaki	*Terminalia bellirica* (Gaertn.) Roxb.	Fruit rind	1 Part

Preparation of the drug - Candanadi lepa:

All the drugs mentioned in Table 1 except Copper sulphate were made into a fine powder and stored in an air - tight container. Copper sulphate was detoxified by triturating it with the fresh juice of lemon[5] (*Citrus limon*) After complete drying, Copper sulphate was powdered finely and mixed well with the above mentioned herbals and stored in an air - tight container.

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Preparation of the drug - Triphala lepa:
The ingredients mentioned in Table 2 were made into a fine powder and stored in an air tight container.

Internal treatment:

The Dushivishari agada common to both the groups was purchased from Vaidyaratnam Oushadalaya. Ollur, Thaikkattussery.

Methodology:

Thirty participants diagnosed as footwear dermatitis by Patch testing with the Standard Footwear Series were selected as per the inclusion criteria and were divided into two equal groups randomly. Group I received Candanaadi lepa and Group II was given Triphala lepa. Dushivishari agada was common in both groups. The clinical assessment was done prior to treatment, eighth, fifteenth and twenty second day of the treatment. The result was analyzed statistically.

Selection of subjects:

Subjects of Paaduka Visha attending the Agadatantra out-patient department of Vaidyaratnam P.S.Varier Ayurveda College Hospital were selected as per the inclusion criteria for the study and randomly divided into two equal groups.

Inclusion criteria:

- ✓ Participants diagnosed as paaduka visha with minimum of two symptoms such as, swelling, numbness, discharge and vesicle with duration not more than 30 days, who have not undergone any other treatment atleast for 30 days prior to the study.
- ✓ Participants irrespective of gender, religion, caste and economic status.
- ✓ Participants in the age group of 15 – 60 years.
- ✓ Participants who give their informed consent.

Exclusion criteria:

- ✓ Participants with a history of atopic dermatitis.
- ✓ Participants with Diabetes mellitus, Hypertension, Rheumatism and other systemic diseases.
- ✓ Pregnant women and lactating mothers.

Research techniques and tools:

Case Record Form (CRF) was designed to collect the data. (Table 6) Proper grading scale was done to calculate the exact intensity of the cardinal symptoms like swelling, numbness, discharge and vesicle, besides the associated symptom of itching.

Patch test kit and the Finn chambers were procured from Creative drugs, Plot no. A 698, T.T.C, M.I.D.C, Navi Mumbai, Batch No. 63C1 and Systopic Laboratoties Private limited, 305, Pragati Chambers, Commercial Complex, Ranjit Nagar, New Delhi – 110008 respectively. Patch test was performed for all the participants with their consent and the essential instructions of patch testing were conveyed. (Table 5)

The sample size in each group was 15 subjects. Group 1 received the trial drug and group 2 received the control drug. The dosage form in both the groups was fine powder, applied externally as a paste in the medium of water. The application was done twice a day for a period of two weeks, with a total of 28 applications.

Orally both the groups received Dushivisha agada in tablet form of one gram. One tablet was administered twice a day after food along with plain water for the initial two weeks. Proper Pathyapathya was advised to the research participants during the course of treatment.

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During the follow up period of a week, both the groups were given wheat flour capsule (500 mg) orally twice a day after food with plain water.

RESULTS

Assessment was done prior to treatment, during treatment (8th day), after treatment (15th day) and after follow-up (22nd day) and the score for the chief complaints was obtained. The data was subjected to statistical analysis and the groups were compared using Student 't' test.

The table 3 shows the overall effect of the therapies on swelling, discharge, vesicles and itching together. In Group I, total mean score before treatment was 1.5, which was reduced to 0.13 with mean difference 1.37 with standard deviation ± 0.090. The 't' value was 58.39, which was statistically highly significant at the level of 0.1% (P< 0.001).

In Group II total mean score before the treatment was 1.8 which was reduced to 0.31 after completion of the treatment with mean difference of 1.49 and standard deviation of ± 0.038. 't' value was 150.4 which was statistically highly significant (P< 0.001)

When the effect of the two therapies was compared on the total mean score of swelling, discharge, vesicle and itching, it was found that the total mean difference in group I was 1.37 with Standard Deviation (SD) 0.090. In group II, the mean difference was 1.49 with SD of 0.038. 't' value was found 1.81, which was statistically insignificant (P>0.05). (Table 4)

Table 3: Overall effect of the therapies on presenting complaints

Group	Mean Score		SM. diff.	SD	t - value	P value
	BT	AT				
I (n=15)	1.5	0.13	1.37	0.090	58.39	5.57
II (n=15)	1.8	0.31	1.49	0.038	150.4	1.28

Table 4: Comparison of the effect of the two therapies

Group	Mean Diff	SD	t – value	P value
I (n=15)	1.37	0.090	1.81	P>0.05
II (n=15)	1.49	0.038		

DISCUSSION

The drug candanaadi lepa [6] was selected as it is mentioned in the context of paaduka visha with swelling, discharge, numbness & papules as its characteristic feature.[7]

Paaduka visha[8] is to be understood as (incompatible contact with the skin) asatmyendriyarta samyoga with respect to twak indriya and under the context of gara visha (artificial poison). It is considered as gara visha due to the fact that the adverse effects of it are not only death but also manifests as sopha (inflammation), pandu (A broad term, not just confined to anemia) etc and the duration of manifestation can be acute, chronic or very chronic.[9] The circumstances of gara can also be accidental (unintentional / unforeseen effects). The term sopha in its true sense includes even the minute intracellular swelling to the most gross apparent forms of fluid accumulation. All these facts point out that gara has its contemporary relevance. The context of agantuja sopha (inflammation / swelling due to exogenous cause), namely abhighataja (traumatic) and vishaja (due to poison) are quite interesting when viewed in its true sense, in a broader perspective. Abhighataja sopha (traumatic swelling / inflammation) is due to external injury, which ranges from a superficial simple scratch or irritation to the skin to a deep one such as fracture. Considering this point, Irritant Contact Dermatitis can be viewed as one of the manifold aspects of Abhighataja sopha. To substantiate this point, the contact with Bhallataka (*Semecarpus anacardium* Linn.) has been quoted as an example in the classics.[10] Similarly, vishaja sopha results in contact with poisons, which includes air borne

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Table 5: Grading of signs of Patch test

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

Table 6: Grading of the associated symptom Itching

Grading of the sign Discharge	Grade
No discharge	0
Moistens the lesion	1
Mild discharge occasionally on scratching	2
Profuse discharge on scratching	3
Discharge without any intervention disturbing routine and sleep	4
Grading of the sign Vesicles	**Grade**
Absence	0
Erythema	1
Confined to area of contact	2
Spread beyond area of contact	3
Generalised lesion	4
Grading of the sign Swelling	**Grade**
No swelling	0
Mild swelling not well appreciable	1
Well appreciable swelling causing no discomfort in wearing footwear	2
Well appreciable swelling causing discomfort in wearing footwear	3
Swelling spread to areas of no contact	4
Grading for the symptom Numbness	**Grade**
No Numbness	0
Blending of sensation	1
Grading of the Symptom Associated Symptoms Itching	**Grade**
No itching	0
Mild itching occasionally	1
Mild itching persists all day	2
Severe itching with scratch marks	3
Continuous severe itching disturbing routine and sleep	4

particles also. The concept of Allergic Contact Dermatitis can be one of the aspects under the broad understanding of vishaja sopha.

The clinical features (rupa) such as itching, vesicles, swelling and blackish discolouration also correlate with vicarcika kusta[11] (eczema), thus the Morphological diagnosis (based on rupa) is vicarcika kusta. The etiological diagnosis (based on nidana) is paaduka visha. The clinical diagnosis (based on samprapti) is vishaja sopha. Understanding the diseased condition as per dosha is the most important factor on the whole, in terms of management.

Lepana (external application of paste) was found to be an ideal method when there is less discharge. It is ideal after cleansing the affected area with lukewarm water. The same lepana, when applied over lesions, characterized by crust formation and intense discharge, only hinders the flow of discharge, leading to formation of swelling and also acts as an irritant, blocking the micro channels. In such cases, avagaha (immersing the affected body part in the liquid medium) or ksalana (seka) (pouring the medicated liquid over the affected body parts with decoction made from the same drugs was found to be ideal. Despite

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the drug being similar, the mode of application should be appropriate for the condition of the disease and this is what makes the difference. Wrongly, one can interpret that the drug is ineffective or adverse if the mode of application is not appropriate.

The period of external application was for two weeks and this fixed period in every subject was not found to be ideal. In a few subjects, a week's application had made the lesions dry, free from discharge. Further applications of the paste only increased the dryness and hence the patient experienced pain. The pain was not due to the drug, but the continuation of the drug in a wrong condition of the disease.

In the present study it was found that both of the drugs, Candanaadi lepa and Triphala lepa were highly significant ($P<0.001$) in reducing the chief complaints such as swelling, discharge, vesicles and itching selected for the study. When the results were compared by unpaired *t* test, it was found that the efficacy of the drugs was insignificant ($P > 0.05$).

On account of percentage of relief, Candanaadi lepa was more effective (91.75 %) in the management of paaduka visha as compared to Triphala lepa (83.7 %). Candanaadi was found ideal in kapha pitta predominance and Triphala was generally found to be tridosha hara.

CONCLUSION

Though both the drugs individually were highly significant, on account of percentage of relief obtained, it was found that Candanaadi lepa was more effective in the management of footwear dermatitis as compared to Triphala lepa. Yet the research should be conducted in large samples to find out the possibilities.

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