

Patch Test Results of 276 Cases with Footwear Dermatitis - A Retrospective Study from a Tertiary Care Centre in South India

Abstract

Background: Allergic contact dermatitis (ACD) is a major cause for foot wear dermatitis. Patch testing is the standard investigation for diagnosis of ACD. Identification of the causative allergen and avoidance of the same is the most important for patient management. **Aims:** This study was conducted to find the common allergens in footwear, causing ACD, by retrospective analysis of the data of patients who had undergone patch testing with footwear series (FWS), approved by the Contact and Occupational Dermatoses Forum of India. **Materials and Methods:** A total of 276 cases with footwear dermatitis who underwent patch test with FWS using Finn chamber method were studied. Statistical analysis was done using statistical package for social sciences (SPSS) version 24. Data was described using frequency and percentages. *P* value of less than 0.05 was considered significant. **Results:** In this study 101 (36.5%) patients had positive patch test to at least one allergen. Among this, 43 (15.6%) were positive for single allergen only and 58 (21.01%) patients had positive patch test reactions to multiple allergens. The most common allergens with positive patch test were black rubber mix, mercapto benzo thiazole, and thiuram mix. Patients with either a positive or negative patch test had no statistically significant difference in the history of atopy. The limitations of this study include the lack of patch testing with the patient's own footwears and lack of follow-up after informing patients regarding allergen avoidance. **Conclusions:** Patch test must be done for all foot eczema cases for early identification of the causative allergen and also to provide suitable alternatives.

Keywords: Allergic contact dermatitis, footwear dermatitis, patch test

Introduction

Footwear dermatitis is a frequently encountered skin problem in dermatology practice, with an overall prevalence of 3–11%. Allergic foot wear dermatitis is commonly caused by constituents of rubber, leather, plastic, adhesives, or linings and dyes. The common sensitizers include rubber accelerators, potassium dichromate, and colophony. Different chemicals, along with a hot and humid environment within the foot wear, give rise to allergic or irritant dermatitis.^[1] Avoidance is the main stay of treatment for footwear dermatitis. Patch testing, interpreted with clinical relevance is the most useful method for diagnosing footwear dermatitis.^[2] Educating about the avoidance of allergen and providing suitable alternatives are very important in the management of footwear dermatitis. We did this study to find the common allergens in footwear, causing allergic

contact dermatitis (ACD), by retrospective analysis of the data of the patients who had undergone patch testing with footwear series, approved by the Contact and Occupational Dermatoses Forum of India (CODFI).

Material and Methods

This was a retrospective study conducted in the Department of Dermatology in a tertiary care centre in South India. In the study, 276 patients who underwent patch test from March 2009 to March 2018 for suspected footwear dermatitis were included, after obtaining the approval of institutional ethical committee.

History regarding age, sex, occupation, aggravating factors like contact with metals, cement, topical medications, type and colour of footwear used, and association with atopy was noted from patch test register. Patch test was done in these

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Access this article online

Website: www.idoj.in

DOI: 10.4103/idoj.IDOJ_560_19

Quick Response Code:



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How to cite this article: Thyvalappil A, Sridharan R, Amrutha MP, Nair G, Sreenivasan A. Patch test results of 276 cases with footwear dermatitis - A retrospective study from a tertiary care centre in South India. Indian Dermatol Online J 2020;11:720-4.

Received: 12-Nov-2019. **Revised:** 27-Mar-2020.
Accepted: 05-Jun-2020. **Published:** 19-Sep-2020.

patients using footwear series (FWS) allergens approved by CODFI.

Inclusion criteria

All Patients with eczematous lesions, exclusively or predominantly involving foot with a history of aggravation on contact with footwear were included in the study.

Exclusion criteria

Patients with acute dermatitis, patients on systemic steroids, dermatoses at the site of application of patch test, and patients with tinea pedis confirmed on direct microscopy were excluded.

Patients were tested with 15 allergens that are known to be the culprit in causing footwear dermatitis. The modified Finn chamber method which consists of circular aluminium chambers, on an acrylate based adhesive was used. Marking was done in numerals with skin marking pencil. Allergen strips were applied to the patient's upper back in vertical rows under occlusion and kept for 2 days (48 hrs). Excessive hair if present was shaved prior to sticking of tape. Care was taken to avoid any folds on the strip. The patients were advised to avoid any strenuous exercise and wetting of the application site. Reading was taken 15–30 minutes after removal of the occlusive strip, so as to allow the transient erythema caused by the occlusive effects of allergens and plaster to subside. Readings were taken at 48 hours, 72 hours, and 96 hours. Some irritant reactions appearing in first 48 hours may disappear by 96 hours, whereas allergic reactions tend to increase. Thus late reading is important to determine if the reaction is an irritant or an allergic one. Results were interpreted using the criteria laid down by the International contact dermatitis research group (ICDRG). All positive grades were taken as significant. Patients who tested positive were further informed regarding the materials containing the sensitizing substances.

Statistical analysis was done using statistical package for social sciences (SPSS) version 24. Microsoft word and Excel have been used to generate graphs, tables etc., *P* value of less than 0.05 was considered significant. Data was described using frequency and percentages.

Results

We included 276 patients in this study. The study included more females (F) than males (M) (F = 180 (65.22%), M = 96 (34.78%)). The age of patients ranged from 5 years to 85 years with a mean age of 25.49 years. Majority of patients were students [n = 133 (48.19%)] followed by house wives [n = 51 (18.48%)] and manual laborers [n = 26 (9.4%)]. Sixty eight patients had history of atopy (24.64%). Patients with positive and negative patch test had no statistically significant difference in history of atopy (*P*-value 0.935). Most of them presented with

scaling (85%). Fissuring, redness, dryness, oozing, pain, and maceration were other manifestations. All the patients had bilateral involvement and the predominant site of involvement was the dorsum of feet.

Among the study population, rubber was the most commonly used footwear material [n = 170 (61.6%)] followed by plastic. Most patients were using black colored footwear [n = 137 (49.6%)]. Twenty seven patients (9.78%) had exacerbation of foot dermatitis on exposure to cement. Twenty five patients (9.06%) showed aggravation of lesion on exposure to metals. Topical medication was the aggravating factor in forty three (15.58%) patients.

Among the total 276 patients included in the study, 101 patients (36.5%) had positive patch test to at least one allergen. Among this, 43 (15.6%) were positive for single allergen only and 58 (21.01%) patients had positive patch test reactions to multiple allergens [Figure 1]. Among those with multiple allergies, 34 patients had allergy to two antigens and 24 patients showed positivity to more than two allergens.

In our study the most common allergen with positive patch test was black rubber (n = 32; 16%) followed by mercapto benzo thiazole (n = 27; 13.4%) and thiuram mix (n = 19; 9.5%). Potassium dichromate (n = 15; 7.5%), disperse blue (n = 14; 7%), colophony (n = 13; 6.5%), nickel sulphate, neomycin sulphate and disperse orange (n = 12; 6% each), dioctyl thalate (n = 10; 5%), epoxy resin (n = 9; 4.5%), glutaraldehyde (n = 8; 4%), kathon CG (n = 7; 3.5%), hydroquinone (n = 6; 3%), and formaldehyde (n = 5; 2.5%) were the other positive allergens [Table 1].

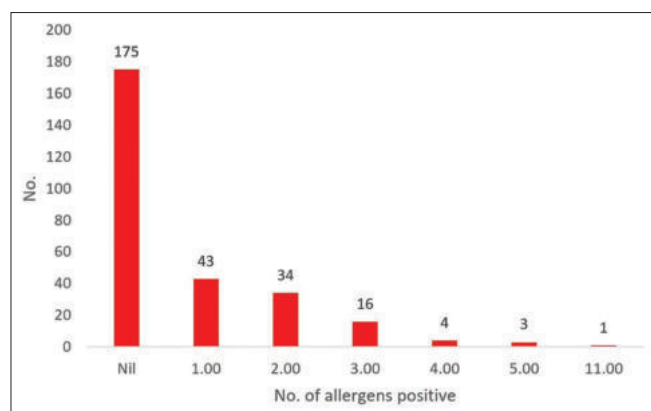
Discussion

In this study, patients who underwent patch test for footwear dermatitis using FWS approved by the CODFI were included. Foot is most often directly exposed to environmental hazards. Hot humid climate, occlusion, and friction by shoes are other factors that promote the development of sensitivity.^[3,4] Contact allergy to shoes is one of the most important causes of dermatitis of the feet. Patch test provides an accurate and relatively simple means of diagnosis and allows the physician to initiate appropriate treatment. If patch test result is negative with specialized series, testing with samples of the patient's own footwear may be done.^[5]

Rubber chemicals including thiuram mix, black rubber mix, hydroquinone mono benzyl ether, mercapto benza thiozole are one of the most common etiological agents in shoe dermatitis. Thioureas used in insoles may cause a chronic, scaly plantar dermatitis on the sole. Leather allergy is usually caused by tanning agents and dyes. Chrome tanning is done to make it more pliable and waterproof and also to take up more variety of colours. Chromium salts like potassium dichromate are used to tan leather. Sweat leaches out chrome and other chemicals from leather. Para-tertiary

Table 1: Results of patch testing

Material	Allergen	Number of positive results
Rubber	Black rubber mix	32 (16%)
	Mercaptobenzothiazole	27 (13.5%)
	Thiuram mix	19 (9.5%)
	Hydroquinone-monobenzyl ether	6 (3%)
Leather	Pottassium dichromate	15 (7.5%)
	Formaldehyde	5 (2.5%)
	Glutaraldehyde	8 (4%)
Plastic	Dioctyl phthalates	10 (5%)
	Epoxy resin	9 (4.5%)
Dyes	Disperse orange	12 (6%)
	Disperse blue	14 (7%)
Glues	Colophony	13 (6.5%)
Antimicrobials	Neomycin sulphate	12 (6%)
	Kathon cg	7 (3.5%)
Metals	Nickel So4	12 (6%)

**Figure 1: Patch test results**

butyl phenol formaldehyde resin (PTBFR) has been used as an additive in rubber glues and is also as a component of neoprene adhesives used to attach shoe linings and insoles. Nickel present in the buckles and straps is another cause of shoe dermatitis.^[5]

Formaldehyde used in processing and tanning of the leather to make it soft and water proof is another sensitizer in footwear. Dyes like disperse blue, disperse orange, and 4-phenylenediamine also cause allergy in sensitised individuals. Sensitization with dyes can occur from the use of colored socks, dress, footwear linings and soaps. Re-dying of leather shoes is more harmful, as there is more chance of leakage of chemicals leading to allergy.^[2]

Our study had more females (65.22%) than males (34.78%). Three similar studies also had more female patients than males.^[3,6,7] This may be because of the fact that women use a variety of footwear more than men. The age of patients ranged from 5 years to 85 years with a mean age of 25.49. Most patients were youngsters in the age group 15–30 years.

This was similar to the study from Mangalore in which 48% were 20–30 years age.^[3] The more number of youngsters is possibly because of the fact that this age group is the active phase of one's life where chances of exposure to allergens are more.^[3] But similar study from Pondichery mostly included patients 30–45 years (29.5%)^[7] and another study from Kolkata mainly included people in their fifth decade (42.58%).^[6] In another study from Pondichery also, majority of patients were 45–60 years of age (40%). In our study, majority of patients were students [n = 133 (48.19%)] followed by house wives [n = 51 (18.48%)] and manual laborers [n = 26 (9.4%)]. In other published studies the major occupation groups were housewives, farmers, and manual laborers.^[6,7]

Sixty eight patients had history of atopy (24.64%). Patients with positive and negative patch test had no statistically significant difference in the history of atopy (*P*-value 0.935). Association with atopy has been found by various authors.^[8,9] Others found no preponderance of atopy.^[10,11] The relationship between atopy and ACD is not clearly understood. Whether persons with atopic dermatitis are more prone to ACD than non atopic persons remains controversial.^[12]

Rubber was the most commonly used footwear material [n = 170 (61.6%)]. Most patients were using black colored footwear. Twenty seven patients (9.78%) had exacerbation of foot dermatitis on exposure to cement. This can be explained as chromium salts like potassium dichromate are used to tan leather. Twenty five patients (9.06%) showed the aggravation of lesion on exposure to metals. Nickel found in buckles or straps may cause ACD. On patch testing, 12 (6%) of our patients were found to have nickel allergy. Topical medication was the aggravating factor in forty three (15.58%) patients. This can be explained by sensitization to topical treatments containing drugs like neomycin taken in the past. Twelve patients (6%) showed reactivity to neomycin on patch testing. Allergy to Kanthon CG that is used as a preservative in cosmetics and toiletries, was seen in 12 of our patients.

Among the total 276 patients included in the study, 101 patients (36.5%) had positive patch test to at least one allergen. This was similar to the study by Chougule, where the patch test positivity was 38.4%.^[7] Among this 43 (15.6%) were positive for single antigen only and 58 (21.01%) patients had positive patch test reactions to multiple allergens.

Rubber and rubber chemicals including black rubber mix, mercapto benzo thiazole, and thiuram mix were the most common allergens contributing to footwear dermatitis in our study. Black rubber mix, used as antioxidants in the manufacture of industrial black rubber products, was the most common allergen noted in our study (n = 32). Twenty percent of patients were positive to black rubber mix in the

study by S Chowdhri *et al.*^[6] But a similar study conducted by K S Priya *et al.* only 4% patients had positive patch test to black rubber mix.^[3] However, the variations in individual allergen sensitivity in different series may be due to the varying chemical composition of footwear, individual susceptibility, and variation of screening series. Black rubber mix is composed of amines, used to prevent drying and cracking of rubber, which itself can cause fissuring and drying of the feet.^[4]

In a recent Indian study patch test positivity was seen in 18.92% of the patients. They found rubber, as the most common material in Indian footwear, to be the cause of allergy.^[2] In a study by Suhail *et al.*, 66% patients showed positive patch test results. Rubber chemicals were the commonest allergen and among the rubber chemicals, the main offending allergen was carba mix as overall 26% patients were sensitive and 16% patients were sensitive to agents used in tanning the leather.^[1]

Previously leather was the most frequent antigen and over time, rubber has emerged as the commonest antigen involved in footwear dermatitis. Many people use rubber and plastic footwear as they are economical, long lasting, easily available, and water proof.^[1] Since rubber chemicals from pervious shoes may be retained in socks, purchasing new socks should also be advised.^[5]

Mercapto benzo thiazole was the second most common allergen (n = 27) in patch test in our study. It is a constituent in rubber and rubber chemicals. Mercapto benzo thiazole was the most common allergen with 36% patients showing positive patch test reaction in the study conducted by K S Priya *et al.*^[3]

Thiuram mix (n = 19) was also a common allergen giving positive patch test result in our study. Positive patch test reaction to thiuram mix was observed in the studies by S Chowdhri *et al.* (10.3%) and K S Priya *et al.* (9%).^[3,6]

Fifty eight (21.01%) patients had positive patch test reactions to multiple allergens in our study. Multiple patch test positive reactions could be due to nonspecific hyper reactivity, multiple primary hypersensitivities or due to cross reactions. Patch test was positive in 24 (60%) patients in a study by Rahima *et al.* Half of them had positivity to multiple allergens. Disperse orange was the commonest allergen (25%) followed by epoxy resin, neomycin sulphate, and black rubber mix.^[4]

If multiple allergens are positive, clinical history should be retaken. Retesting may be necessary, if the patch test is positive to a universal substance that is difficult to avoid. Retesting is not warranted, if it can be explained by similar chemical structure or cross reactivity. Benzocaine and paraphenylenediamine are known cross reactants.

Patch testing with foot wear series is the only reliable method to identify the allergen causing various foot

dermatoses. By identifying the allergen, we can recommend the correct non allergenic footwear. Custom shoemakers can make shoes free of particular allergens. If avoidance of footwear made of suspected allergen is not sufficient, topical emollients, steroids, and calcineurin inhibitors and systemic steroids or immune suppressants in severe cases may be given.^[5] For patients with rubber allergy, all leather shoes with no insole and no attached outer sole may be advised. For leather allergy, plastic, vinyl or all- fabric shoes may be tried.

Limitations

The limitations of this study include lack of patch testing with patient's own footwear and lack of follow-up after informing patients regarding allergen avoidance.

Conclusions

Among the total 276 patients included in the study, 101 patients (36.5%) had positive patch test to at least one allergen. Majority were positive for single antigen only. Black rubber followed by mercapto benzothiazole and thiuram mix are the most common allergens contributing to footwear dermatitis. Patch testing has an important role in finding the causative allergen of foot eczema that otherwise becomes recurrent and chronic, requiring prolonged treatment, thereby interfering the daily activities of the individual. Hence, patch test must be done for all foot eczema cases for early identification of the causative allergen and also to provide suitable alternatives. It is time we recommend the avoidance of black rubber as a foot wear material as multiple studies including this study have shown high incidence of contact allergy to black rubber.

Acknowledgement

The authors wish to thank Dr Binu Divakaran, PhD for her assistance in statistical analysis.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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