Patch Testing in Patients with Suspected Footwear Dermatitis: A Retrospective Study

Abstract

Background: Footwear dermatitis represents a common but often undiagnosed or misdiagnosed condition. Patch testing aids in its confirmation and identification of the offending allergen. Aims: This study aimed to find the frequency of positive patch test reactions in cases with suspected allergic contact dermatitis (ACD) to footwear, as well as the common responsible allergens. Materials and Methods: This is a retrospective record-based study of 37 patients, with suspected ACD to footwear, who underwent patch testing with Indian standard series and Indian footwear series from July 2012 to July 2015. Results: The majority of patients (45.94%) belonged to the age group of 20–40 years. Dorsal aspects of feet (81.08%) and soles (18.92%) were the common sites involved. Patch test was positive in 18.92% patients. The most common causative allergens were hydroquinone monobenzylether (8.11%) and 4-aminoazobenzene (5.41%). Conclusion: Common chemicals implicated in ACD were rubber, rubber additives, and dyes. The principal culprit allergens were hydroquinone monobenzylether and 4-aminoazobenzene.

Keywords: Allergic contact dermatitis, footwear, footwear dermatitis, shoe dermatitis

Introduction

Footwear dermatitis presents as a common diagnostic and therapeutic challenge in dermatological practice in India. It is a common disorder with an overall prevalence of 3–11%. Dermatitis involving the feet may result from footwear materials containing leather, rubber, adhesives, dye, nickel, stockings, topical medicaments, antiseptics, and antiperspirants. The common sensitizers are potassium dichromate, colophony, and rubber accelerators. However, this condition often remains undiagnosed or designated as other skin dermatoses. The diagnosis is often made empirically without identifying the offending allergens by allergic patch testing.

It is beneficial for a dermatologist to know about footwear manufacture and composition to assist the allergic patient in finding shoes that can be worn safely. This knowledge is, however, not easy to acquire or to apply.

We attempted to study the common allergens in footwear, responsible for causing ACD, by retrospectively analyzing the data of patients who had undergone patch testing with Indian Standard Series (ISS) and Indian Footwear Series (IFS).

Materials and Methods

The study was conducted in the department of Dermatology of a tertiary care center as a retrospective, record-based study. A total of 37 patients of age 3 years to 65 years who had presented with suspected ACD to footwear from July 2012 to July 2015 and had undergone patch testing with ISS and IFS were included in the study. The study was approved by the ethical committee of the institute. A detailed history of the symptoms, cutaneous lesions, type and material of footwear used, personal and family history of atopy, seasonal variation, and findings of clinical examination were recorded from the proforma. Relevant investigations were done to rule out other differential diagnosis (KOH examination, Gram’s stain, culture for fungus/bacteria, etc.). The patch test had been performed by the modified Finn chamber method utilizing the IFS, and additional allergens of ISS approved by Contact dermatitis forum of India (CODFI), and manufactured by “Chemotechnique Diagnostics” [Table 1]. Patch test reading was taken after 48 hours.

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hours, 72 hours, and 96 hours. The delayed reading at 96 hours was missing in the data of 4 patients. The results of patch testing were analyzed as per the recommendations of the International Contact Dermatitis Research Group. Positive patch test relevance was based on patient history and history of potential exposure.

**Results**

The age group of our patients ranged from 3.5 to 63 years, and the mean age was 35 ± 16 years. Seventeen patients (45.94%) belonged to the age group of 20–40 years. There were 23 (62.16%) females and 14 (37.84%) males (M:F = 1:1.64).

The duration of symptoms ranged from 15 days to 11 years (Mean = 28.62 ± 39.92 months). Twenty-three patients (62.2%) had a duration of less than a year. The most common presenting complaints were itching in 35 patients (94.59%), scaling in 28 (75.67%), redness in 15 (40.54%), dryness in 15 (40.54%), oozing in 7 (18.92%), fissuring in 5 (13.52%), pain in 3 (8.11%), and maceration and burning in 1 patient (2.71%) each. History of atopy was present in a total of 4 patients (10.81%). Majority of the patients (n=30, 81.08%) had no seasonal variations, 4 patients (10.81%) experienced a summer aggravation, and in 3 patients (8.11%) symptoms worsened in winters.

Bilateral involvement of feet was observed in 32 (86.48%) patients. The remaining 5 patients (13.52%) presented with unilateral involvement (right foot: 10.8% patients, left foot: 2.71% patients), in which the diagnosis was made clinically after ruling out other differential diagnosis. The most common area involved was the dorsal aspects of feet (n = 30, 81.08%) [Figure 1], followed by soles (n = 7, 18.92%), intertriginous area (n = 5, 13.52%), instep (n = 4, 10.81%), and heels (n = 4, 10.81%) [Figure 2]. The majority of patients (n = 34, 91.89%) presented with plaques, and scaling (n = 27, 72.97%). The other forms of presentation were erythema in 14 patients (37.83%), lichenification in 12 (32.43%), fissuring in 4 (10.81%), papulovesicles in 3 (8.11%), exudation in 3 (8.11%), and hypopigmentation in 1 patient (2.71%).

The most common footwear type worn by our study patients was slippers in 32 (86.48%), followed by shoes in 5 patients (16.22%). The various materials of footwear used were rubber in 21 (56.76%), both rubber and leather in 11 (29.73%), plastic in 3 (8.11%), metal velvet, and leather in 1 patient each (2.71%).

**Table 1: Allergens used for patch testing**

| Allergens                  | Concentration |
|----------------------------|---------------|
| IFS allergens              |               |
| Potassium dichromate       | 0.5%          |
| Formaldehyde               | 1 %           |
| Glutaraldehyde             | 0.2%          |
| Thiuram mix                | 1%            |
| Black rubber mix           | 0.6%          |
| 2-mercaptobenzothiazole    | 2%            |
| Dibutyliourea              | 1%            |
| Mercapto mix               | 2%            |
| N,N-diphenylguanidine      | 1%            |
| Hydroquinone monobenylether | 1%       |
| Dioctylphalate             | 2%            |
| Epoxy resin                | 1%            |
| 4-phenylenediamine base    | 1%            |
| 4-Aminoazobenzene          | 0.25%         |
| Disperse orange            | 1%            |
| Disperse blue              | 1%            |
| Tannin natural source      | 1%            |
| Colophony                  | 20%           |
| 4-tert-butylphenolformaldehyde resin | 1%       |
| Dodecyl mercaptan          | 0.1%          |
| 4-tert-butylphenol         | 1%            |
| Neomycin sulphate          | 20%           |
| 5-chloro-2-methyl-4-isothiazolin-3-one | 0.02aq |
| Nickelsulphatehexahydrate  | 5%            |
| Additional iss allergens   |               |
| Petrolatum white           | 100           |
| Cobalt (II) chloride hexahydrate | 1%        |
| Paraben mix                | 15%           |
| Gentamicin sulphate        | 20%           |
| Nitrofurazone              | 1%            |
| Chloro M cresol            | 1%            |
| Wool alcohols              | 30%           |

IFS: Indian Footwear Series, ISS: Indian Standard Series, aq: aqueous

![Figure 1: Allergic contact dermatitis over dorsal and medial aspects of feet](image-url)
Patch test with the allergens of IFS and ISS revealed a positive result in 7 (18.92%) patients [Table 2]. However, total number of positive allergens was 12 (29.78%). Three (8.11%) patients had a positive patch test to hydroquinone monobenzylether while two (5.41%) reacted positively to 4-aminoazobenzene [Figure 3]. Reactions to disperse blue, disperse orange, 4-phenylenediamine, black rubber mix, mercapto mix, and N, N-diphenylguanidine were positive in one patient (2.71%) each. Three patients (8.11%) reacted positively to multiple allergens [Table 2]. The patch testing with allergens of ISS revealed a positive result to nitrofurazone in 1 patient (2.71%). Irritant reaction was not observed in any patient.

**Discussion**

The incidence of footwear dermatitis and newer antigens with allergenic potential has shown an upsurge in the recent years. Indians are particularly prone to develop footwear allergies as it is a common practice to wear shoes and sandals on bare feet without socks. Moreover, the quality control of shoe production industry in India is not strictly regulated. Patch testing when interpreted with clinical relevance is the most useful method for diagnosing ACD.

| Patient Number | Positive Patch Test (IFS) | Positive Patch Test (ISS) | Footwear Suspected | Sites Involved |
|----------------|---------------------------|---------------------------|--------------------|----------------|
| 1              | Disperse blue (1+)        | 0                         | Leather and rubber slippers | Dorsal aspects of feet |
|                | Disperse orange (1+)      | 0                         | Rubber slipper (bright color) | Soles, insteps, heels |
| 3              | 4-Aminoazobenzene (1+)    | 4-phenylenediamine base (1+) | Leather and rubber slippers | Dorsal aspects of feet |
| 4              | N, N-diphenylguanidine (1+) | Black rubber mix (1+)   | Sandles with metal and velvet | Dorsal aspects of feet, soles |
| 5              | Hydroquinone monobenzylether (2+) | Mercapto mix (1+) | Rubber slippers | Dorsal aspects of feet |
| 6              | 4-Aminoazobenzene (2+), Hydroquinone monobenzylether (1+) | Nitrofurazone (2+) | Rubber and leather slippers | Dorsal aspects of feet, soles |
| 7              | Hydroquinone monobenzylether (1+) | 0 | Rubber slippers | Dorsal aspects of feet, soles |

IFS: Indian Footwear Series, ISS: Indian Standard Series
to footwear. Patch test with footwear series in addition to the standard series increases the yield to detect relevant allergens in such patients.[4]

In our study, most of the patients were between the ages of 20 and 40 years in accordance with earlier studies.[3,4] This young age group experiences a higher exposure to various allergens because of their work routine and travelling in adverse hot and humid climate. Contact dermatitis to footwear mostly presents symmetrically, as observed in 86.48% of our patients. The dorsal aspects of feet were most commonly involved site in our study, as observed in a previous Indian study,[9] probably due to large surface area, thin stratum corneum, and maintenance of prolonged close contact with the upper part of footwear.

Constituents of rubber, leather, and adhesives are the leading allergens in footwear implicated in causing contact dermatitis. Substances in natural and synthetic fibres, dyes, and biocides added to the finished or refinished shoe are also common suspects. We found rubber, as the most common material in Indian footwear, to be the cause of allergic footwear dermatitis in more than half of our study patients (56.76%) in concordance with the studies from various countries.[5,10,11] The most common allergen detected on patch test was hydroquinone monobenzylether (8.11%), which is used as a rubber additive. Other positive rubber allergens in our study were black rubber mix, mercapto mix, and N, N diphenylguanidine (used as rubber accelerator). Rubber chemicals were the most common allergens detected in 26 patients in a study by Handa et al.[12] They used 16 allergens of shoe series in 30 patients, and found dyes in 10 cases, leather in 6 cases, glues and neoprene cements in 4 cases, and rubber material from suspected footwear as such in 4 patients. In a study by Bajaj et al.[13] 61.3% of the patients with suspected footwear dermatitis showed positivity to one or more allergens. The most common allergens were potassium dichromate (34.2%), mercapto benzthiazole (30%), and mercapto mix (28%). In another Indian study by Chowdhury et al., the highest positivity was shown by leather and leather-related chemicals in 61.9% cases (n = 96). They used allergens of only Indian Standard Battery for patch testing, and detected potassium dichromate (45.8%) and cobalt chloride (38.06%) as the most common allergens.[14]

Dyes such as 4-aminobenzene (5.41%), disperse blue, disperse orange, and 4-phenylenediamine (2.71% each) were another common group of allergens with positive patch test. Re-dying of leather shoes is more problematic rather than the original dye. Re-dyed shoes do not fix these dyes firmly, probably leading to leaching of chemicals and carry a potential to sensitize. P-aminobenzene accounted for 5 out of 35 positive reactions in foot dermatitis patients in an Indian study.[13]

Multiple patch test reactions were positive in 3 patients. Reaction to both 4-phenylenediamine and 4-aminoazobenzene in one patient could reflect cross reactivity, as their cross reactions have been described previously.[10] However, sensitization to multiple allergens in an individual is also possible, as seen in the other two patients (one was sensitive to black rubber mix, mercapto mix, and N, N diphenylguanidine, while the other reacted to 4-aminoazobenzene, hydroquinone monobenzylether, and nitrofurazone). Reaction to nitrofurazone can be explained by sensitization to topical treatments taken in the past. A previous Indian study has reported that 13% of their patients of footwear dermatitis patch tested positively for medicaments and shoe antigens, and 8% were positive for only medicaments.[9]

In our study, patch test revealed a positive result in only 18.92% of the patients. This could be due to small sample size and an inability to perform patch test with the patient’s own shoe material, which are the limitations of this study. Lynde et al. also reported a relevant positive patch test in less number of patients (26.9%) with shoewear screening tray.[17] Literature states that even extensive series for footwear dermatitis may miss some shoe allergens, including biocides, vegetable tans, hydroquinone and polyurethane agents.[11] In a previous Indian study by Saha et al.,[8] only 3 of 23 patients reacted to their own footwear. Investigation of possible contact dermatitis to footwear can be unsatisfying, as only 10–20% of shoe allergies have been identified even after testing with pieces of the shoe itself.[4]

**Conclusion**

In this retrospective study of patients suffering from footwear dermatitis, we found rubber allergens as the most common allergens, followed by dyes. Although the results of our study cannot be extrapolated to general population due to small sample size, they support the findings of previous literature. Because patch test positivity rate is not very high as that of previous studies, it may indicate that either we need to add or modify allergens in our standard footwear series.

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**Conflicts of interest**

There are no conflicts of interest.

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