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Original Research Article

Common allergens in patients with contact dermatitis identified using patch test in a tertiary care centre in North Kerala

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ABSTRACT

Background: Allergic contact dermatitis (ACD) is a disease characterised by an immune mediated response to a substance. The primary prevention remains avoidance of the implicated allergen. This is done with the help of patch test using the Indian Standard series (ISS).
Methods: Out of the 246 cases of ACD that came to our Dermatology department, 92 patients were selected and subjected to patch testing using the ISS. Results were read after 48 and 96 hours, interpreted as per ICDRG criteria and were analysed.
Results: From 92 patients 59.8% were males and 40.2% were females. Majority of the individuals with ACD who were patch tested belonged to the age range of 21-60 years accounting to 72.8%. The most affected site was the foot. 26.7% showed positivity to Black rubber mix, followed by potassium dichromate 20% and nickel 14.4%. 7.8% produced delayed reactions with positivity revealed at the final reading. One patient gave multiple positive reactions to paraben, PPD and chlorocresol.
Conclusions: In the study middle aged males were mostly affected which may be influenced by the sample selected. Black rubber mix was identified as the most frequent sensitizer followed by potassium dichromate which was also implicated as the sensitizer most seen in the unskilled generally. Fragrance mix was responsible for all delayed responses yielding positivity in the second reading. When not considering the negligible left, patch tests' results could be correlated with the clinical presentations. Patients were treated, educated on ACD and advised to refrain from exposure with suggestions of possible alternatives.

Keywords: Allergic contact dermatitis, Patch test, ISS, Black rubber, Nickel

INTRODUCTION

The inherent urge to socially progress and develop gave way to the emergence of several new and newer chemicals in the process of modernization. Situation was made complicated when laws governing product quality and safety were substantially relaxed drastically giving rise to the number of cases being diagnosed with Allergic contact dermatitis.[1] ACD accounts for 4-7% of all dermatological consultations and became a challenging problem with considerable morbidity and economic impact.[2]

It is a contact allergy that is primarily immune mediated that occurs following sensitization to an allergen.[3] The allergen maybe anything in the environment the individual develops sensitization to when exposed. Workplace related exposure when handling chemicals produced several occupational dermatoses with allergic contact dermatitis commonly implicated as one among

them. Both skilled and unskilled workers have presented with clinical symptoms. Female preponderance was frequently realized.[4]

The exact cause of this contact allergy must be identified for an appropriate management program that primarily involves avoidance of the particular allergen.[5] This knowledge is possible only through careful patch testing. A properly performed and correctly interpreted patch test is presently the only "scientific proof" of ACD and hence is considered the gold standard investigation.[6,7]

Yet patch test was not that frequently carried out when in reality it is most effective in terms of efficacy and cost.[8] It should be considered a necessity and suggested to patients as avoidance is the only definitive treatment in ACD. We have attempted to diagnose suspected patients of ACD with the help of patch test both to confirm and to derive an appropriate solution and treatment strategy**.**

METHODS

The required sample size was selected as per criteria for patch testing from all patients with suspected contact dermatitis who attended the outpatient section and a Cross Sectional Study design was conducted in the prescribed time period in the Department Of Dermatology, Venereology & Leprosy at MES Medical College Hospital, Perinthalmanna.

Inclusion criteria

Inclusion criteria were ACD cases with no lesions over back.

Exclusion criteria

Exclusion criteria were patients with recent history of steroid therapy; patients under ultraviolet therapy; pregnancy.

Study period

January 2017 - March 2018

Equipments

- Indian standard series

Data collection

Patients with suspected ACD willing to be patch tested were selected. Detailed clinical history was obtained using a pre-tested semi structured case-record form. The subjects were clinically examined and if found in the active stage of disease were first treated. The individuals were patch tested with CODFI recommended Indian Standard Series, after obtaining a written informed consent. Minute concentration of chemicals as prescribed was applied to the clinically normal skin of the upper back using aluminium chambers under occlusion with micropore tape. Readings were recorded at 48 and 96 hours from application after uncovering the occluded parts and interpreted using the International Contact Dermatitis Research Group (ICDRG) criteria (Table 1). Patients were advised to keep the area dry until the second reading is done.

Table 1: Grading as per the ICDRG criteria.

Grading as per reaction	Appearance of lesions	Interpretation
-	No reaction	Negative
?/+/-	Faint erythema only	Doubtful reaction
+	Palpable erythema, infiltration, possibly papules	Weak (non vesicular positive reaction)
++	Erythema, infiltration, papules and vesicles	Strong (vesicular positive reaction)
+++	Intense erythema, infiltration and coalescing vesicles.	Extreme (bullous positive reaction)
IR	Purpuric/pustular lesions/Soap effect/bulla/necrosis	Irritant reaction
NT	-	Not tested

Statistical analysis

Data so obtained was entered in Microsoft Excel and analysis done using SPSS for Windows (version 25.0). Descriptive analysis was prepared and the prevailing common allergens identified and expressed in frequencies and percentage. Fisher's exact test was used to analyse the relation of allergens with variables of age, sex and sites of presentation. Any p-value of <0.05 was considered statistically significant.

RESULTS

In the specific time period of the study 246 cases of allergic contact dermatitis were diagnosed and treated in our outpatient department. Of this, 58.1% (n=143) were males and 41.9% (n=103) were females. From among them, 92 (37.4%) subjects were selected for the study to patch test. 59.8% (n=55) were males and 40.2% (n=37) were females. The mean age for the study group calculated was 50, least being 6 and maximum being 81 years. Maximum number of people who had allergic contact dermatitis belonged to the age range of 21-60 years, 183 (74.4%). Maximum number of people who underwent patch test was also within the same age limits, 67 (72.8%) (Figure 1).

Analysis was done with respect to the occupation of the individual subjected to patch testing. They were broadly grouped under skilled workers, unskilled workers, housewives and students.

From the 246 study population, unskilled workers were 89 (36.2%). This was followed by housewives- 75 (30.5%), skilled workers- 49 (19.9%) and then students– 33 (13.4%). From those willing to be patch tested analysis as per employment showed unskilled workers as 42 (45.7%), followed by 28 (30.4%) housewives, 12 (13.0%) students and then 10 (10.9%) skilled workers (Figure 1).

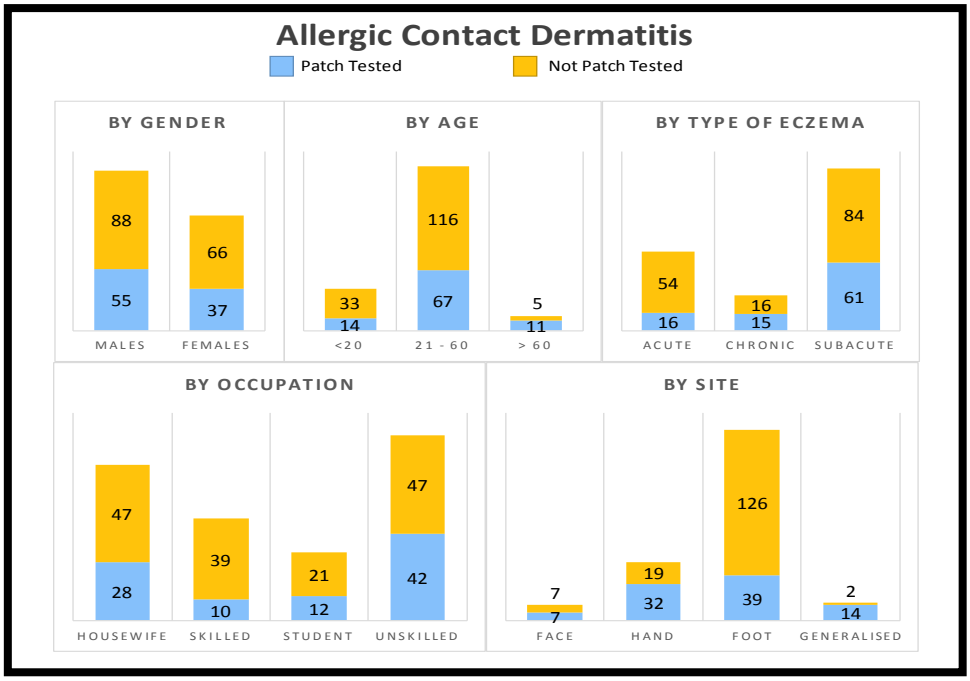

Figure 1: 92 patients were patch tested and analysed from 246 cases of ACD.

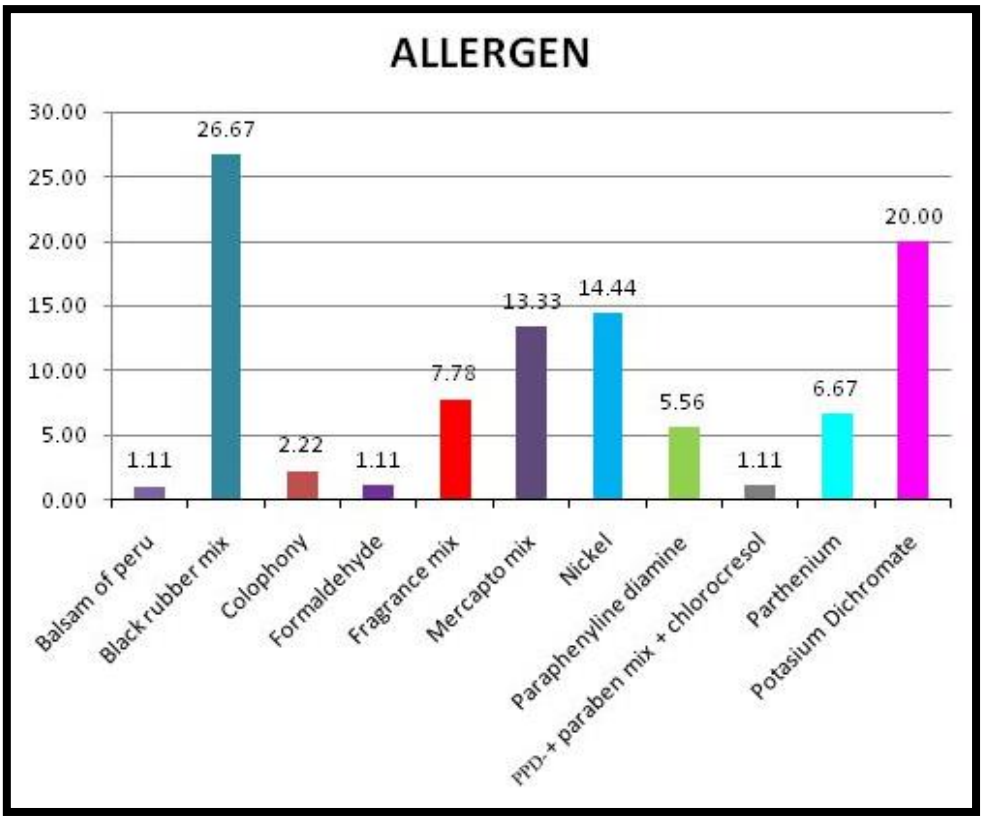

Figure 2: Allergens identified in patients with positive patch test reaction.

The commonest symptom of presentation among those suspected with allergic contact dermatitis in the OPD between the prescribed time period was itching 100% (n=246). Based on the clinical presentation and length of duration of symptoms they were divided into conditions of acute, subacute and chronic eczema. Majority of the patients had subacute eczema 145 (58.9%) that was followed by acute eczema 70 (28.5%) and chronic eczema 31 (12.6%). It was found that significant number of people with subacute eczema were willing to undergo patch test, 61 (66.3%), followed by acute 16 (17.4%) and chronic 15 (16.3%). Those diagnosed as acute eczema were investigated with patch test only after their present lesions had subsided with treatment (Figure 1).

Overall foot 165 (67.1%) was the commonest site affected with lesions in the hands 51 (20.7%) following this. 6.5% (16) of the patients presented with generalized lesions and in 5.7% (14) face was the affected area and considered the least affected part in the body (Figure 1).

Out of the 92 patients who underwent patch test, 83 (90.2%) showed positive results at the end of 48 hours. From the 83, maximum positive results were obtained under 1+ equivalent to 46 individuals (55.4%) that were graded according to the ICDRG criteria. Patient that showed 3+ reaction was not further included in the next reading. The remaining but two individuals (97.8%) i.e., a total of 90 people gave positive results at the end of 96 hours. 1+ grading was most noted in 63 (70%) among all positive results in the end of patch testing. The initial 9 patients, who turned out to have patch test negativity at the end of 48 hours, became positive in the subsequent reading taken at 96 hours except in two cases that remained negative (Table 2). All 7 patients that showed delayed positive results thus, were tested positive for fragrance mix (FM).

Black rubber mix was found to be the commonest allergen with 24 positive results (26.7%). This was followed by potassium dichromate 18 (20%) and nickel with 13 positive results (14.4%). Mercapto mix closely followed nickel showing 12 positive results (13.3%). One patient (1.1%) developed multiple positive reactions to allergens of paraphenylenediamine (PPD), paraben mix and chlorocresol (Figure 2).

Sex distribution and results derived accordingly showed that the common allergens as potassium dichromate exclusively affected most males (n=18) showing 33.96% in the 53 males tested positive in the study followed by black rubber with 9 results in favour of it (16.98%). Allergens like PPD and parthenium were equally common (n=6) with 11.3% and exclusively positive in males like some other allergens. The most frequently encountered allergen among females after Black rubber 40.50% (n=15) was Nickel 29.7% (n=11). No allergen was exclusively found positive in females. 2 among males were tested negative to all allergens. The findings were significant with p value <0.001 (Table 3).

Table 2: Type of interpretation after 48 and 96 hours of patch test.

Readings after 48 hours			Reading after 96 hours	
	Frequency	**Percentage (%)**	**Frequency**	**Percentage (%)**
No reaction	9	9.8	2	2.20
Mild	46	50	63	69.2
Moderate	36	39	26	28.6
Severe	1	1.1	-	-
Total	92	100	91	100.00

Table 3: Distribution of allergens by sex among those patch tested.

Allergen	Sex		Total	Fisher's exact test	P value
	F	**M**			
Balsam of Peru	0	1	1		
Black rubber mix	15	9	24		
Colophony	0	2	2		
Formaldehyde	0	1	1		
Fragrance mix	4	3	7		
Mercapto mix	7	5	12		
Nickel	11	2	13	43.846	<0.001
Paraphenyline diamine	0	5	5		
Paraphenyline diamine+paraben mix+chlorocresol	0	1	1		
Parthenium	0	6	6		
Potassium Dichromate	0	18	18		
Total	37	53	90		

Table 4: Distribution of allergens among occupational groups.

Allergen	Occupation				Total
	Housewife	Skilled	Student	Unskilled	
Balsam of Peru	0	1	0	0	1
Black rubber mix	10	0	6	8	24
Colophony	0	0	0	2	2
Formaldehyde	0	0	0	1	1
Fragrance mix	4	2	0	1	7
Mercapto mix	3	1	6	2	12
Nickel	11	0	0	2	13
Paraphenyline diamine	0	3	0	1	4
Paraphenyline diamine+paraben mix+chlorocresol	0	1	0	0	1
Parthenium	0	0	0	6	6
Potassium Dichromate	0	0	0	18	18
Total	28	9	12	42	90

Table 5: Distribution of allergens by age groups.

Allergen	Age group			Total	Fisher's exact test	P value
	<20	21 - 60	>60			
Balsam of Peru	0	1	0	1	27.158	0.095
Black rubber mix	6	13	5	24		
Colophony	0	2	0	2		
Formaldehyde	0	1	0	1		
Fragrance mix	0	7	0	7		
Mercapto mix	6	6	0	12		
Nickel	1	11	1	13		
Paraphenyline diamine	1	4	0	5		
Paraphenyline diamine+paraben mix+chlorocresol	0	1	0	1		
Parthenium	0	6	0	6		
Potassium dichromate	0	13	5	18		
Total	14	65	11	90		

Table 6: Distribution of allergens in different sites.

Allergen	Site of invovement				Total	Fisher's exact test	P value
	Face	Generalised	Foot	Hand			
Balsam of Peru	0	0	0	1	1	140.309	<0.001
Black rubber mix	0	0	24	0	24		
Colophony	0	0	0	2	2		
Formaldehyde	0	0	1	0	1		
Fragrance mix	0	7	0	0	7		
Mercapto mix	0	0	11	1	12		
Nickel	4	0	0	9	13		
Paraphenyline diamine	3	0	1	1	5		
Paraphenyline diamine+paraben mix+chlorocresol	0	0	0	1	1		
Parthenium	0	6	0	0	6		
Potassium dichromate	0	1	2	15	18		
Total	7	14	39	30	90		

Potassium dichromate was only positive in unskilled workers accounting to 100% (18/18) whereas black rubber mix tested positive commonly in housewives with a total of 10 out of the 24 (41.7%) tested in favour of it followed by positive results in unskilled workers 8/24 (33.3%). Housewives showed maximum sensitivity to nickel 11/13 (84.6%). PPD was frequently observed in skilled workers with 4/6 results (66.7%). One patient had multiple positivity in addition to PPD, to allergens like parabens and chlorocresol. In students black rubber mix and mercapto mix were equally seen. One among the skilled and unskilled gave negative results (Table 4).

Almost in 96.7% which is 89 individuals, patch test results could be correlated with the clinical presentations. 1 patient showed multiple positive reactions and the results of remaining two patients were interpreted as negative.

In age group <20 black rubber mix and mercapto mix were equally common (42.9%). Black rubber mix and potassium dichromate were found to be the most frequent sensitizer in the age group of 21-60 (20%) and above 60(45.6%). But it was not statistically significant (p=0.095) (Table 5).

The commonest allergens found in the face were nickel (57.1%) followed by PPD. Fragrance mix (50%) was the most frequent sensitizer seen in generalized dermatitis. Black rubber mix (62%) was found most in foot and potassium dichromate (50%) most in the hand dermatitis. The findings were significant with p value <0.001 (Table 6).

DISCUSSION

Allergic contact dermatitis is a disease that develops as a result of immune mediated response that occurs following the exposure to an exogenous substance. Whereas, irritant contact dermatitis is a sister reaction that is non immune dependent response characterised by local inflammation of varying severity.[9] Collectively both are identified as contact dermatitis.

ACD is primarily an eczematous reaction following an additional exposure to a hapten in a person who was previously sensitized by the first exposure. Type IV delayed hypersensitivity reaction is noted in these individuals.[10] It is a chronic problem that affects people irrespective of their age sex or race.

In a developing country like India majority of the population have access to poor quality products that are produced due to relaxed adherence to product quality guidelines. The humid and abundant rainfall also heighten the chances of developing the disease. The resultant effect is not only physically restricting but also affects productivity and quality of life.

The concept of ACD was actually put forward by Jadassohn in 1895. He is also considered as the father of Contact dermatitis and Patch testing. Patch test was developed in 1897 and it has since then been the gold standard for the diagnosis of ACD.[11]

Patch test is a simple cost effective bioassay that can be carried out on an outpatient basis that also helps to reduce the overall cost of therapy in patients with severe ACD. It helps in the early diagnosis and timely intervention before it becomes chronic, thus reducing resources used and improving the quality of life of the patient considerably. Many studies have stressed upon the importance of patch testing. Statistical evaluation by Rajagopan et al showed that it is a very basic, feasible and cost effective test.[12] Yet the test astonishingly remains underutilized due to trivial reasons.

Our study showed that the affected majority were males. This can be due to the fact that males have a more outgoing nature in this society than females and have a greater tendency to seek medical care by being the primary earning member in the family with significant exposure to allergens in workplaces. The male preponderance is also influenced by the selection process. A study in Spain showed that there was a gender influence in the risk factor for sensitization seen more in females.[13] Walton et al showed that there was an overall female preponderance- 61%, with 2 peaks of incidence in the 10-20 and 40-50 year age groups, but only 1 peak of incidence in the 40-50 year age group in males.[14] This contradicted the finding in our study about male predominance.

Maximum number of people who had allergic contact dermatitis belonged to the age range of 21-60 years, 74.39%. They are the ones most exposed to the environmental chemicals that act as allergens being the most active age group with respect to profession.

Some studies have depicted prevalence of allergic contact dermatitis among children and adolescents to be low. However this may be due to lesser consideration of ACD in children with dermatitis when presented clinically. Mortz et al has revealed that studies mostly do not have unselected populations in evaluation which in turn influences the outcome and due to many associated reasons the incidence and prevalence of contact allergy and ACD in children and adolescents remains largely unknown.[15] In a study by Militello et al it is said that rates of allergic contact dermatitis in children are on the rise and may be due to the better recognition by pediatricians also with the help of epicutaneous patch testing.[16] There was a steady decline in all sensitivities noted after the 6th decade of life in both sexes.[14]

By occupation of the patients in our study they were broadly classified as skilled workers, unskilled workers, housewives and students. From the 246 study population unskilled workers were 36.2% followed by housewives-

30.5%, skilled workers- 19.9% and then students- 13.4%. Those self employed, involved in agriculture and farming, masonry and others employed as janitors, retail salespersons in textiles were included in the unskilled category. From those willing to be patch tested analysis as per employment showed unskilled workers as 45.7%, followed by 30.4% housewives, 13% students and then 10.9% skilled workers. Unskilled workers were the most affected with the disease and were most willing to undergo patch test probably because of the interference of the disease in their daily life and to carry out their work affecting daily wages due to constant absence from workplace. Allergic contact dermatitis is one of the important occupational hazards in construction workers but it is often neglected as per a study in India by Sarma et al. [17]

Housewives were the next most exposed as per our study and this could be due to the constant exposure to allergens constituted in detergents, ornaments and so, on a daily basis. Substances such as nickel and fragrance mix were commonly used by housewives.

In a similar study in India by Latha et al, ACD was commonly seen in unskilled individuals who were also the most among the patch tested.[18] This was followed by housewives skilled workers and students in that order in both categories of ACD as well as patch tested. They had considered masonry as a separate profession unlike us.

Itching 100% was the ubiquitous symptoms in all patients with ACD who attended our OPD though other symptoms like pain redness were also present in some. Based on the clinical presentation and length of duration of symptoms they were divided into acute, subacute and chronic eczema.

Majority of the patients had subacute eczema- 58.9%. Those in the subacute stage were most willing to be patch tested probably owing to their readiness to be diagnosed and understand the causative allergen to prevent severity of the disease and to attain some control over it.

In the data collected via the questionnaire, atopy was present in 22% of cases among those who were patch tested in our study. In a study by Klas et al it was concluded that the likelihood to have ACD in atopics and non-atopics was the same.[19] But in a study by Jacob SE et al ACD was found to be prevalent in atopic dermatitis though not statistically significant.[20]

The order of presentations by site were foot, hand, generalized and face with 42.4%, 34.8%, 15.2% and 7.6% respectively in those patch tested. These findings were found significant in our study.

The commonest allergen found as per our study could be correlated with the commonest presentation of foot eczema in the study. Use of low quality rubber slippers might be cited as the cause for this. Clinically ACD was presented in the hands following foot closely in those patch tested. This could be also due to the frequent handling of chemicals in workplaces and substances of daily use at homes. Allergic contact dermatitis can also occur due to nickel which is implicated as the common cause of hand eczema.[21]

Figure 3: A patient with ACD foot tested positive for black rubber mix.

Black rubber mix (BRM) was found to be the commonest allergen with 24 positive results (26.7%) all in those with foot lesions as per our study which may be mostly due to the rubber content in footwear (Figure 1). In a study done in India fragrance mix (15.5%) was found to be the commonest sensitizer followed by parthenium (12.4%) and nickel sulphate (10.8%).[18] A study by Narendra showed that nickel sulphate-15% was the commonest allergen detected by patch test that was followed by potassium dichromate-13.75%, cobalt chloride and colophony- 8.75% each, fragrance mix and thiuram mix-7.5% each.[22]

To the best of our ability, we were unable to quote another similar study anywhere in literature which had BRM as the commonest sensitizer.

In our study BRM was followed by potassium dichromate 20% and nickel with 14.4% positive results. Mercapto mix closely followed nickel. Only one patient- 1.1% developed multiple positive reactions to allergens of PPD, paraben mix and chlorocresol.

Multiple positive reactions like observed in one of our patients who was patch tested may be due to cross reactivity to similarly structured chemicals or due to actual sensitization to multiple chemicals in the test. In either case patient is advised to refrain from exposure to these multiple chemicals in future. Dickel et al noticed 12.4% of multiple patch test reactions in their study.[23]

Cross reactions are actually false positive results that occur due to the response of the primed T cells in the body against one particular allergen reacting with structurally similar sensitisers. This generally occurs as a result of failure of identification of the exact allergen the body was originally allergic to as a result of confusion.[24]

Cross reactions to different compounds in the parabens group itself is seen here. As per literature PPD and parabens has similar structures which can give such reactions though some authors do not consider them to be so. Such possibility is observed with chlorocresol and chloroxylenol but this occurs only if the patient is sensitized to chloroxylenol initially.[25]

Though most studies had different allergens in their lists, Nickel was one chemical found consistently in the upper tier of the common allergens. This can be due to its ubiquitous presence in products of common use like ornaments, cloth accessories and also in food items.[26]

In age group <20 black rubber mix and mercapto mix were equally common (42.9%).

Sarma et al found that the common allergens were paraben (43%), potassium dichromate (27%) and fragrance mix (26%) in a study done in children below 15 years of age. Most relevant allergens were potassium dichromate, paraben and fragrance according to the study.[1]

Potassium dichromate exclusively affected most males showing 33.9%. Allergens like PPD and parthenium were equally common and exclusively positive in males. The most frequently encountered allergen among females after Black rubber 40.5% was Nickel 29.7%.No allergen was exclusively found positive in females.

In the study by Madhavi et al potassium dichromate was found to be the commonest allergen with 12 positive results (20.6%) in males.[18] Parthenium and FM had 7 positive results each in males in the study. Whereas in females 13 out of 71 positive results (18.3%) were given by fragrance mix, followed by nickel sulphate10 (14.8%) and parthenium with 9 (12.6%). From the total 14 positive responses to nickel 71% was attributed to women.

A study conducted in Israel in 943 patients using the European standard patch test series nickel sulfate was the most common sensitiser followed by potassium dichromate and fragrance mix. They said that positive reactions to nickel sulfate were commoner among women particularly in those less than 40. Positive reactions to balsam of Peru were seen commonly among men but in the older age group more than 40.[7]

Thyssen et al showed that nickel was an important cause of contact allergy in the general population and that it was widespread in both men and women.[27]

According to our study potassium dichromate was only positive in unskilled workers accounting to 100%. When the concept of cement contact allergy was understood and the reason for the same being chromium was realized, many countries started passing legislations making mixing of iron in cement mandatory which in turn dramatically reduced related ACD in those exposed in the industry.[28]

PPD was frequently observed in skilled workers. This can be due to the common use of hair dyes by men belonging to the middle and upper class. In students black rubber mix and mercapto mix were equally seen. One among the skilled and unskilled gave negative results.

In a study conducted in India PPD was the commonest allergen observed in the skilled workers (20%). FM was the most common allergen seen in housewives and students collectively accounting to around 39%. This was explained by the casual use of cosmetics by them.[18]

The commonest allergens found in the face were nickel (57.1%) followed by PPD.

Generalised reactions were noted in Parthenium positive reactions as observed in several other studies though the allergen most presented with generalized eczema was Fragrance mix (50%). Parthenium is one cause of airborne contact dermatitis and is the commonest cause of plant dermatitis in India.[29] It was also the commonest allergen found by patch test by Yoganand et al.[30]

One female who presented with dermatitis in the face in our study was suspected with Kumkum allergy by its site of occurrence - the glabella which was validated by Babu et al.[31] But this patient turned out to be positive for nickel and could be stated that the ACD developed was actually due to nickel that was a constituent of the Kumkum container (Figure 4).

Figure 4: Patient with ACD patch tested positive to nickel from kumkum container.

Out of the 92 patients who underwent patch test, 90.2% showed positive results at the end of 48 hours. All 7 patients that showed delayed positive results thus, were tested positive for FM later.

Morphologically assessed and graded positive tests of patch test are identified as allergic and thus the patient is deemed sensitized to that particular antigen with ACD. Though typically at least two readings are required when ideally readings obtained on days 2, 3 or 4 and 7 are preferred.[32] However a recent study by Mayo clinic on 36,064 patch test reactions found that the most optimal time to read the test is on Day 3 and 5.[33] In the study it was shown that late patch test readings (≥day 7) were useful in cases of metals and topical antibiotics, but it was not so when other allergens are considered. Fragrance like allergens may dissipate after 5 days thereby necessitating a reading within this period.

By 96.7% patch test results could be correlated with the clinical presentations. This may be influenced by the sample selected as only patients with suspected ACD were included for the study. With 1 patient who showed multiple positive reactions it may be assumed that cross reaction had taken place. Though the results of remaining two patients were interpreted as negative, the possibility of ACD still remains inconclusive in them. According to Lazzarini it is necessary to do other variants of patch tests like ROAT to refine the attained response and to derive a conclusive diagnosis.[34]

CONCLUSION

Better said than done, it is in fact difficult to practically implement abstinence from exposure. Strong recommendations to safety guidelines and laws ensuring good product quality becomes the crucial deciding factor in the fate of all those exposed.

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