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PLASTIC FILM AS PROTECTION AGAINST PRIMARY IRRITANTS

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Abstract. With patch testing, using the Rokstad adhesion chamber test method, it was demonstrated that polyetoxiethylmetacrylate film (Nobecutane) provides good protection against skin reactions provoked by sapo kalinus, sodium lauryl sulphate, benzalkonium chloride and croton oil. Somewhat less protection was observed against hydrochloric acid. With drop testing, good protection was likewise demonstrated against phenol. In contrast an *accentuated* skin reaction was provoked by using the plastic film for "protection" against trichloracetic acid. Etoxiethylmetacrylate is soluble in trichloracetic acid. It is important to ascertain the chemical properties of an irritant substance before using Nobecutane as a protective measure against it.

A polymer of etoxiethylmetacrylate, Nobecutane® (AB Bofors, Nobel-Pharma), was used in this study. As the solution of the monomer in ethylacetate evaporates rapid polymerization takes place, resulting in the production of a transparent elastic film. It is used in surgery as a dressing and in dermatology as a vehicle for medicaments such as tar and cignolin. In occupational dermatology it is utilized for its protective effect against external irritants.

The efficiency of Nobecutane to provide protection was proved in guinea pigs with trichloracetic acid (6) and acids and alkalis (9). In man this protective effect was shown against potassium hydroxide, phenol and surface-active substances (6, 8), acids, alkalis and water-soluble salts (5, 7) and adhesive plaster (4). Protection against allergic reactions was shown in patch tests with chromium (3) and plants (2).

Present investigation

The aim of the present investigation was to study the protective effect of Nobecutane on skin reactions to different primary irritants. The investigation was performed in two parts: 1. As patch tests with five irritants; 2. As drop tests with two other irritants.

I. PATCH TESTING

Patients

The tests were performed in two series of about 85 people, patients with hand eczema and normal individuals who had never any major skin disease. All the eczematous patients had their lesions strictly localized to their hands during the period of testing and no eczema had been observed at any site other than the hands during the preceding three months. On examination, the patients had no skin lesions other than eczema and there was no history of any other skin disease. All patients who might have atopic dermatitis, as judged from a history of dermatitis of the face and/or flexures during childhood or of the flexures during adolescence, were excluded from the series. The hand eczema was diagnosed from morphological criteria and no attempt was made to separate those with contact eczema into toxic and allergic types. Patients with dyshidrotic eczema were excluded. The healthy individuals had never had any major skin disease. The two series tested, those with hand eczema and the normal subjects, had the same distribution as to sex, age, occupation and menstrual cycle. All were 15–70 years old. Thus no children were tested. The sex distribution of men to women was roughly 1: 5. Most had intense occupational contact with external irritants. Women of child-bearing age were tested between periods, avoiding the week before and after menstruation.

Test technique

The Rokstad adhesion chamber test method was used as originally described by Rokstad. The test unit consists of a circular plastic disc with a central dome-shaped impression, in which the test substance is applied on a small cellulose patch. The test unit is fastened to the skin with adhesive plaster (Leucoplast, Beiersdorf). The following test substances were used: 50% sapo kalinus in vaseline, 3% sodium lauryl sulphate in distilled water, 20% hydrochloric acid in distilled water, 2% benzalkonium chloride in distilled water, 0.5% croton oil in vaseline. That the amount of test substance used on each patch was always the same was ascertained by using dosage pipette bottles

for the solutions (Blohm). The substances in ointment bases were also applied in definite quantities. In this way the amounts of test substances applied to the patches was standardised and the influence of Nobecutane could be studied.

The investigation was made as a comparison between two skin test reactions, one on unprotected skin and the other on skin covered with Nobecutane. The skin of the test sites was not washed for 24 hours preceding the application of the chambers. The two tests to be compared were placed close together on the lateral aspect of the thigh, the distance being a few centimetres. The Nobecutane preparation consisted of a cloth with Nobecutane simplex, having a weight of 0.2 g corresponding to an area of 2×2 cm. The cloth was fastened to the skin by acetylacetate, and the Rokstad test was applied on the top of the Nobecutane impregnated cloth.

After an exposure time of exactly 24 hours the two tests were removed, and after a further 20 min the skin reactions were evaluated. A second reading of the test results was made after another 48 hours, that is 72 hours after the application of the patches. This reading generally gave a more clear-cut evaluation of the more severe reactions as the early, slight, erythematous responses had usually disappeared. Therefore, to illustrate the protective effect of Nobecutane only the 72 hour readings are reported in this paper.

The skin regions used for the two tests to be compared were practically identical, thus errors which occur from varying skin reactivity at different sites were avoided. External pressure caused by the clothes or different positions during work or sleep do not seem to influence the comparisons between the adjacent areas.

The cloth impregnated with Nobecutane was used as a control test in all cases to ensure the lack of irritancy of Nobecutane.

Assessment of the skin reactions

This was based on the appearance of the test reaction and on its extension. Based on earlier experience it was possible to grade, by morphological criteria, the reactions to each substance as weaker or stronger in relation to each other. The clinical features of the reactions differed and depended on the irritant used.

The test concentrations of the different irritants were initially chosen so as to provoke moderate skin reactions in most of the tested subjects, the eczema patients as well as the normal subjects. A detailed comparison between the intensities of skin reactions in patients with hand eczema and in controls had been reported earlier (1).

Results

The results may be summarized as follows:

1. *Sapo kalinus.* Complete protection by Nobecutane. The only response when using Nobecutane was a transitory erythematous reaction after 24 hours in one patient with hand eczema.

2. *Sodium lauryl sulphate.* Almost complete protection by Nobecutane.

3. *Hydrochloric acid.* The protection by Nobecutane was not complete. After 72 hours severe reactions also occurred under Nobecutane and were observed in eczema patients as well as in normal subjects.

4. *Benzalkonium chloride.* Almost complete protection by Nobecutane.

5. *Croton oil.* Almost complete protection by Nobecutane.

The Nobecutane-impregnated cloth gave by itself no skin reactions.

II. DROP TESTING

In the second part of the investigation the drop method was used as described by Wedroff–Dolgoff. Initially a Nobecutane-impregnated cloth was used as in the patch tests and the drops of irritant solutions were applied on top of it. However, it was found that the time taken for the test drops to dry was so long that as a practical technique it was impossible to perform the tests in this way.

Therefore a modification of the Nobecutane protection was made in the study with phenol and trichloracetic acid.

Patients

The study was performed on 15 metalworkers using phenol and 21 metalworkers using trichloracetic acid. Healthy skin on the back of their legs was utilized. Some of the workers had eczema localized to the hands; others were healthy individuals. None had been exposed to soap or skin irritants on the test areas 24 hours prior to the tests.

Test technique

For each test concentration of these two irritants four test areas were used, Nobecutane being sprayed as a thin film in circles of 1 cm diameter. The first area was left untreated, the second was sprayed with one layer of Nobecutane, the third with two layers and the fourth with three layers of Nobecutane. In each of the four test areas 0.03 ml of the test solution was applied and allowed to dry at room temperature. The reactions were read at 24 and 72 hours, the last readings being reported in the present paper. Phenol was used in the concentrations of 20%, 15%, 12%, 10%, 7.5%, 5%, 3%, i.e. a total of 28 tests was done with this substance in each individual tested. Trichloracetic acid was used in concentrations of 30%, 20%, 10%, 7.5% making a total of 16 tests in each individual.

With the stronger concentrations most subjects noticed a stinging pain with both substances, but in no case was this severe enough to stop the tests.

Results

The protection given by Nobecutane against *phenol* became greater when the thickness of the

films was increased from one to three layers. Three layers gave complete protection from skin reactions up to a 15% concentration, but with 20%, reactions of a necrotic type were seen in about one-third of those tested even when using three layers of protective film. With this concentration all individuals reacted strongly on their untreated skin.

Trichloracetic acid, in contrast to phenol, gave increasing skin reactions as the thickness of the "protective" Nobecutane film was increased! With 10% trichloracetic acid, six individuals reacted severely on their untreated skin but when used over three layers of Nobecutane, 14 individuals exhibited severe reactions. In the comparisons between the severity of the skin reactions in the untreated skin and in the skin covered with three layers of Nobecutane, statistically significantly stronger skin reactions were demonstrated in the pretreated skin to 7.5% ($P<0.05$), 10% ($P<0.05$), 20% ($P<0.01$), 30% ($P<0.05$), that is to each concentration of trichloracetic acid. The tendency towards stronger reactions occurs as the thickness of the Nobecutane film increases (one, two and three sprayings). Thus it was shown that the Nobecutane film does not protect the skin from epicutaneously applied trichloracetic acid. On the contrary the irritant effect was more intense as the thickness of the Nobecutane layer increased. The surface area of the skin reactions under the Nobecutane were usually smaller than those on the untreated skin. One had the impression that the trichloracetic acid quickly penetrated the Nobecutane on a small field thus giving a comparatively severe skin reaction in a limited area, whereas on the untreated skin it spread out over a larger surface.

DISCUSSION

In both parts of the present investigation, using the patch test and the drop test techniques, it was shown that Nobecutane will provide protection of the skin against externally applied primary irritants. The protection was almost complete to sapo kalinus, sodium lauryl sulphate, benzalkonium chloride and croton oil (patch tests). Although it was less effective against hydrochloric acid it could be demonstrated clearly, as compared with the untreated skin. With phenol (drop test), good protection was also shown. In contrast to the effect when testing with all these substances, Nobecutane provoked a more intense skin reaction when used in conjunction with trichloracetic acid. By increasing the thickness of the "protective" Nobecutane layer the severity of the skin reactions to trichloracetic acid became even more pronounced. This experimental observation is in accord with the theoretical fact that trichloracetic acid dissolves Nobecutane, thus increasing the skin irritant effect of trichloracetic acid. Phenol, too, is a solvent for Nobecutane but in this study no exaggeration of the skin reactions from this chemical was noticed when using Nobecutane. The protective effect of Nobecutane against 50% trichloracetic acid, which has been demonstrated in guinea pigs (6), could not be confirmed in the present study in humans.

It has been shown previously that Nobecutane film may provide different degrees of protection against various substances, and this may be dependent on different penetration. Heite (5) found that Nobecutane protected against acids and alkalis, but not against turpentine and formalin and Greither (3) demonstrated a protective effect against allergic patch test reactions to potassium bichromate, but not to formalin.

In using Nobecutane as a protection against skin reactions to various epicutaneous applied irritants it is imperative to consider first the chemical nature of these substances in relation to the properties of Nobecutane.

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