

Use of Two Prophetic Patch Tests for the Practical Determination of Photosensitization Potential of Widely Used Deodorant Soaps*

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Synopsis—Schwartz-Peck and Draize-Shelansky human patch tests, modified to include UV irradiation, with soaps containing 3,4',5-tribromosalicylanilide and 4',5-dibromosalicylanilide caused no photosensitization in the 150 subjects tested. These results confirm that these antimicrobial agents have a very low photosensitization potential.

INTRODUCTION

The attention of the physician has become increasingly focused on cases of photosensitivity from therapeutic agents used internally and from antibacterial agents employed in topical products. Regarding the latter, a recent editorial in the *Journal of the American Medical Association* stressed the importance of the need for physicians to be alerted on these occurrences with reference to deodorant soaps (1).

The fact that antimicrobial agents used in soap have been implicated in isolated cases of photodermatitis is not a cause for alarm. It is generally accepted that in the population at large susceptibility by hypersensitive people to many useful agents (perfumes, sulfonamides, tranquilizers, and even certain natural products) does occur and manifests itself as dermatitis of the skin in the exposed areas. Of course, it is vital that the physician be cognizant of such incidents in order to be in a position to diagnose, treat effectively, and advise the patient accordingly. Reports by Jillson and Baughman (2), Baughman (3), Epstein and Enta (4), Molloy and Mayer (5), and Harber *et al.* (6), of case histories of hy-

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persensitive patients shown to be photoallergic to deodorant agents employed in topical products are valuable in alerting the physician to such incidents.

Unfortunately, however, some of these reports are being misconstrued and interpreted to indicate that widely accepted antibacterial agents, such as polybrominated salicylanilides, may be possible hazards to the normal healthy subject. The facts do not support such implications. These agents have been used for the past nine years in toilet soaps, *not* introduced recently as mistakenly stated by Harber *et al.* (6). During this time, literally hundreds of millions of bars have been marketed with excellent consumer acceptance.

The strong upward trend in consumer sales in recent years, in part, reflects the significant health contributions of soaps with bacteriostats, namely: (i) regular use of soaps containing effective antibacterial agents results in significant reductions in cutaneous bacterial counts (7); (ii) maintenance of low cutaneous counts has the effect of reducing body odor development due to bacterial attack on skin waste products and secretions for sustained periods (8); and (iii) maintenance of low cutaneous counts and the presence of trace amounts of antibacterial agents which remain on skin after washing have the effect of helping to suppress secondary skin infections (9).

Despite the impressive mildness data on soap containing polybrominated salicylanilides obtained in standard toxicological tests and human studies, reports of isolated cases of photodermatitis attributed to such soaps are being misconstrued as being more widespread than the facts indicate. One of the soaps mentioned in recent reports (4-6) was Lifebuoy[®]*, a product which the authors have examined for some time. It seems appropriate, therefore, to report clinical results which put the photodermatitis data in the proper perspective.

EXPERIMENTAL

Two standard prophetic patch tests, the Schwartz-Peck and Draize-Shelanski procedures, modified to include UV-irradiation of the treated skin sites, were employed to assess the photosensitizing potential of deodorant soaps on 150 normal subjects. Over a period of about two months, during which time the patch test series was conducted, the panel members were also given a test bar containing polybrominated salicylanilides (test soap B) for regular washing at home and at work. The study was carried out in the vicinity of New York City during the hot,

* Lifebuoy is a registered trade name of Lever Brothers Co.

dry summer of 1966, during which this area experienced an unusual number of clear sunny days. The subjects were allowed to go about their usual summer activities, which included visits to the beach.

The test procedures employed were as follows:

Modified Schwartz-Peck Human Patch Test

Test Samples:

Soap A,* a white bar containing 0.75% 3,4'-tribromosalicylanilide†

Soap B,* a green bar containing 0.75% of a mixture of 4',5-dibromo- and 3,4',5-tribromosalicylanilide‡

Soap C,* a coral bar containing 0.75% of a mixture of 4',5-dibromo- and 3,4',5-tribromosalicylanilide‡

Soap D,* a white bar with no soap bacteriostat

Panel: One hundred males and females, ranging in age from thirteen to sixty-five, without any known allergies were used.

Procedure: Two per cent solutions of each of the test products were applied (0.1 ml on gauze) to the skin of the upper back, covered with "Elastoplast" coverlets and left in contact with the skin for forty-eight hours. The test areas were examined immediately after removal of the patches and again in fifteen minutes or more for evidence of delayed reaction. The skin sites were irradiated with a marginal erythemic dose using a Hanovia ultraviolet lamp of a wavelength range up to 3600 Å. The light source was 26 cm from the skin area which was irradiated for two minutes. The skin sites were examined for possible erythema development on the following day. Simultaneously, open patches were made using the skin sites near the right ear, left ear, inside right elbow, and inside left elbow.

After a rest period of fourteen days, the subjects returned for a second application of the test products applied as open and closed patches as described above. The skin sites were again irradiated and examined twenty-four hours later.

Modified Draize-Shelanski Human Patch Test

Test Samples: Same as for the modified Schwartz-Peck test.

Panel: Fifty subjects, ranging in age from twenty-four to sixty-eight, without any known allergies were used.

* Soaps A, B, and C are sold commercially under the name of Lifebuoy. Soap D is Ivory.

† Temasept II, Fine Organics, Inc., Lodi, N. J.

‡ Temasept I, Fine Organics, Inc., Lodi, N. J.

Procedure: Two per cent solutions of each of the four test products were applied both as open and closed patches, as described for the Schwartz-Peck test, with repeated applications on different skin sites made every Monday, Wednesday, and Friday until a total of ten applications had been performed. Each patch was in contact with skin for twenty-four hours. Following the tenth patch, there was a rest period of twelve to fourteen days, at which time a final or challenge insult was applied as open and closed patches.

The skin sites after contact with the closed patches were irradiated with the Hanovia ultra-violet lamp after the first, fourth, seventh, tenth, and challenge treatments. The irradiated sites were always read twenty-four hours after exposure.

RESULTS

No erythema development was observed on *any* of the skin sites exposed to repeated closed patches, open patches, and after marginal erythemic doses of UV-irradiation.

DISCUSSION

Commercial deodorant soaps containing polybrominated salicylanilides were found to be very mild in tests conducted on 150 people using the Schwartz-Peck and Draize-Shelanski human patch tests, modified to include UV-exposure of the patch sites. During the test periods (approximately two months), the subjects regularly used one of the soaps (green Lifebuoy) for personal hygiene.

The two polybrominated salicylanilides employed in soaps—3,4',5-tribromosalicylanilide (TBS) alone and in combination with 4',5-dibromosalicylanilide (PBS)—evidently behave differently on skin from tetrachlorosalicylanilide (TCSA) which was reported in 1961 to be a significant photosensitizer by Wilkinson (10). Vinson and Flatt (11) demonstrated that subjects photosensitized to soap containing TCSA were not cross-sensitized to soap containing TBS. Recently, Vinson and Borselli (12) have described a new guinea pig test for assessing photosensitizing potential of topical germicides. They were able to demonstrate that TCSA and bithionol are photosensitizers but that TBS and PBS are not.*

* The manufacturer of the Temasepts, brands of PBS and TBS, has issued a dermatological report on his plant workers who have handled these chemicals (as 100% active) for years. No cases of dermatitis or photosensitivity were encountered (13).

SUMMARY AND CONCLUSIONS

Commercial soaps containing the bacteriostats 3,4',5-tribromosalicylanilide alone and in combination with 4'5-dibromosalicylanilide failed to induce photosensitization in 150 subjects under exaggerated testing conditions. This is confirmation of previous studies and long marketing experience that these polybrominated salicylanilides have a very low photosensitization potential. The tests employed were the Schwartz-Peck and Draize-Shelanski human patch tests; these were exaggerated by exposing the patch sites to marginal erythemic doses of UV-irradiation and by having the subjects use one of the soaps with the bacteriostat for regular washing during the test periods.

The modified prophetic patch test procedures described are believed to afford a good assay for measuring photosensitizing potential of topical agents.

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