Investigation of the Allergenicity of a Refined Peanut Oil–Containing Topical Dermatologic Agent in Persons Who Are Sensitive to Peanuts

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We determined if a topical oil containing 0.01% fluocinolone and refined peanut oil (Derma-Smoothe/FS™ topical oil), among other ingredients, included materials to which peanut-sensitive individuals were sensitized. No immediate (15-min) or delayed (72-h) skin test reactivity was demonstrated in any of the 14 subjects tested. These results suggest that this refined peanut oil–containing dermatologic preparation is safe to use, even in persons who are sensitive to peanuts.

Peanut allergy is one of the most common food allergies, with an estimated prevalence of 1% in the United States.[1] Symptoms usually appear during early childhood, often when a toddler is offered peanut butter for the first time. Peanut-sensitive persons have IgE antibodies specific to one or more peanut storage proteins.[2] Sensitization is assumed to occur by prior ingestion of peanut-containing foods, but parents frequently insist that their child's symptoms occurred with the first known ingestion. Infants and toddlers may be exposed to peanut oil in vitamin drops,[3,4] infant formulas,[5] or dermatologic preparations.[6]

The aim of the present study was to investigate whether a topical oil containing, among other ingredients, 0.01% fluocinolone and refined peanut oil (Derma-Smoothe/FS™)—widely used for the treatment of atopic dermatitis, psoriasis, and seborrheic dermatitis of the scalp—was capable of eliciting positive immediate or delayed skin tests in peanut-sensitive children and adults.

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Methods

Study Populations—From computer listings of patients with allergies and local advertising, we identified and enrolled peanut-sensitive children (n=8) and adults (n=6). All volunteers gave clinical histories of generalized allergic reactions (diffuse urticaria, cutaneous or laryngeal angioedema, bronchospasm, vomiting or diarrhea, and/or hypotension) following ingestion of peanuts. All volunteers, or the parents of children younger than 18 years, provided written informed consent, and the study was reviewed and approved by the Mayo Institutional Review Board.

Study Medication and Administration—These agents included the complete dermatologic product itself (Derma-Smoothe/FS), the product vehicle only (without fluocinolone), and the refined peanut oil contained in the product.

Allergy Skin Testing—Peanut sensitization was documented by prick skin tests on the forearm using commercial peanut extracts (Hollister-Stier, 1/10 wt/vol in 50% glycerin), along with negative (50% glycerin alone) and positive (histamine phosphate 1.8 mg/mL in 50% glycerin) control solutions, and the 3 study materials listed above. One peanut-sensitive subject was tested with a 1/100 wt/vol peanut extract because of the severity of the peanut allergy. The resulting wheal diameters were measured and recorded after 15 minutes.

Patch Testing—The 3 study materials listed above were also patch-tested using Finn chambers placed onto the mid back. Chambers were left in place for 48 hours, when they were removed, and the sites were inspected. Volunteers returned after

Patient Demographics and Skin Prick Test Reactivity to Histamine (1.8 mg/mL), Crude Peanut Extract (1/10 wt/vol, Unless Otherwise Noted), and the Undiluted Refined Peanut Oil Used in Derma-Smoothe/FS

Patient No.	Sex*/Age, y	Histamine, mm diameter	Peanut, mm diameter	Peanut Oil, mm diameter
1	M/30	4×5	10×7	0
2	F/40	5×5	5×6 (1:100)	0
3	F/13	3×3	5×8	0
4	M/8	4×4	5×5	0
5	M/51	5×5	12×7	0
6	M/39	5×5	11×7	0
7	M/12	4×4	13×6	0
8	M/9	2×2	5×6	0
9	F/45	4×4	8×7	0
10	M/40	5×5	16×11	0
11	M/9	4×5	20×13	0
12	F/10	4×5	9×10	2×2
13	F/7	3×3	5×6	0
14	M/9	4×4	7×8	0

*M indicates male; F, female.

another 24 hours, and final readings were made 72 hours after placement of tests.

Results

The characteristics of the study group are listed in the table, along with the prick skin test results to the histamine positive control solution, the crude peanut extract, and the refined peanut oil. Only one volunteer had a trace positive reaction to the refined peanut oil. No positive prick skin tests were obtained with the Derma-Smoothe/FS itself, the Derma-Smoothe vehicle, or the 50% glycerin negative control solution. All patch test readings were negative at 48 hours and 72 hours, respectively.

Comment

Peanut oil is purified by several physical and chemical methods, including filtration, chemical extraction, degumming, heat refining (>150°C), blanching, and deodorization.[7] Protein has not been detected in most virgin refined peanut oil.[8,9] Some peanut oils are extracted from the seed by a mechanical expeller process at a temperature range of 65°C to 95°C[10]; the term *cold pressed* has been used to describe this process because of the lower temperatures achieved.

Several groups have investigated the allergenicity of peanut oil. Bock and Atkins[11] safely administered up to 30 mL of refined peanut oil to 4 persons with confirmed peanut allergy. In double-blind oral challenge studies performed in the United States[12] and the United Kingdom,[7] refined peanut oil has been well-tolerated by peanut-sensitive persons. Conversely, cold-pressed peanut oil may contain residual allergenic proteins.[10] In a double-blind, crossover challenge feeding study by Hourihane et al,[7] none of the 60 peanut-sensitive persons reacted to refined peanut oil, whereas 6 of the

60 persons reacted to the crude peanut oil. However, trace quantities of peanut proteins (100–200 ng per gram of oil) have been measured in refined peanut oil from France,[13] and positive labial provocation tests using refined peanut oil were seen in 14 of 62 French peanut-sensitive persons.[14] Based on these somewhat conflicting data, food and medication labeling laws should be clarified to distinguish between crude and refined peanut oil.

Because peanut allergy and atopic dermatitis frequently coexist in infants and toddlers,[15] it is useful to document that the use of peanut oil–based topical medications in these children does not pose additional risks. Although the number of volunteers in the present study was small, our results suggest that the refined peanut oil-containing product tested should be safe for use in individuals who are allergic to peanuts.

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