Negative Results

Poison Ivy Extract, Alum Precipitated

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POISON IVY EXTRACT, alum precipitated (Aqua Ivy, A.P.), the oral tablets in particular, has enjoyed popular appeal and widespread use for poison ivy hyposensitization primarily because of its reported effectiveness in very low dosage and its lack of side effects.[1-4] However, doubt has been raised as to its value, and the absence of adverse reactions has been attributed to its inertness.[5] Because of this conflict, a controlled double-blind study was undertaken, comparing various dosages of poison ivy extract, alum precipitated, with placebo.

Method and Procedure.—Volunteers with history of poison-ivy dermatitis were divided randomly into groups receiving different dosages or placebo over a 50-day period. The total dosages were 120, 240, and 480 mg in 1961; 480 and 960 mg in 1962; and 1,920 mg in 1963. The subjects were observed at five different centers; the period of study extended from midwinter to early spring.

Results of Patch Test Before and After Treatment

Total Dosage, Mg	Subjects Showing Disk Shift* No./Total	%	Subjects Showing Decrease in Reactivity† No./Total	%	Subjects Showing Increase in Reactivity‡ No./Total	%
1964						
Placebo	20/65	30	18/65	28	....	....
120.0	17/55	31	11/55	20	....	....
240.0	20/71	28	13/71	19	....	....
480.0	38/77	49	20/77	26	....	....
1962						
Placebo	39/148	26	27/148	19	44/148	30
480.0	39/132	30	27/132	20	32/132	24
960.0	4/15	27	3/15	20	5/15	33
1963						
Placebo	1/12	8	2/12	17	3/12	25
1,920	1/11	9	1/11	9	3/11	27

*Negative reaction to serial dilution to which previously positive.
†Reduction in degree of reaction to same serial dilution.
‡Increase in degree of reaction to same serial dilution.

Quantitative closed-patch testing was done with 3-pentadecylcatechol [6] (3-PDC) prior to and immediately following treatment. The 3-PDC was dissolved in acetone in serial dilutions of 1:100, 1:1,000, and 1:10,000. The patches, prepared as described by Vassallo,[4] were applied for 24 hours; reactions were read 48 hours after removing the patches.

The reactions were graded as follows: 0, no reaction; 1+, mild erythema confined to the area of the disk; 2+, marked erythema and one or two vesicles confined to the area of the disk; 3+, reaction beyond the area of the disk with vesicles and marked erythema.

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Results.—The results are shown in the Table. In the 1961 series there was a significant difference between the 480-mg group and the placebo ($P<0.02$). This was not replicated in 1962; in this series, as well as in the 1963 series, the number of patients experiencing an increase in reactivity was appreciable.

Since the number of subjects was small in the 960- and 1,920-mg groups, statistical analysis was not possible. However, there was no clinical evidence of poison-ivy hyposensitization.

Comment.—Poison ivy extract, alum precipitated, failed to produce effective hyposensitization in poison-ivy sensitive subjects. The oral administration of 1,920 mg over a period of 50 days without side effects is also indicative of the drug's inertness. These findings are consistent with Kligman's [5] conclusions and with our inability to demonstrate any active antigenic property when the drug was incubated with fresh duodenal secretions.

In view of the lack of response with high dosages, we viewed with extreme suspicion the apparent effect obtained at the 480-mg level in 1961. The significant difference in the disk shift in the 480-mg group compared with the placebo in 1961 does not appear to be due to therapeutic success of the drug. The inability to duplicate these results in 1962 supports such a conclusion. The results obtained in 1961 are inexplicable; factors other than chance or the effect of the preparation are apparently responsible. Even if the statistical difference favors the 480-mg dosage over the placebo, the fact that, at best, one can affect the sensitivity of only one fifth of the subjects receiving the preparation does not warrant its widespread use.

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Generic and Trade Names of Drugs

Poison ivy extract, alum precipitated—*Aqua Ivy, A.P.*

References

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