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TREATMENT OF ALLERGIC CONDITIONS
WITH ALUM-PRECIPITATED
(ALLPYRAL) EXTRACTS OF ALLERGENS
OTHER THAN RAGWEED

By

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In previous publications, the author and his associates reported favorably about their experiences with the use in ragweed hay fever patients of an alum-precipitated extract of ragweed pollen first introduced into clinical use by Fuchs and Strauss in 1959¹ and designated by them as «Allpyral»¹. In preparing this extract, undefatted whole ragweed pollen is treated with an extracting fluid containing 1 part pyridine, 1 part 0.3 per cent sodium bicarbonate or sodium chloride which gives a clear extract of proteins, polysaccharides, and pollen oil. The active material from this extract then is precipitated with alum and the excess of pyridine and alum is washed away from the alum-precipitated complex. The final preparation is standardized in protein nitrogen units. As a result of our reported experiences (4) in the treatment of ragweed pollinosis patients with Allpyral extracts during the succeeding seasons from 1961 to 1964 inclusive, we found that

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¹ For the sake of brevity, the term "Allpyral" will be used throughout this paper to designate an alum-precipitated pyridine extract in aqueous suspension.

treatment with ragweed Allpyral extracts seemed to possess the following advantages over treatment with aqueous extracts:—the ability (a) to give fewer injections at longer intervals with fewer reactions, (b) to give larger doses to highly reactive patients with greater safety, (c) to administer larger doses in the coseasonal or rush type of treatment, and (d) to give large doses at longer intervals to patients treated perennially, all with satisfactory clinical results.

Although our previous reports were concerned solely with the results of our treatment with Allpyral extracts of ragweed, the author also has been using similar extracts of other allergens in treatment. The purpose of the present communication is to summarize the author's experience in the use of Allpyral pollen extracts (other than ragweed), alternaria, house dust, and animal danders.²

ALLPYRAL EXTRACTS OF AIR-BORNE ALLERGENS

Included in this group are those patients from the private practice of the author who were treated with the Allpyral extracts of tree, grass, and English plantain pollens, and of alternaria. All had definite clinical evidence of seasonal pollinosis (positive history and/or clinical observation) supplemented by either positive skin tests or positive eye tests with powdered allergens, and in many instances by both. All patients had intracutaneous skin tests for purposes of classification with the dilutions of the aqueous pollen extracts used routinely (from .0001 N to .1 N). While this information helped somewhat in determining the initial dose, increases in dosage depended more upon the degree of local reaction provoked by each injection than upon the skin test results. The dosage schedule employed was similar to that utilized in the treatment of ragweed pollinosis patients as reported in our previous publications (4). The initial dose varied between

² The author is indebted to Miss Margaret Strauss of the Allergen Laboratories of Dome Chemicals, Inc., New York City, for the various Allpyral extracts used in the treatment of the patients reported in these studies.

10 and 50 units; and as shown in Table 1, succeeding doses were increased as rapidly as feasible, especially in those previously treated patients whose dosage tolerance was known.

TABLE 1
Average Dosage Schedule with Allpyral Extracts of Air-Borne Allergens.

Very sensitive AA or A	Mildly or moderately sensitive B or C	Previously treated High dosage
10*	30	50
30	60	100
50	100	400
100	300	1,000
200	500	3,000
400	1,000	5,000
600	2,000	10,000
1,000	3,000	
2,000		

* Protein nitrogen units per cubic centimeter.

Most of the patients who received Allpyral extracts of the airborne allergens were treated by the preseasonal method beginning two to three months before the onset of the pollen season and continuing at weekly or biweekly intervals either until the maximum tolerated or the optimum³ dose was reached or until the beginning of the pollen season, at which time treatment usually was discontinued. These patients returned each spring for similar preseasonal treatment. In a small number of patients the injections were continued throughout the season either in the same or usually in lowered dosage

³ It will be noted that we use the term "optimum" instead of "maximum" or "maximum tolerated" dosage throughout this presentation. In our opinion the term "optimum" conveys the idea more clearly that a dosage level was reached which was considered sufficiently high to induce satisfactory tolerance. On the other hand the term "maximum" suggests that the dosage level attained is the highest which a patient can tolerate without inducing reaction, and in many patients no attempt was made to determine such a maximum.

and then continued in optimum dosage on a perennial basis. But in making our calculations, especially in the perennial group, we utilized only the figures for the initial year when the preseasonal treatment was begun. Furthermore, in calculating the number of doses and the optimum dosage we excluded those patients who did not receive a full course or did not have an opportunity to do so.

TREE POLLENS

Thirty eight tree pollinosis patients (including 2 children) ranging in age from 7 to 69 years had sufficiently satisfactory data to be included in this group. Most of the patients were allergic to more than tree pollen but most often in order of frequency to sycamore, oak, maple, and hickory pollens. All are prevalent in the Philadelphia area. Because of this multiple allergy and for the sake of convenience, patients in this group were treated with an Allpyral extract which included all those tree pollens. Seven of the thirty-eight patients were treated for three consecutive seasons (from 1963 to 1965 inclusive), nine for two seasons, and twenty for one season. Because detailed report of the results of each season's treatment would serve no useful purpose, we have chosen for our calculations the most recent season (usually 1965) during which the patient received complete treatment.

Results. With the above criteria as a basis, it was found that the number of injections required to reach the optimum dose in the 38 patients varied between 4 and 12 injections⁴ with an average of about seven. (Table 2). It is of interest in this connection that patients who had been treated in previous seasons required the fewest number of injections. The optimum dosage attained by 34 of the 38 patients varied between

⁴ It will be noted that all the figures contained in Table 2 are in round numbers and do not contain any fractions or decimals as obtained in the actual calculations. This was purposeful since a statement, for example, that the average patient got 7.3 injections or 4253 units, while statistically correct, would have no practical meaning for the reader.

TABLE 2
Results of Treatment with Allhyral Extracts of Air-Borne Allergens

Allergen	Number Patients	No. Inject. to reach Maximum			Maximum Dose in P. N. U.			Local Reactions				Constitutionals	Clinical Results			
		Least	Most	Average	Low	High	Average	No.	Pts.	Slight	Moderate		Excellent	Good	Fair	Poor
Trees	38	4	12	7	2000	10,000	4500	16	8	1	1	0	18	16	4	0
Grass	69	5	11	8	1000	12,000	5000	28	15	7	7	1	38	28	3	0
English Plantain	10	7	10	8	3000	10,000	4500	2	2	1	1	0	1	8	1	0
Alternaria	25	6	14	10	500	8000	5000	25	12	4	3	1	5	17	3	0

2000 and 10,000 P. N. U. with an average of 4500 P. N. U. In two adult patients and two children who previously were unable to take average doses of the aqueous extracts, the dosage could not be increased beyond 300 to 400 units without inducing local reactions. However, in all other patients, reactions were minimum—there were 16 slight reactions in 8 patients and one moderate reaction in one patient but no constitutional reactions.

As already indicated in recording the clinical results of treatment in our ragweed pollinosis patients, such evaluation is difficult and at best depends upon the clinical judgement of the attending physician. Depending upon an estimate of the number of bad symptom days reported by the patients and upon the amount of medication required during the season, the results were classified as excellent (up to three days of bad symptoms), good (three to five bad days), fair (five to seven bad days), and poor (seven or more bad days). For purposes of this report, patients who had fair or poor results were regarded as clinical failures. Using these criteria for evaluation, the clinical results in our 38 tree pollinosis patients were excellent in 18, good in 16, fair in 4, and poor in 0 patients. Combining the fair and poor results, treatment failures occurred in 4 patients. In reviewing the treatment of the latter patients, we found that one factor contributing perhaps to the poor results was low dosage. This was due to the fact that the tree Allpyral mixtures used in treatment were prepared from four tree pollens as was true of similar aqueous extracts. As a result, the dosage of the specific tree pollen to which the patient was allergic was reduced because of dilution. Perhaps in the future the utilization of Allpyral extracts of the individual trees might improve these results. Nevertheless, we feel that the results of treatment with Allpyral extracts in our tree pollinosis patients was as effective as that with aqueous extracts with the added advantages already cited for the Allpyral extracts—namely, fewer injections, larger dosage, and minimum reactions.

GRASS POLLENS

Sixty nine grass pollinosis patients (including 6 children) ranging in age from 7 to 67 had satisfactory data for proper evaluation of their treatment with Allpyral extracts. All had definite evidence of grass pollinosis including positive allergy tests (skin and eye) to the grasses indigenous to this area—namely, timothy, sweet vernal, June, orchard, and red-top. Because these grasses were believed to have a common antigen, many allergists treated these patients for many years either with the aqueous extracts of timothy pollen or in our own case with an aqueous extract of timothy and sweet vernal grass pollen. Because of uncertainty and recent experimental evidence of the lack of common antigenicity (2), we treated this group of pollinosis patients with a stock Allpyral grass extract containing not only the five grasses already mentioned but also perennial rye and meadow fescue grasses.

Results. Of the sixty nine patients whose records were reviewed, eleven were treated with Allpyral extracts for three seasons, twenty two for two seasons and thirty six for a single season. The number of injections required to reach an optimum varied from five to eleven with an average of about eight. The optimum dosage attained by 64 of the 69 patients varied between 100 and 12,000 units with an average of approximately 5000. Of the other 5 in this group, two could not take more than 200 units without reaction, one 250, one 400, and one 500 units. All of the latter patients also had similar difficulty with the aqueous extracts. Reactions were minimum:—local reactions in slight degree occurred 28 times in 15 patients, and in moderate or marked degree seven times in seven patients. One patient had a mild constitutional reaction consisting of increased sneezing immediately after the injection but no hives or asthma.

Evaluation of the clinical results in this group in this group done in the same manner as for the tree cases showed it to be excellent in 38, good in 28, fair in 3, and poor in 0. This means that failures in treatment occurred in only 3 out of

69 patients. This is unusually good and even better than the results we obtained in the treatment of our ragweed pollinosis patients with Allpyral extracts. We believe therefore that treatment with the Allpyral extracts not only produced good results in these patients but had the added advantages already cited.

English Plantain. Ten patients,, including nine adults ranging in age from 16 to 64 and one child, aged 9, make up this group. It is small because of the low incidence of plantain pollinosis in our area. When a patient's symptoms coincide with the pollinating period of English plantain (from early May to early September in the Philadelphia area), and the skin test is positive, the clinical diagnosis of plantain pollinosis may be made readily. But since most patients have other pollen sensitivities, diagnosis based upon the history alone may be difficult. This explains why plantain pollen extracts sometimes are included in spring mixtures because of a positive skin test and an indefinite clinical history. Eight of the ten patients had definite clinical evidence of plantain pollinosis plus positive skin and/or eye tests. The other two, both of whom had grass pollinosis, were included because of suggestive clinical histories and positive skin tests. Seven patients were treated preseasonally and three perennially. The number of injections required to reach the optimum dosage varied from 7 to 10 with an average of about 8; the optimum dosage varied from 3000 to 10,000 units with an average of about 4500 units. Reactions were minimum. There were two slight and one moderate local reactions in three patients and no constitutionals. Eight of the ten patients had good results, one excellent, and one had only a fair result. Since all ten patients were sensitive to other allergens and were being treated with extracts of the latter, it is not possible to say whether treatment with plantain Allpyral extract was entirely responsible for the satisfactory outcome.

ALTERNARIA

Twenty five patients, including nineteen adults ranging in age from 14 to 62 and six children aged 3 to 12 years, had satisfactory data for proper evaluation. As with plantain pollinosis, clinical diagnosis of allergy to alternaria is not made easily because their symptoms do not always conform to definite seasonal periods as is true of pollen allergy. While alternaria spores are found in the air in the Philadelphia area from mid-March until November (5), the concentration in the atmosphere fluctuates irregularly during that period. Clinical diagnosis based solely upon a definite seasonal pattern such as is seen in pollinosis patients often is difficult. But a history of cough and/or asthma rather than itchy eyes and sneezing occurring predominantly in the early evening often helps in making a clinical diagnosis. This was true, interestingly enough, in 24 of the 25 patients in this group.

As with patients with pollinosis, it required from 6 to 14 injections with an average of about 10 injections of alternaria Allpyral extract to reach an adequate optimum dose. In the 19 adults, the latter varied from 500 to 8000 P. N. U. with an average of about 5000 P. N. U. In the six children in the group, the dosage varied from 200 to 3000 P. N. U. with an average of about 900 P. N. U. Aside from the fact that the initial dose in the children usually was smaller (10 P. N. U.) than in most of the adults (30 P. N. U.), an additional explanation for the lower optimum dosage in the children was their greater tendency to develop local reactions from smaller dosages. Nevertheless, the dosage of Allpyral extract accepted by the children was higher generally than that of aqueous alternaria extracts.

Reactions on the whole were minimal. There were 25 slight local reactions in 12 patients and 4 moderate to marked local reactions in 3 patients. One patient who tolerated only small doses not only of aqueous extracts but even of Allpyral extract, had a questionable constitutional reaction (constriction in the chest) after one but not after subsequent injections.

Because of the difficulty in making an accurate diagnosis of alternaria allergy, it was not easy in the 25 patients in this series to accurately assess the clinical results of treatment with the Allpyral alternaria extracts, especially as compared with similar aqueous extracts. As can be seen in Table 2, good to excellent results were obtained in 22 out of 25 patients in this series; but since all these patients were being treated coincidentally with other extracts, it is difficult to say what part of the good results obtained can be attributed to the use of the alternaria Allpyral extract. However it is of interest in this connection that 12 of the 14 of the 25 patients who were treated previously with aqueous alternaria extracts, formerly had reactions from low doses of the aqueous extracts; however, of the 12, all but two (both children) were able to tolerate adequate doses of the Allpyral extract. This was illustrated so strikingly in the following patient as to warrant its citation:

CASE REPORT

This patient was a 36-year old male with recurrent rhinitis and asthma since childhood, worse during June after moving to an agricultural area. The skin test to alternaria was markedly positive; eye test was not only positive but the test itself induced rhinitis and asthma similar to his complaints during the season. Treatment with aqueous alternaria extract was begun but the dosage had to be kept low and could not be increased without inducing local and constitutional reactions; for example, the maximum tolerated dose of the aqueous extract was 0.15 c. c. of a 1-100 dilution which is less than 1/100 the average dose tolerated by most of our other alternaria-allergic patients. While the patient obtained a little relief from treatment, results on the whole were poor and he needed epinephrine frequently to control his symptoms. In November, 1963, the patient was started on alternaria Allpyral extract beginning with 10 units and increasing gradually at weekly intervals. He reached 1000 units by the summer of 1964 with only slight local reaction. This dose then was maintained every two weeks throughout that summer. He had the best summer he ever had and for the first time needed no epinephrine injections for the control of his symptoms. He is now getting 5000 units without reaction.

Our experience in this patient, duplicated in other patients, exemplifies one of the advantages already cited for the use of

pollen extracts; namely, the ability to give optimum doses to patients who cannot tolerate average doses of aqueous extracts.

ALLPYRAL HOUSE DUST EXTRACTS

Allpyral extracts of house dust have been used in the treatment of allergy patients for a much shorter period of time than Allpyral extracts of plant pollens. For that reason there are as yet no published reports giving information about its use. This extract became available to the author early in 1963. Since then he has had an opportunity to use it in the treatment of 77 adult patients ranging in age from 13 to 67 years and suffering from a variety of allergy conditions either singly or in combination. Of the 77 patients, 27 patients had pollinosis as their chief complaint, 13 had perennial allergic rhinitis, 33 had asthma, and 4 had atopic dermatitis. All the patients in this group not only had a positive intracutaneous skin test to aqueous house dust extract, but also evidence of specific sensitization to house dust either in the form of a positive clinical history of the induction of symptoms after house dust contact or a positive eye test to dry house dust powder or both. Many of the patients (56 of the 77) had been treated previously with aqueous house dust extract, and in some patients the conversion to Allpyral extract was made either because of low dosage tolerance of the aqueous extracts or induction of reactions or for both reasons.

Because we were using Allpyral dust extract for the first time, all patients were given 10 units as the initial dose regardless of the degree of skin test reaction. In two patients, the dose had to be decreased to 1 unit because of repeated local reactions to the 10 unit dose. However, both patients later were able to make much higher doses (1000 P. N. U. and 6000 P. N. U.) without reaction. Increases in dosage in all patients were made in similar fashion as with pollen Allpyral extracts although somewhat more slowly in those who had reactions to aqueous extracts. However, a special attempt was made in some patients to determine the maximum dose the

patient could tolerate without reaction, especially since we now had available a stronger concentration (40,000 P. N. U.) of Allpyral dust extract than of pollen Allpyral extract. For that reason, the maximum dosage taken as the point at which a mild local reaction was induced varied from as little as 200 P. N. U. to as much as 40,000 units. However, the dose was less than 1000 units in only 15 of the 77 patients whereas it was 10,000 or more in 19 patients. Injections of the Allpyral dust extract were given usually at weekly intervals unless there was a local reaction, in which case the injection was omitted or the interval lengthened. When the optimum dose was reached, the interval was lengthened to two weeks or longer and continued on a perennial basis, except in those pollinosis patients who were being treated preseasonally and in whom all treatment was discontinued at the end of the season.

Since most patients were being treated perennially, the number of injections required to reach an optimum or adequate dose varied considerably; however, we found that 10 to 12 injections were sufficient in most patients.

Reactions to the injection of house dust Allpyral extract were minimal as compared with that following aqueous extracts. But they were a little more frequent with the former than with Allpyral pollen extracts. Thus, local reactions lasting less than 24 hours but of small size occurred 38 times in 23 patients. Local reactions of moderate to marked degree, lasting more than 24 hours, occurred 11 times in 6 patients; and in two of the latter patients, there was a small infiltration at the site of the injection which persisted for periods of one to two weeks. In both patients no further injections were given until the infiltration disappeared. Subsequent dosage was lowered and no further infiltrations occurred. It is of interest in connection that most of the patients in whom local reactions followed injections of the Allpyral dust extract in low dosage were able subsequently to take larger doses without similar reaction. We also have found that the tendency to local reactions and especially infiltration could be minimized if

injections are given more deeply into the subcutaneous tissues rather than superficially just below the epidermis.

Constitutional reactions of the immediate type similar to that known to occasionally follow the injection of aqueous pollen extracts and consisting of urticaria, asthma, etc., did not occur in any of our patients treated with the Allpyral house dust extract. However, two patients developed mild delayed constitutional reactions, especially when the treatment first was begun. These reactions happened 12 to 24 hours after the injection and were characterized in one asthmatic patient by mild nocturnal wheezing and in the second patient (one with atopic dermatitis) by increased itching and eruption in the antecubital and wrist areas. In both patients, the next dose was decreased and then gradually increased to the maximum dose tolerated by the patient depending upon the amount of local reaction induced.

As with alternaria extracts, accurate assessment of the clinical effectiveness of Alpyral house dust extracts in the treatment of this group of patients was difficult to make because nearly all the patients were being treated with other extracts and such treatment necessarily influenced the outcome. Although most of our patients in this group reported that they were greatly improved clinically, it was not always possible to determine in the 77 patients what part the treatment with Allpyral dust extract played in the successful outcome. However, all the patients in whom optimum dosage had been reached and in whom treatment had been continued long enough to make a proper evaluation were questioned as to whether they noted any change in their tolerance for house dust after contact with it.

Satisfactory information for such evaluation was obtained in 66 of the 77 patients. Of the sixty-six, forty-eight felt that their tolerance for house dust upon contact was definitely improved. Ten felt there was no change at all and the remaining 8 (mostly males) were uncertain as to the effect of treatment upon their dust tolerance because of a lack of sufficient exposure to evaluate it. The fact that the tolerance for

house dust of a high proportion of the patients treated had been increased and that the clinical condition of these patients and especially those with atopic dermatitis, was greatly improved, would seem to indicate that treatment with Allpyral house dust extract had been therapeutically effective. This effect plus the ability of these patients to accept without difficulty larger doses than was possible with aqueous extracts and after fewer injections warrants the conclusion that the Allpyral extract of house dust seems more effective and more useful in treatment than aqueous extracts of house dust.

ALLPYRAL EXTRACTS OF ANIMAL DANDERS

All allergists are aware of the difficulty of inducing adequate tolerance by hyposensitization with aqueous extracts of various animal danders. In the past, the author has attempted to hyposensitize many patients with aqueous extracts of various animal danders, including cat, dog, rabbit, guinea pig, and rat with very little success even after prolonged treatment (up to five years). The encouraging report by *Gould* (5) as to the successful induction of tolerance to animal dander contact after treatment with the Allpyral extracts of animal danders stimulated our trial with these extracts.

Eighteen adult patients ranging in age from 17 to 43 years are included in this group—7 were dog-sensitive, 9 cat-sensitive, 1 horse-sensitive, and 1 rat-sensitive. All had definite positive histories of clinical sensitiveness to the incriminated animal dander plus positive intracutaneous tests and/or ophthalmic tests with powdered dander or both. Because of the apparent futility of using aqueous extracts in treatment, only one patient had been treated previously with aqueous extracts—this was a laboratory research technician allergic to rat dander who could not avoid contact with that allergen.

The initial dose given and the dosage schedule employed followed that utilized with other Allpyral extracts. Most patients received 10 units initially. As with pollen extracts, increases then were made rapidly and an optimum dosage of

from 2000 to 10,000 P.N.U. was reached in from eight to twelve injections in most patients. Reactions, usually of local character, on the whole were minimal. There was one mild constitutional (wheezing) in the rat-sensitive patient. Where it was possible to determine this, improved clinical tolerance to contact with the animal was noted, sometimes within four to six months after treatment was instituted. This was true for example of the patient who was horse-sensitive and got asthma whenever she went riding or even from contact with horse dander present in her daughter's clothes. She was given an initial dose of 10 units of horse dander Allpyral extract and reached a dosage of 5,000 units without reaction in 10 injections given on an average of every two weeks. At the time she noted that she could ride horses without asthma and with only mild nasal symptoms. She stopped treatment for about three months and noticed recurrence of slight asthma after horse contact. But after several more doses, her tolerance improved. She is now receiving monthly booster injections of 7,000 unit doses and it is planned soon to lengthen the interval to two months or even longer.

Improved tolerance to animal contact likewise was observed in four dog-sensitive and four cat-sensitive patients all of whom had opportunities to determine this. The improvement in tolerance noted by the rat-sensitive technician after Allpyral treatment was rather striking and emphasized its superiority over treatment with aqueous extracts. This patient had been treated with aqueous extracts of rat dander for 3 years with very little improvement in tolerance; furthermore, the patient was unable to take sizeable doses without the induction of marked local and on several occasions mild constitutional reactions. She was started on rat-Allpyral extract and although she at first could not tolerate large doses of the latter without the induction of moderate and on one occasion a mild constitutional reaction, she eventually was able to take 2,000 units without difficulty. Furthermore within 12 months after treatment was instituted, the patient noted a definite improvement in her clinical tolerance; for example, she now could

walk into the room where the rats were kept and could even handle them (with the aid of a mask) without getting asthma, which was not possible when she was being treated with aqueous extracts. Our experience in the treatment of animal dander-sensitive patients with Allpyral extracts would seem to indicate that the latter are more effective in inducing clinical tolerance than corresponding aqueous extracts with the added advantage of the patient being able to take larger doses after fewer injections and at longer intervals.

SUMMARY

The author reviews his experiences in the treatment of allergic patients with Allpyral extracts of grass, tree, and plantain pollens, of alternaria, of house dust, and finally, of various animal danders. The results obtained substantiates the advantages over aqueous extracts as previously reported by the author and his associates and by others both in relation to ragweed and to other Allpyral extracts. These advantages include the ability to give fewer injections in larger dosage at longer intervals with greater safety and with satisfactory clinical results.

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