

Nasal hyposensitization and hay fever

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Summary

A clinical trial of pre-seasonal hyposensitization with intra-nasal grass pollen extract was carried out in forty-two patients. Results were assessed subjectively, by clinical examination during the pollen season, and by measurements of nasal air flow. Useful relief of symptoms was considered to have occurred in fifteen out of twenty-one patients who had pre-seasonal treatment with pollen extract and in five out of twenty-one patients who had similar treatment with carbol saline as a placebo. Of twelve patients who were symptom free in the pollen season ten had nasal hyposensitization. It is concluded that this simple and safe method of treatment gives results comparable with those of pre-seasonal injections.

Introduction

Prophylactic inoculation against hay fever was first reported by Noon in 1911. Since then many authors have claimed very good results from various modifications of this treatment and good or excellent results have been claimed in clinical trials in as many as 79% of hay fever sufferers (Frankland & Augustin, 1954). In spite of this, pre-seasonal injections for hay fever have never been universally accepted as desirable or safe and most patients rely on symptomatic treatment which, although much improved in recent years, is not completely satisfactory.

Taylor & Shivalkar (1972) reported some success by repeated spraying of the nose with a grass pollen solution which would initially double the nasal airways resistance as measured by their own, somewhat complicated method (Taylor & Shivalkar, 1971). Cook (1974) has repeated this work and using a simplified method of measuring the degree of nasal blockage has found that pre-seasonal nasal hyposensitization has promising results. We now report a clinical trial carried out in forty-two cases as far as possible on a double blind basis.

Materials and methods

The patients were mainly school children, the age distribution being shown in Table 1,

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with typical summer hay fever observed during at least one previous season and large wealing reactions on prick testing to grass pollen extract (Bencard). Patients with multiple sensitivities and perennial symptoms of asthma or allergic rhinitis were excluded but most of the patients had some degree of asthma during the pollen season as well as hay fever.

Table 1.

Age (years)	No.
6	2
7	2
8	3
9	5
10	—
11	5
12	5
13	5
14	3
15	8
16	3
17	—
18	3
18+	2
All ages	46

During January and February 1974 the patients had nasal provocation tests carried out. The nose was sprayed with dilutions of a concentrated grass pollen extract supplied by the Bencard Allergy Unit in dilutions of 1 in 10,000, then 1 in 1000, 1 in 100 and 1 in 10 in succession but only to the point where the 'Nasal FEV' was reduced by 50%. This 'Nasal FEV' measurement (Cook, 1974) is the amount of air which can be expelled from the nose in 1 sec after a full inspiration. It is used as a simple substitute for the 'Nasal Airways Resistance' described by Taylor & Shivalkar (1971) and requires only a well-fitting anaesthetic mask and a spirometer.

Having established the strength of solution required to effect a 50% fall in 'Nasal FEV' the patient was supplied with a glass nasal spray containing this solution with instructions to spray the nose every 3 days on ten occasions. Forty-six patients were included in the trial and, following the initial tests, the treatment allocated on a random basis with the appropriate pollen solution in twenty-three cases and a placebo consisting of 0.5% buffered carbol saline in the other twenty-three cases. This trial might not be truly double blind in that some of the patients became aware that their treatment was unlikely to be with the active pollen extract. Four patients failed to complete the trial, one because the reaction to the pollen solution was considered by the patient to be too severe and three because they failed to attend for assessment during the pollen season.

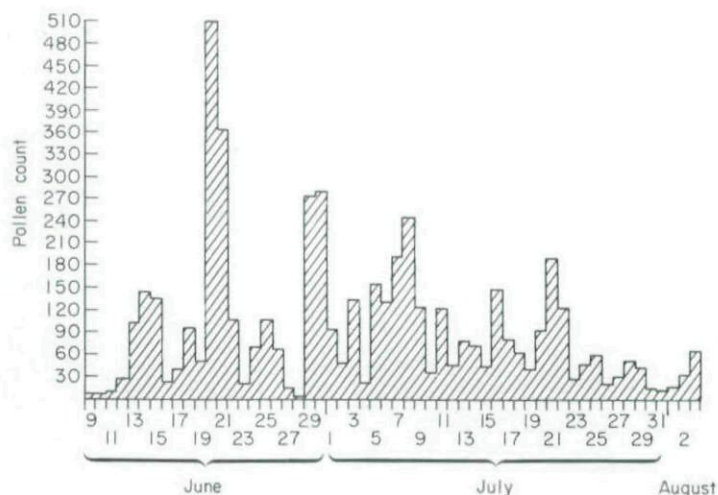
Table 2 shows the dilutions of concentrated pollen extract which provoked a 50% fall in 'Nasal FEV' in the two groups of patients.

From the middle of June to the end of July 1974 the patients were seen as frequently as possible for clinical examination and so that symptomatic treatment could be

Table 2. Reactions to nasal provocation tests

	Dilutions			
	1/10,000	1/1000	1/100	1/10
Active treatment cases	1	3	10	7
Placebo cases	0	4	8	8

prescribed where necessary. In most cases the measurement of 'Nasal FEV' was repeated during the pollen season for comparison with similar measurements made during the winter. Pollen counts were available from day to day from the Midlands Asthma and Allergy Research Centre in Derby as a rough guide to the degree of pollen exposure on the days when these measurements were made (Fig. 1). Assessment

**Fig. 1.** Grass pollen counts 1974 (Derby). From Midlands Asthma and Allergy Research Association.

of results was made by taking together the patient's experience, the surgeon's observations made during the pollen season, and a comparison of 'Nasal FEV' measurements in the pollen season with those made in the winter; a fall of less than 50% during the pollen season was accepted as being a satisfactory result. A final conclusion was based on two out of three of these assessments being in favour of benefit or otherwise.

Results

The results are shown in detail in Table 3 and summarized in Table 4. Fifteen of the twenty-one patients who received active treatment with the appropriate pollen solution were considered to have benefited whereas five out of twenty-one patients who had the placebo spray were considered to have benefited. Of the twelve patients who were virtually symptom free in the pollen season ten had been given active treatment and two the placebo. The overall assessment of results was based on agreement in two of the three methods of assessment. Symptoms closely followed the appearance

Table 3.

No.	Pollen dilution	Treatment	Symptoms	Clinical state	Pollen count	Pre-season 'Nasal FEV'	Seasonal 'Nasal FEV'	Percentage fall in 'Nasal FEV'
1	1/1,000	A	+	+	364	750	300	60
2	1/1,000	P	—	—	364	600	0	100
3	1/100	P	—	—	364	400	150	62
4	1/10	A	++	++	144	1800	1600	11
5	1/1,000	P	—	—	364	1200	1000	16
6	1/10,000	A	++	++	3	1100	Not done	
7	1/100	A	++	++	3	850	Not done	
8	1/1,000	A	+	+	144	800	800	0
9	1/10	A	+	+	364	750	600	20
10	1/1,000	P	—	—	144	1500	600	60
11	1/10	A	—	—	364	250	0	100
12	1/1,000	P	++	++	364	1150	1050	8
13	1/100	A	Failed to attend					
14	1/100	P	—	—	144	700	250	62
15	1/10	P	—	—	144	1250	1500	0
16	1/100	A	++	++	3	2000	1800	10
17	1/100	A	++	++	144	1500	1500	0
18	1/10	A	—	—	144	900	400	55
19	1/100	A	++	++	144	750	750	0
20	1/1,000	P	—	—	364	300	200	30
21	1/100	A	++	++	144	2600	2100	19
22	1/100	P	—	—	144	1250	950	28
23	1/10	P	—	—	155	550	400	16
24	1/100	P	—	—	144	850	400	52
25	1/100	P	Failed to attend					
26	1/10	P	—	—	364	600	300	50
27	1/100	A	U	U	155	600	Not done	
28	1/100	P	—	—	364	1000	600	40
29	1/10	A	+	+	364	750	300	60
30	1/100	A	++	++	364	1000	600	40
31	1/100	P	++	++	144	550	400	26
32	1/10	P	+	+	144	250	250	0
33	1/10	A	++	++	155	1200	1200	0
34	1/10	P	—	—	144	300	Not done	
35	1/1,000	A	U	U	155	700	Not done	
36	1/1,000	A	Refused treatment					
37	1/100	A	—	—	3	600	Not done	
38	1/100	A	++	++	3	100	Not done	
39	1/100	P	Failed to attend					
40	1/100	P	—	—	155	300	0	100
41	1/100	P	+	+	155	300	200	30
42	1/100	A	—	—	144	1300	800	46
43	1/10	P	U	U	155	1100	600	45
44	1/10	A	++	++	144	800	600	22
45	1/10	P	+	—	155	800	500	38
46	1/10	P	+	U	155	350	Not done	

Key. Pollen dilution=the dilution which reduced the 'Nasal FEV' by 50%; treatment: A=active, P=placebo; symptoms: patient's opinion of symptoms throughout the pollen season, ++=virtually symptom free, +=better than before, —=no better, U=uncertain; clinical state: On examination during the pollen season, ++=near normal mucosa, +=minimal mucosal changes, —=severe mucosal changes; pollen count (Derby) on day of examination.

Table 4. Summary of results

Assessment	Active			Placebo			Probability
	Benefit	No benefit	Uncertain	Benefit	No benefit	Uncertain	
Patient's opinion	15	4	2	5	14	2	$t=3.09$ $P<0.01$
Clinical state	15	4	2	5	14	2	$t=3.09$ $P<0.01$
'Nasal FEV'	11	4	6	12	7	2	$t=0.31$ NS
Overall conclusion	15	4	2	5	14	2	$t=3.09$ $P<0.01$

The overall conclusion was based on two out of the three assessments being in favour of benefit or no benefit.

In twenty-three cases all three assessments agreed. Ten out of twelve who had active treatment showed benefit while four out of eleven who had placebo showed benefit ($P<0.01$).

on clinical examination. In twenty-three cases all three assessments agreed and of these twelve had had active treatment, ten of these benefited and two did not, while eleven had had the placebo, four of whom benefited and seven did not. Among the patients who received the active treatment no clear relation was noted between the response and the strength of pollen solution which provoked a positive pre-seasonal test. In those patients with asthma no clear benefit was seen in the asthmatic symptoms. These were usually well controlled with 'Intal'. With the exception of one patient who did not accept the treatment none complained of distressing symptoms during the preliminary testing or hyposensitization.

Discussion

This simple method of hyposensitization of the nose in hay fever seems free of risk or distress and is self-administered. Results of prophylactic treatment in hay fever are very difficult to assess owing to the high degree of variability in allergen exposure from day to day, season to season, and patient to patient. Pollen counts are not a completely satisfactory index of this exposure. Symptoms may easily subside after an hour spent indoors even on days with high pollen counts in the outside air, although counts of over 50 pollen grains/m³ of air are generally considered to provoke symptoms in most subjects.

From experience we would consider the results of nasal hyposensitization to be roughly comparable with those of injection courses. Significant benefit can be demonstrated in about two thirds of the cases treated. Provided such treatment is free of risk and distress it is worth while, especially in young people who may be faced with examinations during June or July and who wish to lead an active open-air life in the summer.

The nasal hyposensitization method is unlikely to benefit asthma occurring with hay fever but the use of 'Intal' has made this easily and safely treatable in most cases (Morrison Smith & Mills, 1970) and a few days on steroid treatment in severe cases is fully justified. It is the nasal symptoms which are generally most difficult to

control without resort to unacceptably high doses of antihistamines and even with the introduction of nasal cromoglycate ('Rynacrom') and beclomethasone dipropionate ('Beconase') a simple and safe method of pre-seasonal hyposensitization still has a place in treatment.

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