

GENERAL PRACTITIONER CLINICAL TRIALS

INEFFECTIVENESS OF VITAMIN C IN TREATING CORYZA

FROM time to time claims have been made that vitamin C, in the form of 'massive doses', may be effective in aborting or modifying the course of the common cold, if given early in the attack. This trial is concerned with such treatment of colds when they have started, but is not concerned with prophylaxis.

THE TRIAL

This was a double-blind comparison between 'massive doses' of vitamin C and a placebo, in the treatment of acute coryza. The vitamin C was provided in the form of effervescent tablets ('redoxon'), each containing 1000 mg. Similar placebo tablets were prepared, containing no vitamin C. Treatment with either active or placebo tablets was determined by random selection. All members of the Group were circulated with an invitation to participate with their families. It was felt that this would be more likely to produce accurate results than if ordinary patients were used, mainly owing to the difficulty with defaulters in a trial of this nature. The doctors taking part in the trial were asked to treat: members of their families in order, as colds appeared during the course of the winter. The trial was conducted from the beginning of October 1966 to the end of April 1967.

Dosage.—This was standardized at 1 tablet thrice daily, treatment being started as soon as coryza symptoms appeared and continued for as long as necessary, up to a total of fourteen days.

Clinical data.—The following records were made: age and sex, smoker or non-smoker, and month of onset of the cold. Assessments were then made of improvement in those of the following symptoms which were present: sore throat, stuffy nose, sneezing, watery nasal discharge, purulent nasal discharge, headache, and aching back and limbs. In addition, temperature was recorded and a note made of whether the patient was confined to bed and whether any other treatment was given. These records were made daily and a four-point scale was used to record the severity of individual symptoms.

In fact, the winter proved to be a very mild one, and cases of coryza were not as numerous as expected. Nevertheless, returns were received from 78 doctors, and this covered a total of 270 cases. On breaking the code it was found that 147 patients had been treated with vitamin C and 123 with the placebo. Males and females occurred in equal numbers, with the following distribution of cases according to age: 0 to 5 years (5 per cent.), 6 to 10 years (19 per cent), 11 to 20 years (15 per cent), 21 to 35 years (18 per

cent). 36 to 50 years (34 per cent.), 51 to 65 years (7 per cent.) and 66 years and over (2 per cent.). Smoking habits were recorded by 259 patients; but of these only 57 (22 per cent.), were smokers. The commonest symptom was stuffy nose (91 per cent.), followed by watery nasal discharge

Treatment and severity	Days											
	1	2	3	4	5	6	7	8	9	10	14	
VITAMIN C												
No. of cases	95	94	86	68	56	32	25	17	12	8	2	
Grade 3	5	6	4	2	2	1	—	1	—	—	—	
Grade 2	37	29	16	10	5	3	1	2	2	1	—	
Grade 1	47	33	28	12	14	8	6	3	2	2	1	
Grade 0	6	26	38	44	35	20	18	11	8	5	1	
Total scores	136	109	72	38	30	17	8	10	6	4	1	
Mean scores	1.43	1.16	0.84	0.56	0.53	0.53	0.32	0.59	0.50	0.50	0.50	
PLACEBO												
No. of cases	87	82	77	70	54	36	22	12	6	4	2	
Grade 3	7	3	1	2	1	—	—	—	—	—	—	
Grade 2	29	21	9	5	6	2	2	1	1	1	1	
Grade 1	44	39	26	12	10	10	3	1	—	—	—	
Grade 0	7	19	41	51	37	24	17	10	5	3	1	
Total scores	123	90	47	28	25	14	7	3	2	2	2	
Mean scores	1.41	1.10	0.61	0.40	0.46	0.39	0.32	0.25	0.33	0.50	1.00	

TABLE I.—Results achieved with vitamin C and with a placebo in the treatment of sore throat in patients with a common cold.

(87 per cent.), sneezing (81 per cent), sore throat (67 per cent.), headache (52 per cent.) and aching back and limbs (38 per cent.). The two treatment groups were comparable with one another in respect of the various patient data recorded.

RESULTS

These were recorded by daily assessments of the severity of individual symptoms, using the following defined criteria:

(a) *Sore throat*.—

(3) *Severe*: Throat red and inflamed. Sore all day long with pain on swallowing and requiring analgesics.

(2) *Moderate*: Throat less red and inflamed, probably sore only in the mornings and on eating, and requiring only occasional analgesics.

(1) *Mild*: Throat sore for only a short time first thing in the mornings.

(b) *Stuffy nose*.—

(3) *Severe*: Both nostrils completely blocked, resulting in mouth-breathing. This may not be completely continuous throughout the day and night, but is present for more time than it is not. Nostrils cannot be cleared by blowing.

(2) *Moderate*: Intermittent obstruction of nostrils, or obstruction may be confined to one side only. Nostrils can sometimes be cleared by blowing.

(1) *Mild*: No obstruction to nose-breathing, but blowing necessary to keep nostrils clear.

(c) *Sneezing*.—

(3) *Severe*: Sneezing more or less continuous throughout the day.

(2) *Moderate*: Bouts of sneezing on and off throughout the day.

(1) *Mild*: Occasional sneezing, which may be confined to the early mornings only.

(d) *Watery nasal discharge*.—

(3) *Severe*: Nose running all day long, necessitating continuous use of handkerchiefs.

(2) *Moderate*: Nose running on and off during the day, and requiring intermittent use of handkerchiefs.

(1) *Mild*: Nose running probably only for a short time in the mornings, and necessitating only one or two handkerchiefs per day.

(e) *Purulent nasal discharge*.—

(3) *Severe*: Discharge thick and purulent.

(2) *Moderate*: Discharge less thick and less purulent.

(1) *Mild*: Muco-purulent.

(f) *Headache*.—

(3) *Severe*: Headache of such a degree that continuous use of analgesics is required.

(2) *Moderate*: Headache such that occasional use of analgesics is required.

(1) *Mild*: Headache present but not inconveniencing patient in any way and not requiring analgesics.

(g) *Aching back and limbs*.—

(3) *Severe*: Pain of such a degree that continuous use of analgesics is required.

(2) *Moderate*: Pain such that occasional use of analgesics is required.

(1) *Mild*: Pain present but not inconveniencing patient in any way, and not requiring analgesics.

With both preparations severity of the following symptoms was maximal during the first four to five days, and then fell off sharply: sore throat, stuffy nose, sneezing, watery nasal discharge, headache and aching back and limbs. In the case of purulent nasal discharge, the severity was relatively low on the first day, building up to a maximum by the fifth day and gradually falling off with both preparations. With regard to the comparative results with the two preparations, there were virtually no differences at all in respect of any of these individual symptoms. Lack of space prevents giving the detailed figures for all these different assessments, but table I shows the results for the first symptom recorded, sore throat. Results for the other individual symptoms were recorded in similar manner.

Pyrexia was present in 22 per cent, of the vitamin C cases on the first day, and in 24 per cent, of the placebo cases. Maximum effect in respect of this symptom was achieved by the 5th to 6th day with both preparations, and again there were no differences between them. Patients fell out of the trial as they became completely relieved of all symptoms, and this occurred maximally with both preparations between four and seven days. Thus, with vitamin C 14 per cent, were relieved of all symptoms by the fourth day, 21 per cent, by the fifth day, 22 per cent, by the sixth day and 10 per cent, by the seventh day. With the placebo the figures were: fourth day 13 per cent., fifth day 19 per cent., sixth day 12 per cent, and seventh day 19 per cent. Only small proportions were confined to bed, these amounting to 8 per cent.

GENERAL PRACTITIONER CLINICAL TRIALS

in the vitamin C series on the first day, as compared with 6 per cent, in the placebo series on the first day. There were no differences between the two preparations in the time taken for patients to become ambulant again.

Side-effects.—One patient had to omit treatment after four days on the placebo, because of nausea. Otherwise there were no side-effects.

Other factors.—No other treatment was given to 62 per cent, of those on vitamin C and to 61 per cent, on the placebo; whilst analgesics were used in 15 per cent, on vitamin C and in 17 per cent, on placebo. Antihistamines were used in 11 per cent, on vitamin C and in 8 per cent, on placebo, whilst nasal decongestant drops were used in 7 per cent, on vitamin C and in 11 per cent, on the placebo. Finally, antibiotics were given to 14 per cent, of the vitamin-C treated patients and to 12 per cent, of the placebo-treated patients. It is therefore concluded that the results were not affected by this factor.

Further analysis of the results did not show any differences in either over-all or comparative effects of the two preparations, in relation to the factors of: sex, age or smoking habits.

CONCLUSIONS

It was concluded that the trial had not demonstrated any effect from vitamin C in either the relief of individual symptoms or the shortening or amelioration of coryza in these patients.

The following doctors took part in this investigation:

P. Abbott	I. M. Brooker	J. M. Lunn
M. Abrahams	K. Browne	D. Mahon
M. S. M. Adams	R. P. Callaghan	D. J. R. Morgan
S. J. P. Adcock	L. J. Clark-Wilson	J. F. Morris
G. Addleston	J. G. Cochrane	S. D. Moss
D. G. Aitken	D. Connan	N. E. Nathanson
P. Allebone	P. G. Cronk	D. Oriel
B. Anderson	K. Dalton	W. L. Owen
R. Andrew	N. Derounian	B. A. W. Perkins
R. A. Andrew	G. G. M. Edelsten	A. J. Pinkerton
R. L. Armitstead	L. S. Galazka	F. W. Richards
P. D. Arnold	J. Golaszewski	J. R. Richardson
R. H. Arnold	R. H. Goulder	H. H. Ronn
P. G. Atkinson	M. A. H. Graham	I. O. Roxburgh
M. H. Aylward	W. J. Gray	W. A. I. Rushford
G. A. Baker	C. B. Grimaldi	F. S. Shepherd
B. N. Ballantine	H. I. Howard	R. G. Sinclair
T. C. Barker	N. C. Jain	T. M. Sinclair
B. M. Barren	E. C. Jelly	E. M. Sklar
B. J. Batt	G. Kagan	H. Sless
R. M. Berrington	D. Kelleher	M. M. Sundle
C. E. S. Bill	J. D. S. Knight	B. Taylor
S. Blaxland	R. Lai	H. W. K. Thompson
P. S. Boffa	A. Latham	H. W. Trusted
B. Bond	N. Lawrence	F. O. Wells
E. I. Boxer	D. A. Levin	A. R. F. Williams

This is Report No. 117 of the General Practitioner Research Group.