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The Role of Diet in the Treatment of Pulmonary Tuberculosis*

An Evaluation in a Controlled Chemotherapy Study in Home and Sanatorium
 Patients in South India

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Before the advent of antituberculosis chemotherapy, a diet rich in calories, proteins, fats, minerals and vitamins was generally considered to be an important, if not essential, factor in the treatment of tuberculosis. The introduction of specific antituberculosis drugs, however, has so radically altered the management of the disease that the role of diet has to be reconsidered in the light of the recent advances in treatment. An evaluation of the influence of diet in the treatment of pulmonary tuberculosis with isoniazid plus p-aminosalicylic acid was recently undertaken by the Tuberculosis Chemotherapy Centre, Madras, in the course of a controlled comparison of home and sanatorium chemotherapy for tuberculous patients from a poverty-stricken community in Madras City. Despite the fact that during the year of treatment the home patients subsisted on a markedly poorer diet, were physically more active and, on the average, gained less weight than the sanatorium patients, the overall response to treatment in the home series closely approached that in the sanatorium series, although there was a tendency for tubercle bacilli to disappear earlier in the latter. Direct evidence has been presented that none of the dietary factors studied (calories, carbohydrates, total and animal proteins, fats, minerals and vitamins) appears to influence the attainment of quiescent disease among tuberculous patients treated for one year with an effective combination of antimicrobial drugs, and that initial chemotherapy of patients at home can be successful even if the dietary intake is low throughout the period of treatment.

The role of diet in the treatment of tuberculosis, both in human beings and in experimental animals, has been the subject of a large number of papers, and many standard works recommend a diet rich in calories, proteins, fats, minerals and vitamins in therapy (McLester & Darby, 1952; Pagel, Simmonds & Macdonald, 1953; Hudson, 1957; Davidson, Meiklejohn & Passmore, 1959). The opportunity has been taken during a controlled chemotherapy study of tuberculous patients conducted by the Tuberculosis Chemotherapy Centre, Madras to re-evaluate the role of diet in treatment when an effective combination of antimicrobial drugs is being administered.

A dietary study was undertaken among patients with newly diagnosed pulmonary tuberculosis who were admitted to a comparison of home and sanatorium treatment for 12 months with a standard oral combination of antituberculosis drugs, isoniazid plus the sodium salt of p-aminosalicylic acid (sodium PAS) (Tuberculosis Chemotherapy Center, 1959). The patients in this study were drawn from the lower income groups or from the unemployed in Madras City, which is the largest urban community in South India. Their living conditions were, with few exceptions, poor. The patients were allocated at random to treatment at home or in sanatorium and all were prescribed the same chemotherapy. The diet of the patients in the home series depended on their economic status and their individual tastes. On the other hand, the sanatorium patients had a diet, which conformed to standards laid down by the Madras Government for

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tuberculous patients and was occasionally supplemented by food obtained from outside the sanatorium. There were, therefore, grounds for expecting a difference in the diet of the home and the sanatorium series of patients during the year of treatment. The present report is an evaluation of the magnitude of this difference in the diet and its influence, in the presence of standard combined chemotherapy, on the course of the disease in the home and the sanatorium patients, as judged by the radiographic response and the attainment of bacteriological quiescence.

The Medical Research Council of Great Britain, through its Tuberculosis Research Unit, is responsible for the scientific direction of the research in accordance with the plans prepared by a Project Committee consisting of representatives of the co-

operating agencies and the Senior Medical Officer of the Centre.

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I. GENERAL PLAN AND CONDUCT OF THE STUDY

PATIENTS IN THE PRESENT ANALYSIS

Between September 1956 and September 1957, 193 patients were allocated at random to treatment at home or in sanatorium; all of them were aged 12 years or more and had newly diagnosed disease with tubercle bacilli in their sputum, and the majority had advanced cavitated lesions and were clinically ill on admission to treatment. (Tuberculosis Chemotherapy Centre, 1959). Of these, 30 were excluded from the main analysis for reasons detailed in the 1959 report, leaving 163 patients (82 home, 81 sanatorium) with initially isoniazid-sensitive organisms, in the main comparison. Of these 163 patients, six (three home three sanatorium) were excluded from the dietary study because complete data were not available. Three (one home, two sanatorium) died before any dietary assessments could be made. A fourth (home) was electrocuted at work before an assessment during treatment could be undertaken, and one patient (home) had dysphagia due to carcinoma of the oesophagus, restricting his dietary intake. Another patient (sanatorium) was discharged before the assessment of his diet in sanatorium could be made. There remain 157 patients, seven (all home) were strict vegetarians, who, quite apart from not eating meat or fish, did not even have eggs in their diet, although they drank milk.

THE USUAL DIETARY

The usual diet of the income group from which the patients were drawn consists of a very light breakfast (often the water in which the rice is cooked, with perhaps a small quantity of rice) and two fuller meals (sometimes only one), one at noon and the other in the evening. The main meals consist largely of cooked rice, one of them, or sometimes both, having a small amount of green vegetables and pulses; on some occasions very small quantities of flesh foods (usually fish), fats and fruits are also eaten. Beverages, usually tea and occasionally coffee, are drunk two to four times a day, but with very little milk.

METHODS AND PROCEDURES

The methods of diet survey were employed :

- a) The oral questionnaire method.
- b) Weighment of uncooked and cooked foods.

The oral questionnaire was the standard procedure for the great majority of the assessments in this report. The weighment method was used in parallel with the oral questionnaire in a comparatively small number of the patients to confirm the reliability of the oral questionnaire results.

Oral questionnaire

The assessment of dietary intake by the oral questionnaire method was conducted as follows. The

dietitian carefully interrogated the individual patients and, sometimes, other members of the family. The aim was to elicit precise information on the amounts of different articles of food consumed by the patient and the various members of the family in the course of the day. Standard vessels and containers and measures of graded sizes were shown to the patients to help them express the amounts of various articles of diet consumed. This method was the same as the one used by the Nutrition Research Laboratories of the Indian Council of Medical Research (Pasricha, 1958, 1959) except that there was a slight modification in respect of the use of the adult equivalent adopted by Aykroyd, Patwardhan & Ranganathan, (1951). It is usually possible to make a fairly accurate assessment of an individual's dietary intake by assessing the total quantity of food consumed by the whole family and, on the basis of adult equivalents, calculating the proportion of food consumed by the individual. In the present study, however, most of the patients were seriously ill when they started treatment (Tuberculosis Chemotherapy Centre, 1959) and had little or no appetite, so that they were consuming very much less than their normal intake of food. In such circumstances, the adult equivalent gives misleadingly high values and the patients were therefore asked to express, with the aid of standard vessels, the actual quantities of food they ate. The adult equivalent was applied only for items like oil, dhal (pulses) and sugar, where it is difficult to measure the actual quantity consumed. As reported elsewhere (Tuberculosis Chemotherapy Centre, 1959), the centre distributed small quantities of milk powder to the families of patients under treatment for consumption by the whole family. The quantity of milk powder consumed by the patient was calculated, on the basis of adult equivalents, from the total quantity distributed to the family for the month. Special articles of diet consumed by the patient alone - for example, eggs or fruits - were also taken into consideration in calculating the dietary intake of the patient. In order to make valid comparisons of the diet before and during treatment, the above procedure was adopted for all the dietary assessments during the year.

The dietary surveys were performed at the Centre, in the patient's homes or in the sanatorium. Because of the severely limited family budgets and the consequently almost unvarying diet, the patients in both series were able to state with confidence the quantity of food consumed by them when at home;

it was only occasionally necessary to consult other family members. There is no doubt that the good relationship established between the patients' families and the Centre's staff prior to the commencement of the dietary study greatly facilitated the dietitian's assessments. In sanatorium also, the diet was a standard one, and again the patients had no difficulty in describing it.

Weighment

The weighment method of dietary assessment involved the actual weighing of foods, both in their raw, uncooked state and again after cooking. This technique was used for an assessment at the end of three months of treatment in a group of patients studied intensively (see page 342 et seq.) The weighment technique had to be applied differently in the home and the sanatorium series.

Weighment at home. The weighment assessment was made on three consecutive days, domestic scales being used. The dietitian visited the home by appointment twice a day, once in the morning to weigh the raw foods and the second time to weigh the raw foods and the second time to weigh the total food cooked for the family and to assess the patient's share of it. The following instructions were given to the patients and their families prior to the visits:

- a) All purchases for the day were to be made early in the morning or on the previous evening and shown to the dietitian at her morning visit.
- b) No food was to be included in the diet if it had not been shown to the dietitian in the morning when the raw food was weighed.
- c) The family was not to eat the cooked food before it was weighed at the second visit.
- d) For convenience in weighment, the family was asked to use the same vessels on all the three days.
- e) The family was instructed not to make any extra or unusual purchases of food.

Raw foods, such as rice, dhal, vegetables, meat, sugar and jaggery (coarse brown sugar), were weighed. (Tea leaves, condiments and the like were not taken into account). The mean dietary intake for the family over the three days was first calculated from the raw foodstuffs. Next, the amount of cooked food consumed by the patient during this period was expressed as a proportion of the total food consumed by the family. By applying this proportion to the mean dietary intake for the family based on the raw foodstuffs, the patient's dietary intake was calculated. It was necessary to adopt

this procedure because food values were available only for raw foodstuffs.

There were 22 patients in the home series whose diets were assessed by the weighment technique (see below). The wage-earners were casual labourers receiving daily wages in 14 of the 22 families and were paid monthly in eight. Four of these eight monthly wage-earners were patients and therefore not in employment when the weighment assessment was made. Thus, the majority of patients were in families who did not have a lump sum available once a month to alter the standard of their diet in the days immediately after its receipt. In the remaining four patients the weighment assessment was commenced six, 11, 14 and 29 days, respectively, after the payment of the monthly wage.

Weighment in sanatorium. In sanatorium, the cooked foods actually consumed by the patients were weighed, the equivalents in terms of raw food were determined, and the dietary values were calculated. For items such as oil, the mean quantity consumed per sanatorium patient was taken. As the diet was a standard one, a 1-day assessment was considered adequate. Food supplements, such as coffee and snacks from the sanatorium canteen, or food brought by relatives from home, were also taken into account.

COMPARISON OF ORAL QUESTIONNAIRE AND WEIGHMENT TECHNIQUES

In order to verify whether the oral questionnaires were yielding reliable data for the patients under study, a comparison was made of the oral questionnaire and weighment techniques in the last 45 patients (22 home, 23 sanatorium) in the main analysis of the chemotherapy study. The comparison was made three months after admission to treatment, the oral questionnaire being conducted on the day before the weighment survey was started. The results are presented in Table 1. The distributions of calories, total proteins, animal protein, fats and carbohydrates by the two methods were closely similar both for the home and for the sanatorium series. Thus, 13 patients in the home series had a daily intake of 2000 calories or more when assessed by the oral questionnaire method, as compared with 12 patients by the weighment technique; the corresponding figures for the sanatorium patients were 21 and 22, respectively. Considering patients with an intake of at least 50 g of total proteins, the numbers in the home series were 13 by the oral questionnaire

TABLE 1
COMPARISON OF ORAL QUESTIONNAIRE
AND WEIGHMENT METHODS IN THE ASSESSMENT
OF DIETARY INTAKE AT THREE MONTHS

		Home		Sanatorium	
		Oral	Weigh-ment	Oral	Weigh-ment
Calories	Less than 1 000	1	1	0	0
	1 000-	1	0	0	0
	1 200-	3	4	0	0
	1 400-	2	3	1	0
	1 600-	1	1	0	0
	1 800-	1	1	1	1
	2 000-	2	1	2	0
	2 200-	6	6	17	20
	2 600-	3	2	2	2
	3 000 or more	2	3	0	0
Total proteins (g)	0-	0	0	0	0
	10-	1	0	0	0
	20-	0	2	0	0
	30-	6	6	0	0
	40-	2	2	1	0
	50-	8	7	0	1
	60-	2	1	14	9
	70-	1	0	8	12
80 or more	2	4	0	1	
Animal proteins (g)	0-	9	10	0	0
	10-	10	8	0	0
	20-	1	2	1	0
	30-	0	0	18	20
	40-	2	2	4	3
50 or more	0	0	0	0	
Carbo- hydrates	Less than 100	0	0	0	0
	100-	1	1	0	0
	200-	4	6	2	0
	300-	3	3	14	12
	400-	8	8	7	11
	500-	5	2	0	0
	600 or more	1	2	0	0
Fats (g)	0-	4	6	0	0
	10-	8	7	0	0
	20-	7	4	0	0
	30-	1	2	1	1
	40-	0	1	5	4
	50-	0	0	5	9
60 or more	2	2	12	9	
Total patients		22	22	23	23

and 21 by the weighment method, and the corresponding figures in the sanatorium series were 22 and 23, respectively. There was also a general similarity in the findings in respect of the animal protein, carbohydrates and fats. It may be concluded that the oral questionnaire method, which was simple and not so time-consuming as the weighment technique, was just as reliable. This observation is in general agreement with the findings reported by Venkatachalam, Srkantiah & Gopalan (1954) and Pasricha (1959). It was decided, in the light of the comparison, that there was no need to undertake further weighment assessments in this study.

THE TWO GROUPS FOR DIETARY ASSESSMENT

For the purpose of the dietary assessments, the 157 patients in this report were studied in two main groups:

- a) the less intensively investigated group of 112 patients (57 home, 55 sanatorium);
- b) the intensively investigated group of 45 patients (22 home, 23 sanatorium);

The patients in the less intensively investigated group were assessed by the oral questionnaire method at some time during the second six months

of treatment. On that occasion, two assessments were undertaken for each patient, the first being a retrospective assessment of the dietary intake immediately before admission to treatment, and the second an assessment of the patient's current diet. The pretreatment assessments, being retrospective and, hence, dependent on the patient's memory, are probably less reliable than the current assessments. Nevertheless, they permit valid comparisons between the home and the sanatorium series.

In the intensively investigated group the oral questionnaire was undertaken at six set dates - namely, on admission to treatment, and at six weeks, three months, six months, nine months and one year after the start of treatment; none of the assessments in this group was retrospective. In addition, a weighment assessment was undertaken at three months.

In cases of gross exaggeration or underestimation of the dietary intake which were not compatible with the family's spending capacity, the diet survey was repeated. If the patients were suffering from an illness other than tuberculosis that interfered with their usual intake of food, the dietary assessments were postponed.

II. RESULTS OF ORAL QUESTIONNAIRE SURVEY

This section presents the distributions of dietary intake (a) both before treatment and during the second six months of treatment, for all the patients - that is, for the 112 (57 home, 55 sanatorium) patients in the less intensively investigated group and the 45 (22 home 23 sanatorium) in the intensively investigated group combined (for the latter group, the results included in the tabulations are those of the pretreatment assessment and the assessment at nine months) - and (b) at the six set examinations, for the intensively investigated group.

RESULTS IN THE TWO GROUPS COMBINED

Total calories

Before the start of treatment the daily calorie intake was low in the majority of patients in both series (Table 2). Thus, 71% of the 79 home and 68% of the 78 sanatorium patients had a total daily intake of less than 1800 calories, 22% in each series having less than 1000 calories. At the assessment during treatment the intake had increased in both series, but to a greater extent in the sanatorium patients,

58% of the home as compared with 99% of the sanatorium patients having an intake of more than 1800 calories a day. However, 11 (14%) patients at home and only one in sanatorium claimed a daily intake of 3000 calories or more.

Proteins

Before the start of treatment the total daily protein intake was less than 50 g in 80% of the home and 79% of the sanatorium patients (Table 3). There were seven patients (five home, two sanatorium) who had an intake of less than 10g, the intake being 5-9 g in six and 1.5 g in the seventh. These patients all had severe toxæmia. (Six had an intake of less than 500 calories and the seventh 514 calories a day). At the assessment during treatment 47% of the home patients and all (100%) of the sanatorium patients had a total protein intake of more than 50 g. The animal-protein data have not been tabulated here, but during treatment six (8%) of the home and all of the sanatorium patients had a daily intake of 30 g

TABLE 2
TOTAL CALORIE INTAKE : ASSESSMENTS
BEFORE TREATMENT AND DURING TREATMENT *

Calories	Before treatment		During treatment	
	Home	Sana- torium	Home	Sana- torium
	No. %	No. %	No. %	No. %
Less than 1 000	17 2 2	17 2 2	4 5	0 0
1 000-	10 1 3	5 6	3 4	0 0
1 200-	18 2 3	13 1 7	4 5	0 0
1 400-	9 1 1	5 6	13 1 6	0 0
1 600-	2 3	13 1 7	9 1 1	1 1
1 800-	5 6	11 1 4	6 8	2 3
2 000-	4 5	3 4	6 8	14 1 8
2 200-	10 1 3	7 9	15 1 9	49 6 3
2 600-	2 3	0 0	8 1 0	11 1 4
3 000 or more	2 3	4 5	11 1 4	1 1
Total patients	79 102	78 100	79 100	78 100

*Assessed in the second six months of treatment.

or more of animal protein; the majority of the home series—namely, 61 (77%)—had an intake of less than 20 g a day, and 27 (34%) had an intake of less than 10 g.

Fats

The great majority of patients—namely, 72 (91%) of the home and 65 (83 %) of the sanatorium series—had an intake of less than 40 g of fat daily before treatment, the intake being less than 20 g in 59 % of the home and in 41% of the sanatorium patients. During treatment the intake of fat in the home series remained practically unaltered, but in sanatorium it increased to a marked degree. Thus, only nine (11%) of the home as compared with all (100%) of the sanatorium patients had an intake of more than 40 g at the assessment during treatment, 59 % of the latter having an intake of 60 g or more of fat per day. The results have not been tabulated here.

Carbohydrates

The pretreatment daily intake of carbohydrates (not tabulated here) in both series was similar and in the majority of patients—namely, 81% of the home and 83 % of the sanatorium series—it was less than

400 g, 27% and 26%, respectively, having an intake of less than 200 g. During treatment a greater proportion of the home patients (48 %) than the sanatorium patients (28%) had an intake of 400 g or more. Whereas 12 patients in the home series consumed over 600 g of carbohydrates a day, none of the sanatorium patients had so large an intake. On the other hand, 18 % of the home patients and only 1% of the sanatorium patients had a daily intake of less than 300 g. In summary, though the mean intake of carbohydrates was the same in both series, there was greater variation among the home patients, for whom carbohydrates, in the form of rice, were the major article of diet.

Minerals and vitamins

In view of the similarity in the pretreatment diet of the two series of patients in terms of total calories, proteins, fats and carbohydrates, the mineral and vitamin contents of the diet before the start of treatment were not calculated. However, the intakes of minerals—namely, calcium, phosphorus and iron

TABLE 3
TOTAL PROTEIN INTAKE : ASSESSMENTS
BEFORE TREATMENT AND DURING TREATMENT *

Proteins	Before treatment		During treatment	
	Home	Sana- torium	Home	Sana- torium
	No. %	No. %	No. %	No. %
0-	0 0	1 1	0 0	0 0
5-	5 6	1 1	0 0	0 0
10-	2 3	1 1	0 0	0 0
15-	8 10	4 5	1 1	0 0
20-	8 1 0	7 9	2 3	0 0
25-	10 1 3	9 1 2	3 4	0 0
30-	19 2 4	21 2 7	18 2 3	0 0
40-	11 1 4	18 2 3	18 2 3	0 0
50-	12 1 5	6 8	13 1 6	3 4
60-	1 1	3 4	13 1 6	23 2 9
70-	2 3	3 4	4 5	32 4 1
80 or more	1 1	4 5	7 9	20 2 6
Total patients	79 100	78 100	79 100	78 100

*Assessed in the second six months of treatment.

TABLE 4
TOTAL MINERAL INTAKE ASSESSMENT DURING
TREATMENT ^a

		Home		Sanatorium	
		No.	%	No.	%
Calcium (g)	Less than 0.5	22	28	0	0
	0.5-	39	49	1	1
	1.0-	14	18	54	69
	1.5-	4	5	22	28
	2.0 to 2.5	0	0	1	1
Phosphorus (g)	Less than 0.5	4	5	0	0
	0.5-	22	28	0	0
	1.0-	38	48	10	13
	1.5-	14	18	53	68
	2.0 to 2.5	1	1	15	19
Iron (mg)	Less than 5	1	1	0	0
	5-	2	3	0	0
	10-	21	27	3	4
	15-	15	19	36	46
	20-	11	14	33	49
	25-	16	20	1	1
	30-	10	13	0	0
	35-	0	0	0	0
	40-	0	0	0	0
	45 or more	3	4	0	0
Total patients		79	100	78	100

^a Assessed in the second six months of treatment.

(Table 4)– and of vitamin A, carotene, thiamine, riboflavine, nicotinic acid and ascorbic acid *during treatment* were calculated to see whether differences existed between the two series. The calculations are based on the mineral and vitamin contents of uncooked foodstuffs and, as such, the results do not take into account losses in cooking.

Calcium. Among the home patients, 77% had a daily dietary intake of less than 1 g of calcium, as compared with 1% of the sanatorium patients, 28 % of the home patients receiving less than 0.5 g of calcium a day (Table 4).

In South India, betel leaves, to which slaked lime has been added, are commonly chewed, and this habit adds to the daily intake of calcium. Before

their admission to treatment 63 (79 %) of the patients in the home series and 48 (62 %) of those in the sanatorium series chewed betel leaves. After admission to treatment it was easier for the patients in the home series to continue the habit, which was forbidden in sanatorium although the restriction was not rigidly enforced. This additional source of calcium has not been taken into account in the calculations.

Phosphorus. In the home series only 67% of the patients had an intake of 1 g or more of phosphorus (Table 4) daily, as compared with all (100%) of those in the sanatorium series.

Iron. Considering the intake of iron (Table 4), the means were the same though the distributions were widely different. Thus, 30% of the home series received less than 15 mg daily, as compared with 4% in the sanatorium series, and at the other extreme, 37 % of the home patients and 1% of the sanatorium patients had an intake of 25 mg or more. The great majority of the sanatorium patients—namely, 95 %—had a daily intake of 15-24 mg of iron in their diet.

Vitamin A. While 96% of the 79 home patients had less than 1000 International Units (IU) of vitamin A in their diet daily, all (100 %) of the sanatorium patients had an intake of more than 1000 IU and 68 % had an intake of 2000 IU or more.

Carotene. Of the home patients, 37 (47%) were receiving less than 600 IU of carotene daily, as compared with one (1%) of the sanatorium patients. At the other end of the scale, four (5 %) of the home and 10 (13 %) of the sanatorium patients had a daily intake of 2000 IU or more.

Thiamine. Of the home patients, 38 (48 %) had an intake of less than 400 IU of thiamine, as compared with none (0%) of the sanatorium patients. In all, 13 (17 %) of the home and 54 (69 %) of the sanatorium patients had intakes of 600 IU or more.

Riboflavine. Whereas 69 (87%) of the home patients received less than 500 µg of riboflavine daily, none of the sanatorium patients had such a low intake, 76 (97 %) having 1500 µg or more daily.

Nicotinic acid. Although the mean intakes were very similar for the two series, 22 (28 %) of the patients in the home series had an intake of less than 15 mg of nicotinic acid a day, as compared with five (6%) of those in the sanatorium series. At the other extreme, 14 (18 %) of the home but none (0 %) of the sanatorium patients had an intake of 25 mg or more daily.

TABLE 5
SERIAL ASSESSMENTS OF THE TOTAL CALORIE INTAKE DURING THE 12 MONTHS

Calories	Home						Sanatorium					
	Before treatment	6 weeks	3 months	6 months	9 months	12 months	Before treatment	6 weeks	3 months	6 months	9 months	12 months
Less than 1 000	4	0	1	0	0	0	6	0	0	0	0	0
1 000-	3	1	1	1	2	1	2	0	0	0	0	0
1 200-	5	3	3	6	1	0	3	0	0	0	0	0
1 400-	4	2	2	2	6	5	4	0	1	0	0	0
1 600-	0	4	1	1	0	1	4	1	0	0	0	0
1 800-	0	3	1	0	1	1	3	2	1	0	0	0
2 000-	0	2	2	3	0	3	1	7	2	1	2	3
2200-	6	1	6	6	5	5	0	11	17	17	18	14
2 600-	0	3	3	2	4	2	0	2	2	4	3	6
3 000 or more	0	3	2	1	3	4	0	0	0	1	0	0
Total patients	22	22	22	22	22	22	23	23	23	23	23	23

Ascorbic acid. At home, 20 (25 %) of the patients had an intake of less than 25 mg of ascorbic acid a day, as compared with four (5%) in sanatorium. The majority of patients in both series—namely, 67 (85%) of the home and 67 (86%) of the sanatorium patients—had intakes of less than 100 mg a day.

It may be concluded, on the basis of the above findings, that the dietary intakes were similar in the two series before the start of treatment. Once treatment had begun, however, patients admitted to sanatorium received a clearly superior diet. The differences in the mean intake of calories, total proteins, animal proteins, fats, calcium, phosphorus, vitamin A, thiamine and riboflavine all attained statistical significance at the 0.1% level. While there was little difference in the mean intake of carbohydrates between the two series, there was a greater variation among the home patients.

RESULTS IN THE INTENSIVELY INVESTIGATED GROUP

A more detailed study of the trend of dietary intake over the 12-month period was possible in the intensively investigated group of 45 patients (22 home, 23 sanatorium). The findings for calories, total proteins, animal proteins, fats and carbohydrates are set out below.

Total calories

Considering the calorie intake (Table 5), the pretreatment distributions for the two series were broadly similar, 16 patients in the home and 15 in the sanatorium series receiving less than 1600 calories daily. At six weeks the calorie intake had increased in both series, but to a greater extent in the sanatorium series; six home patients but no sanatorium patient still had an intake of less than 1600 calories. At three months there was evidence of a further, though slight, increase in calories in both series. The assessments at six, nine and 12 months showed little further change, and the greater calorie intake in the sanatorium patients was maintained.

Total proteins

The six assessments of total protein intake made in the 12-month period are set out in Table 6. In both series there was an increase in the intake at six weeks, as compared with the pretreatment findings, the increase being more marked in the sanatorium series. Thus, the total protein intake was 40 g or more in eight of the home patients before treatment, as compared with 13 at six weeks. In the sanatorium series the corresponding figures were eight before treatment and 23 at six weeks. There was little change in the distribution in the home series at the

TABLE 6
SERIAL ASSESSMENTS OF THE TOTAL PROTEIN INTAKE DURING THE 12 MONTHS

Proteins (g)	Home						Sanatorium					
	Before treatment	6 weeks	3 months	6 months	9 months	12 months	Before treatment	6 weeks	3 months	6 months	9 months	12 months
0-	1	0	0	0	0	0	0	0	0	0	0	0
10-	0	0	1	0	0	0	1	0	0	0	0	0
20-	6	0	0	3	2	0	5	0	0	0	0	0
30-	7	9	6	4	7	6	9	0	0	0	0	0
40-	2	4	2	4	2	4	6	0	1	0	0	0
50-	4	4	8	5	2	6	1	1	0	0	0	0
60-	1	2	2	4	4	1	1	17	14	1	1	2
70-	1	0	1	1	3	1	0	5	8	6	12	10
80 or more	0	3	2	1	2	4	0	0	0	16	10	11
Total patients	22	22	22	22	22	22	23	23	23	23	23	23

rest of the assessments, but in the sanatorium series at six, nine and 12 months there were 22, 22 and 21 patients, respectively, with an intake of more than 70 g, as compared with five at six weeks and eight at three months.

Animal protein

The animal protein in the diet was low in both series before the start of treatment, 19 of the home and 17 of the sanatorium patients having an intake

of less than 20 g. The intake remained low at all the assessments during treatment for the home series, 20 patients at six weeks, 19 at three months, 18 at six months, 18 at nine months and 17 at 12 months still having an intake of less than 20 g. In contrast, no patient in the sanatorium series had so low an intake during treatment and all at six weeks and 22 at three months had an intake of 30 g or more a day and the considerable majority—namely, 18, 19 and 19—received 50 g or more at the assessments made

TABLE 7
SERIAL ASSESSMENTS OF THE TOTAL FAT INTAKE DURING THE 12 MONTHS

Fats (g)	Home						Sanatorium					
	Before treatment	6 weeks	3 months	6 months	9 months	12 months	Before treatment	6 weeks	3 months	6 months	9 months	12 months
0-	4	5	4	3	6	6	2	0	0	0	0	0
10-	6	9	8	9	7	7	7	0	0	0	0	0
20-	9	4	7	6	4	2	5	0	0	0	0	0
30-	0	2	1	3	1	5	7	0	1	0	0	0
40-	2	0	0	0	2	0	1	5	5	1	0	0
50-	1	0	0	0	1	1	1	7	5	4	4	1
60 or more	0	2	2	1	1	1	0	11	12	18	19	22
Total patients	22	22	22	22	22	22	23	23	23	23	23	23

at six, nine and 12 months, respectively. The data have not been tabulated here.

Fats

There was little change in the intake of fats among patients in the home series at any time in the year (Table 7). In the sanatorium series, however, there was a marked increase in intake at six weeks and a further increase in the last three assessments. Thus, no sanatorium patient had an intake of 60 g or more before admission to treatment, as compared with 11 at six weeks, 18 at six months and 22 at 12 months.

Carbohydrates

An analysis of the carbohydrate intake (not tabulated here) showed an increase in both series

in the first six weeks. Thus, 10 home patients had an intake of 300 g or more a day before treatment, as compared with 17 at six weeks. In the sanatorium series the corresponding figures were eight and 21. There was little change in the sanatorium series for the rest of the year, but in the home series rather more patients had large carbohydrate intakes (400 g or more) at three months and subsequently than at six weeks. The analysis confirmed the finding in the less intensively investigated group that the home series had a wider range of carbohydrate intake than the sanatorium series.

In summary, the findings in the intensively investigated group of patients showed that the patients had very stable diets from three to 12 months and that the sanatorium series were at a clear-cut advantage throughout the year.

III. REST AND PHYSICAL ACTIVITY

The home patients were advised to rest for the first month or two and were then allowed, if their disease showed signs of improvement, to undertake light activity. The majority of the patients were ambulant much of the time and were quite often not at home when visits were paid by the staff. In sanatorium, very ill patients had absolute bed rest with bed-pan facilities. The less ill patients had their activity restricted, and throughout the 12

months the maximum time that the patients were officially allowed to be out of bed was four hours a day. A fuller description of the management is given in an earlier report (Tuberculosis Chemotherapy Centre, 1959).

The physical activity of the patients at six and 12 months is set out in Table 8. While 41% of the home patients were engaged in at least part-time activity at six months, only 10% of the sanatorium

TABLE 8
ASSESSMENT OF THE PHYSICAL ACTIVITY OF THE PATIENTS DURING THE 12 MONTHS

Physical activity	Home				Physical activity	Sanatorium			
	6 months		12 months			6 months		12 months	
	No.	%	No.	%		No.	%	No.	%
Resting	5	6	1	1	Complete bed rest	1	1	0	0
Slight	42	53	10	13	Up to toilet only	6	8	0	0
Part-time	29	37	34	44	Up 2 hours	62	81	66	85
Full-time	3	4	32	42	Up 4 hours	8	10	12	15
All patients	79	100	77 ^a	100	All patients	77 ^b	100	78	100

^aExcluding at 12 months only, two patients in whom chemotherapy was changed on account of serious radiographic deterioration at the 10th and 12th months, respectively.

^bExcluding, at six months only, one patient who was discharged from sanatorium at the time of assessment.

patients were up for four hours a day. At 12 months the proportions were 86% and 15%, respectively, 42% of the home patients being on full-time activity. It is difficult to compare the activity of the home and sanatorium patients, but it is considered that part-time activity in a home patient clearly

represented more than the maximum permitted activity of a sanatorium patient. It may be concluded that the home patients were physically much more active during the 12 months than the patients in sanatorium. This greater physical activity in the home patients increases their dietary disadvantage.

IV. INCOME OF THE HOME FAMILIES DURING THE YEAR

Considering an adult male (15 years or over) as being equivalent to one standard unit, an adult female (15 years or over) as 0.8 standard unit, and a child under the age of 15 years as 0.6 standard unit (India, Ministry of Commerce, 1949), the average monthly income per standard unit over the 12 months was calculated for the families of home patients. Thus expressed, 87% of the families had less than Rs. 301 per standard unit per month, 68% having less than Rs. 20. The figure varied from Rs. 2.54 to Rs. 40.50, the average for all home families being Rs.17.20.

An indication of the purchasing power of income per standard unit is given by the sum that was spent by the Madras Government on food for the patients in the sanatorium series. Rs.1.84 daily was spent

for the non-vegetarian patients and Rs.1.66 daily for the vegetarian patients - that is, Rs.55.20 for a 30-day month for the non-vegetarians. These sums are based on bulk purchases of food for an institution with over 600 patients, so that it is very unlikely that a patient treated at home would be able to purchase the same with an identical daily expenditure. Also, Chaudhuri (1959), when referring to the current cost of living in India, wrote: "At present price levels, a balanced diet for one adult costs at least Rs. 1.50 a day (Rs. 45.00 a month); and the minimum total requirement, including food and clothing, is about Rs.60-70per month." It may therefore be concluded that the economic status of the home families was poor during the year.

V. RESPONSE TO TREATMENT OF THE HOME AND THE SANATORIUM SERIES.

A detailed analysis in an earlier report (Tuberculosis chemotherapy Centre, 1959) showed that the response to treatment of the patients at home closely approached that of the patients in sanatorium. Because the patients under treatment at home had, on the average, more extensive disease on admission to the study, statistical standardization of the results was undertaken, to allow for the pretreatment differences. For the full details the reader is referred to the earlier (1959) report. In brief, measures of the radiographic and the bacteriological response were standardized for pretreatment differences in (a)the extent of cavitation, (b) the number of lung zones involved in disease and (c)the extent of cavitation and the lung-zone involvement combined; these factors were selected because they were found to be of major prognostic importance (Tuberculosis Chemotherapy Centre, 1959), and because the two series differed in both respect at the start of treatment. Whereas in the earlier report the statistical standardization was based on 163 patients, the

percentages in Table 9, referred to below, are based on the 157 patients in the present analysis.

RADIOGRAPHIC RESPONSE

Considering the radiographic response first, the important findings are set out in Table 9 (first part). For the period 0-6 months, the unstandardized percentages for patients showing considerable or exceptional radiographic improvement were 30.8 for the home series and 38.5 for the sanatorium series, the former being 80% of the latter. When allowance was made for the pretreatment differences in the extent of cavitation between the series, the standardized percentages were 32.8 and 36.2, respectively, the former being 91% of the latter. Standardization for lung-zone involvement also slightly reduced the difference between the series, the response in patients at home becoming 82% of that in the sanatorium patients. When allowance was made simultaneously for both the pretreatment differences, the standardized percentages were 31.8 for the home patients and

* Rs 4.76 = US\$ 1.00

TABLE 9

PERCENTAGES OF PATIENTS SHOWING FAVOURABLE RADIOGRAPHIC AND BACTERIOLOGICAL RESPONSE, STANDARDIZED FOR PRETREATMENT DIFFERENCES IN EXTENT OF CAVITATION AND LUNG-ZONE INVOLVEMENT

Radiographic response					Bacteriological response						
Nature of response		Percentages standardized for pretreatment differences in :			Nature of response		Percentages standardized for pretreatment differences in :				
		Home	San.	Home as % of san.			Home	San.	Home as % of san.		
Percentage of patients with considerable or exceptional radiographic improvement	0-6 mths	(Unstandardized)	30.8	38.5	80	Percentage of patients with negative culture on a single collection specimen	6 mths	(Unstandardized)	87.2	97.3	90
		Extent of cavitation	32.8	36.2	91			Extent of cavitation	88.4	96.8	91
		Lung-zone involvement	31.5	38.2	82			Lung-zone involvement	88.4	97.2	91
		Cavitation and lung zones	31.8	35.9	89			Cavitation and lung zones	90.4	97.0	93
	0-12 mths	(Unstandardized)	41.8	52.6	79	12 mths	(Unstandardized)	87.0	93.4	93	
		Extent of cavitation	42.5	51.0	83		Extent of cavitation	89.0	92.3	96	
		Lung-zone involvement	43.3	53.1	82		Lung-zone involvement	87.9	92.3	95	
		Cavitation and lung zones	44.0	49.6	89		Cavitation and lung zones	89.4	92.2	97	
Percentage of patients with cavitation before treatment in whom it disappeared	at 12 mths	(Unstandardized)	37.1	54.9	68	12 mths	(Unstandardized)	83.5	92.3	90	
		Extent of cavitation	42.6	50.6	84		Extent of cavitation	85.4	91.7	93	
		Lung-zone involvement	41.5	53.2	78		Lung-zone involvement	85.3	91.4	93	
		Cavitation and lung zones	43.3	49.8	87		Cavitation and lung zones	86.1	92.0	94	

35.9 for the sanatorium patients, the former being 89% of the latter. Considering the period 0-12 months, the percentages of patients showing considerable or exceptional radiographic improvement were 41.8 for the home series and 52.6 for the sanatorium series, the former being 79% of the latter. The contrast between these percentages was reduced by standardization for both cavitation and lung-zone involvement; thus, the standardized percentages were 44.0 for the home and 49.6 for the sanatorium patients, the former being 89% of the latter. Standardization for both pretreatment factors considerably reduced the difference between the home and the sanatorium series in respect of cavity closure for the 12-month period, the standardized percentages being 43.3 for the home series and 49.8 for the sanatorium series, the former being 87% of the latter.

BACTERIOLOGICAL RESPONSE

The bacteriological response is considered in Table 9 (second part). The effect of allowing for the pretreatment differences in extent of cavitation and lung-zone involvement was a slight reduction in the contrast between the results for the home and the

TABLE 10
DISTRIBUTION OF FIRST MONTH OF PERSISTING CULTURE NEGATIVITY IN PATIENTS WITH BACTERIOLOGICALLY QUIESCENT DISEASE AT ONE YEAR

First month of persisting culture negativity	Home patients		Sanatorium patients	
	No.	%	No.	%
1	9	15	12	17
2	9	15	19	27
3	15	25	19	27
4	17	29	16	23
5	2	15	1	6
6	1		2	
7	2		0	
8	1		1	
9	2		0	
10	1		0	
Total	59	99	70	100

sanatorium patients. This applies to all three measures of response—namely, the percentage of patients with a negative culture on a single collection specimen at six months and at 12 months and the percentage of patients no longer having bacteriologically active disease at 12 months. Thus, for example, the unstandardized percentage of patients with a negative culture at six months was 87.2 for the home and 97.3 for the sanatorium patients, whereas after standardization for both extent of cavitation and lung-zone involvement, the percentages were 90.4 and 97.0, the former being 93 % of the latter. At 12 months, the same percentage, standardized both for cavitation and lung-zone involvement, was 89.4 for the home and 92.2 for the sanatorium patients, the former being 97% of the latter. Considering patients who no longer had bacteriologically active disease at 12 months, the standardized percentage (86.1) for the home patients was 94 % of that for the sanatorium patients (92.0).

A corresponding analysis (not tabulated here), undertaken to standardize both for extent of cavitation and for bacterial content of sputum, led to very similar conclusions.

Thus, when allowance was made, so far as was possible, for some of the important pretreatment differences, the difference in the disease status of the home and the sanatorium patients at the end of one year was small. However, there was evidence that the patients in the sanatorium series attained bacteriological quiescence more rapidly than those in the home series (Table 10). Thus, 50 (71 %) of the 70 sanatorium patients who attained bacteriological quiescence had shown sputum conversion by three months, as compared with 33 (56%) of 59 home patients (P = 0.1). This difference was practically unchanged when standardization was undertaken for the pretreatment differences in the extent of cavitation and the number of lung zones involved in disease.

VI. WEIGHT CHANGES IN THE 12-MONTH PERIOD

Gain in weight is a time-honoured method of assessing clinical improvement in patients with active tuberculosis. It is, therefore, of particular interest to compare the gains in weight in the two treatment series. (The mean weights on admission to treatment were 88, 88, 70 and 75 lb., respectively,

for the home males, sanatorium males, home females and sanatorium females.) The findings are set out in Table 11 and in the accompanying figure. It will be seen that the males and females in both series gained, on the average, a considerable amount of weight, the gains being consistently greater in the

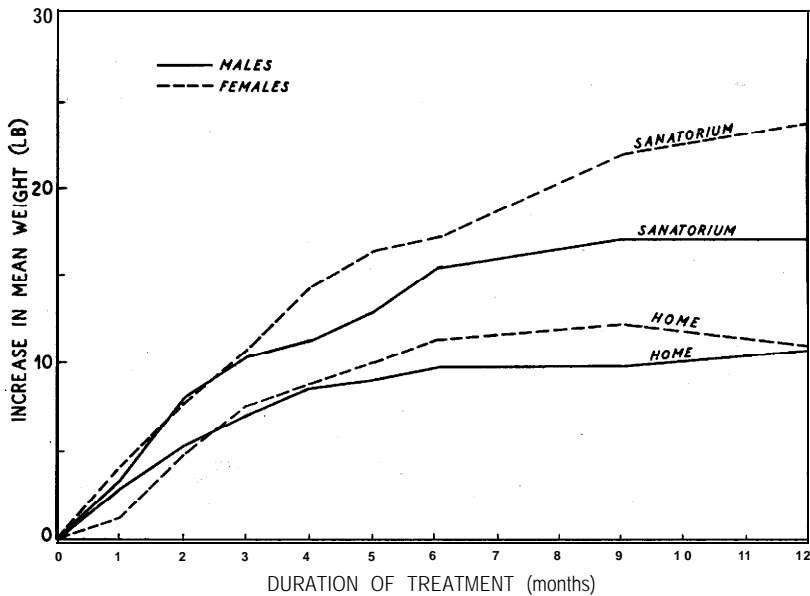
TABLE 11
WEIGHT CHANGES IN THE 12-MONTH PERIOD, ACCORDING TO SEX OF PATIENTS AND PLACE OF TREATMENT

Period	Males				Females			
	Home		Sanatorium		Home ^a		Sanatorium	
	Total patients weighed	Increase in mean weight (lb. ^b)	Total patients weighed	Increase in mean weight (lb.)	Total patients weighed	Increase in mean weight (lb.)	Total patients weighed	Increase in mean weight (lb.)
0-1 month	46	2.9	48	3.2	26	1.2	30	4.0
0-2 months	46	5.2	48	8.0	26	4.7	30	7.7
0-3 months	46	7.0	48	10.3	26	7.5	30	10.7
0-4 months	46	8.5	48	11.2	26	8.7	30	14.4
0-5 months	46	9.0	48	13.0	26	10.0	30	16.4
0-6 months	46	9.7	48	15.4	26	11.3	30	17.3
0-9 months	46	9.7	48	17.1	26	12.2	30	22.1
0-12 months	46	10.7	48	17.1	26	11.0	30	24.2

^aExcluding seven patients who became pregnant during the 12-month period.

^b1 lb. = 0.45 kg.

WEIGHT CHANGES IN THE 12-MONTH PERIOD, ACCORDING TO SEX OF PATIENTS AND PLACE OF TREATMENT



sanatorium patients. A clear difference was apparent between the home and the sanatorium series from the second month onwards in respect of the males, and from the first month onwards in respect of the females. By six months, the home males had gained, on the average, 9.7 lb. while those in sanatorium had gained 15.4 lb.; the corresponding gains for the females were 11.3 lb. and 17.3 lb., respectively. The differences, both for the males and for the females, attain statistical significance at the 1% level. There was little change in the average weight of the home patients in the second six months, but the sanatorium patients continued to gain weight, especially the females, who gained a further 6.9 lb. on the average. This continuing gain in weight can be clearly seen in the figure. It may be concluded that the sanatorium patients, both male and female, gained considerably more weight than the home patients. However, as already demonstrated in the previous section, this did not result in over-all superior clinical results at the end of the year in the sanatorium series.

Further analyses were undertaken to investigate whether the patients who gained considerable amounts of weight had also responded better than the patients who gained less weight or who failed to gain weight. The findings are set out in Tables 12 and 13.

WEIGHT GAIN IN RELATION TO RADIOGRAPHIC RESPONSE

Considering favourable radiographic response (Table 12), defined as moderate, considerable or exceptional improvement (assessed by an independent observer unaware of the treatment of any patient), 20 (77%) of 26 patients, who gained at least 14 lb. during the year, showed a favourable radiographic response at 12 months, as compared with 80 % of 20 who gained 7-13 lb. and 68 % of 22 who gained less than 7 lb. There was, thus, no evidence of an association between gain in weight and favourable radiographic response. In the sanatorium series there was also no evidence of an association; 88 % of 34 patients who gained 21 lb. or more had a favourable radiographic response during the year, as compared with 86 % of 22 patients who gained 14-20 lb., 100 % of 16 who gained 7-13 lb. and 83 % of six who gained less than 7 lb. There were four patients in the home series who failed to gain weight, and none had had a favourable radiographic response, but this finding may well be due to a failure of some of the patients to gain weight *because* their disease was responding unfavourably. It cannot be assumed that unfavourable radiographic response is necessarily a direct consequence of a failure to gain weight.

TABLE 12
FAVOURABLE RADIOGRAPHIC RESPONSE AT 12 MONTHS, RELATED TO WEIGHT CHANGE OVER THE 12 MONTHS^a

Weight change (0-12 months)	Home			Sanatorium		
	Number of patients	Patients with favourable radiographic response		Number of patients	Patients with favourable radiographic response	
		No.	%		No.	%
Loss or no change	4	0	(0) ^b	0	-	-
Gain of:						
less than 7 lb. ^c	22	15	(68)	6	5	(83)
7-13 lb.	20	16	(80)	16	16	(100)
14-20 lb.	18	14	(78)	22	19	(86)
21 lb. or more	8	6	(75)	34	30	88
Total patients	72	51	71	78	70	90

^aExcluding seven home patients who became pregnant during the 12-month period.

^bThe parentheses indicate percentages based on fewer than 25 observations.

^c1 lb = 0.45 kg.

WEIGHT GAIN IN RELATION TO BACTERIOLOGICAL RESPONSE

Considering bacteriologically active disease at twelve months (Table 13), three (12%) of 26 patients

in the home series who gained at least 14 lb. during the year had active disease, as compared with six (14 %) of 42 who gained 13 lb. or less. In the sanatorium series, the corresponding proportions were

TABLE 13
BACTERIOLOGICALLY ACTIVE DISEASE AT 12 MONTHS, RELATED TO WEIGHT CHANGE OVER THE 12 MONTHS^a

Weight change (0-12 months)	Home			Sanatorium		
	Number of patients	Patients with bacteriologically active disease		Number of patients	Patients with bacteriologically active disease	
		No.	%		No.	%
Loss or no change	4	3	(75) ^b	0		-
Gain of:						
less than 7 lb. ^c	22	1	(5)	6	1	(17)
7-13 lb.	20	5	(25)	16	0	(0)
14-20 lb.	18	3	(17)	22	4	(18)
21 lb. or more	8	0	(0)	34	2	6
Total patients	72	12	17	78	7	9

^aExcluding seven home patients who became pregnant during the 12-month period.

^bThe parentheses indicate percentages based on fewer than 25 observations.

^c1 lb. = 0.45 kg.

six (11%) of 56 and one (5%) of 22 patients. These figures provide no evidence that the larger gains in weight were associated with a favourable bacteriological response in either series. There were four patients in the home series who had failed to gain weight and three of these had bacteriologically

active disease at 12 months, so that there was some evidence that failure to gain weight and a poor bacteriological response were associated. As with the radiographic findings, however, it cannot be assumed that the poor response was a consequence of the failure to gain weight.

VII. RESPONSE TO TREATMENT IN RELATION TO THE DIETARY INTAKE DURING THE YEAR

The object of this section is to relate directly the level of the dietary intake during the year to two important measures of the response to treatment—namely, radiographic improvement at 12 months, and the bacteriological assessment of the disease status at 12 months.

RADIOGRAPHIC RESPONSE AT 12 MONTHS

Table 14 relates various factors of the diet to favourable radiographic response at 12 months (moderate, considerable or exceptional improvement at an independent assessment). The findings for the home and the sanatorium patients are presented separately. Considering total calories first, there was no association between the dietary intake and the radiographic response. In the home series, 25 (76%) of 33 patients with an intake of less than 1800 calories showed at least moderate improvements, as compared with 24 (71%) of 34 patients with an intake of 2200 or more calories. In the sanatorium series, also, there was no difference between the responses of patients with low and high total calorie intakes. Considering total proteins, 75% of 24 home patients with an intake of less than 40 g a day responded well, as compared with 67% of 24 receiving 60 g or more a day. In the sanatorium patients, also, there was no association between protein intake and response; thus, 95% of 58 patients receiving less than 80 g or more. Considering animal proteins, 83% of 30 home patients receiving less than 10 g a day responded well, as compared with 76% of 17 patients receiving 20 g or more. In the sanatorium series, too, there was no evidence of a beneficial effect of a large intake of animal protein, 93% of 27 patients receiving between 30 and 40 g a day responding well, as compared with 85% of 34

patients receiving 50 g or more a day. Both at home and in sanatorium, the response in relation to total intake of fats was very similar for the different levels of intake. Considering total carbohydrates, 78% of 32 patients in the home series with an intake of less than 350 g a day responded well, as compared with 71% of 31 with an intake of 450 g or more a day. In the sanatorium series, the response was also, if anything, less satisfactory in the patients with a higher intake, for all of 24 patients consuming less than 350 g fared well, as compared with 85% of 54 with higher intakes.

A number of analyses (not tabulated here) were undertaken to investigate possible associations of certain vitamin contents of the diet—namely, vitamin A, Carotene, thiamine, riboflavine, nicotinic acid and ascorbic acid—and the mineral content of the diet—namely, calcium, phosphorus and iron—with the radiographic and bacteriological response to treatment; none showed any evidence of association.

It may be concluded that there was no association between radiographic improvement and the intake of any of the dietary factors studied.

BACTERIOLOGICAL RESPONSE AT 12 MONTHS

Table 15 relates various dietary factors to unfavourable bacteriological response—that, is bacteriologically active disease at 12 months. (A patient was considered to have active disease if he never had three consecutive months of culture negativity or if two or more cultures were positive among an average of seven to nine examined in the last three months of the year, i.e., at 10, 11 and 12 months. Two patients who produced an isolated positive culture at 12 months and were classified as having disease of

TABLE 14
FAVOURABLE RADIOGRAPHIC RESPONSE
AT 12 MONTHS, RELATED TO THE DIETARY INTAKE
DURING TREATMENT

	Home		Sanatorium	
	Total patients	Favourable radio-graphic response	Total patients	Favourable radio-graphic response
		No. %		No. %
Calories :				
Less than 1 400	11	7 (64) ^b	0	- -
1 400-	22	18 (82)	1	1 (100)
1 800-	12	9 (75)	16	15 (94)
2 200-	15	11 (73)	49	46 94
2 600 or more	19	13 (68)	12	8 (67)
Total proteins (g):				
Less than 30	6	4 (67)	0	- -
30-	18	14 (78)	0	- -
40-	18	14 (78)	0	- -
50-	13	10 (77)	3	2 (67)
60-	13	9 (69)	23	22 (96)
70-	4	2 (50)	32	31 97
80 or more	7	5 (71)	20	15 (75)
Animal proteins (g):				
0-	30	25 83	0	- -
10-	32	20 63	0	- -
20-	11	9 (82)	0	- -
30-	3	2 (67)	27	25 93
40-	3	2 (67)	17	16 (94)
50 or more	0	- -	34	29 85
Fats (g):				
Less than 10	18	13 (72)	0	- -
10-	30	22 73	0	- -
20-	22	16 (73)	0	- -
40-	8	6 (75)	32	29 91
60-	0	- -	31	30 97
70 or more	1	1 (100)	15	11 (73)
Carbohydrates (g):				
Less than 300	14	10 (71)	1	1 (100)
300-	18	15 (83)	23	23 (100)
350-	9	6 (67)	32	30 94
400-	7	5 (71)	16	11 (69)
450-	6	5 (83)	5	4 (80)
500 or more	25	17 68	1	1 (100)
Total patients	79	58 73	13	70 90

^a Defined as moderate, considerable or exceptional improvement.

^b The parentheses indicate percentages based on fewer than 25 observations.

TABLE 15
BACTERIOLOGICALLY ACTIVE DISEASE AT 12 MONTHS,
RELATED TO THE DIETARY INTAKE DURING TREATMENT

	Home		Sanatorium	
	Total patients	Patients with bacterio-logically active disease ^a	Total patients	Patients bacterio-logically active disease
		No. %		No. %
Calories :				
Less than 1 400	11	2 (18)	0	- -
1 400-	22	4 (18) ^b	1	0 (0)
1 800-	12	3 (25)	16	0 (0)
2 200-	15	4 (27)	49	6 12
2 600 or more	19	1 (5)	12	1 (8)
Total proteins (g):				
Less than 30	6	0 (0)	0	- -
30-	18	3 (17)	0	- -
40-	18	6 (33)	0	- -
50-	13	3 (23)	3	0 (0)
60-	13	2 (15)	23	2 (9)
70-	4	0 (0)	32	3 9
80 or more	7	0 (0)	20	2 (10)
Animal proteins (g):				
0-	30	4 13	0	- -
10-	32	8 25	0	- -
20-	11	1 (9)	0	- -
30-	3	1 (33)	27	2 7
40-	3	0 (0)	17	3 (18)
50 or more	0	- -	34	2 6
Fats (g):				
Less than 10	18	1 (6)	0	- -
10-	30	8 27	0	- -
20-	22	5 (23)	0	- -
40-	8	0 (0)	32	4 13
60-	0	- -	31	1 3
70 or more	1	0 (0)	15	2 (13)
Carbohydrates (g):				
Less than 300	14	3 (21)	1	0 (0)
300-	18	2 (11)	23	1 (4)
350-	9	3 (33)	32	4 13
400-	7	2 (29)	16	2 (13)
450-	6	1 (17)	5	0 (0)
500 or more	25	3 12	1	0 (0)
Total patients	79	14 18	78	7 9

^a For definition, see opposite page.

^b The parentheses indicate percentages based on fewer than 25 observations.

bacteriologically doubtful status in an earlier report (Tuberculosis Chemotherapy Centre, 1959) have been regarded in the present paper as having bacteriologically active disease, since they produced a positive culture at 13 months also).

Considering the total calories, 18% of 33 home patients with an intake of less than 1800 calories had bacteriologically active disease at 12 months, as compared with 15% of 34 with an intake of 2200 calories or more. In the sanatorium series, seven patients had active disease and all had an intake of 2200 or more calories. Considering total protein, 12% of 24 patients with an intake of less than 40 g in the home series had active disease, as compared with 8% of 24 with an intake of 60 g or more. The percentage of sanatorium patients with active disease was very similar for patients receiving between 60 and 80 g a day (9%) and for those receiving 80g or more a day (10%). The amount of animal protein appeared unimportant, for 13% of 30 patients receiving less than 10 g a day had bacteriologically

active disease at 12 months, as compared with 12% of 17 patients with an intake of 20 g or more. In the sanatorium series, too, there was no evidence of an association between intake of animal protein and bacteriological response. Examination of the findings for fats and carbohydrates likewise revealed no evidence of an association between intake and bacteriologically active disease. Further analyses (not tabulated here) showed no evidence of an association between the vitamin and mineral content of an association between the vitamin and mineral content of the diet and the likelihood of bacteriologically active disease at 12 months.

In summary, an examination of the response to treatment as measured by two major assessments—namely, favourable radiographic response at 12 months and unfavourable bacteriological response during the year—yielded no evidence that the diet played an important role either for the either for the patients at home or for those in sanatorium.

VIII. DISCUSSION

Many authorities still consider that a rich diet makes a definite contribution to the treatment of pulmonary tuberculosis (McLester & Darby, 1952; Pagel, Simmonds & Macdonald, 1953; Hudson, 1957; Davidson, Meiklejohn & Passmore, 1959). A recent correspondence in the Transactions of the Royal Society of Tropical Medicine and Hygiene illustrates how debatable the question is (Barlovatz, 1959; Haddock, 1959). A search of the literature, however, has not revealed any evaluation of the role of diet in patients undergoing treatment for tuberculosis with standard combined chemotherapy. A controlled comparison has now been made of the response to isoniazid plus sodium PAS of patients with pulmonary tuberculosis treated at home for a year with that of patients treated with the same combination of drugs in sanatorium (Tuberculosis Chemotherapy Centre, 1959), with concomitant observations on the diet. The patients were drawn from a poverty-stricken, malnourished and overcrowded section of the community in Madras City. On admission to treatment, the great majority had far advanced cavitated disease and all had tubercle bacilli in the sputum, a large proportion on smear examination, the organisms being sensitive to isoniazid. Whereas the patients admitted to

sanatorium were treated under favourable conditions of accommodation, rest and nursing and received that sanatorium diet, the poverty-stricken patients treated at home remained in their overcrowded conditions and had much less rest, a poor diet, little nursing and could not be depended upon to take their medicament regularly (Tuberculosis Chemotherapy Centre, 1959). The present report is based on 157 patients who had dietary assessments.

The diet before treatment and during treatment was assessed by the oral questionnaire technique (Pasricha, 1958, 1959); the reliability of this method had already been shown by other workers. (Venkatchalam, Srikantiah & Gopalan, 1954; Padmavati, Lakhanpal & Gupta, 1958; Pasricha, 1959) and has been confirmed in the present study by a comparison with the weightment technique. In the present study, closer agreement was obtained for protein intake as assessed by the two methods than that reported by Pasricha (1959). The oral questionnaire method was selected for the present investigation because the technique is particularly suited to assessments of the "poor South Indian" diet which is so commonly encountered in the community under investigation (Patwardhan, 1952; Dakshinamurti & Devadatta, 1956, because the number of

assessments to be undertaken was large and because the assessments of the diet before treatment for 112 of the patients had to be made retrospectively.

Before the start of treatment the patients in both the home and the sanatorium series had similar diets, the total calories, total and animal proteins, fats and carbohydrates all being low. The patients were, at that time, clinically ill, many seriously so, and their appetites were poor. During treatment the patients in sanatorium received a superior diet in terms of total calories, total fats and total and animal proteins, as well as in terms of phosphorus and several vitamins. The main food factor in the diet of the home patients during treatment was carbohydrate, for the staple article of their diet was rice. As an example of the inferiority of the diets in the home series during treatment, 30% of the patients treated at home, as compared with 96% of the sanatorium patients, had an intake of 60g or more of protein, and only 8% of the patients treated at home, as compared with all the patients treated in sanatorium, had a daily intake of 30g or more of animal protein. The difference in the diet is magnified by the fact that the home patients had much less rest, for the majority had returned to part-time or full-time activity and many were in their normal occupations before the end of the year. In contrast, in sanatorium only a small proportion of the patients were permitted to be up four hours a day, a degree of activity which was clearly less than the part-time activity in the home series.

The dietary intake in both series increased in the first three months of treatment, especially in the first six weeks, and from six months onwards the dietary intake was essentially stabilized. The increase in dietary intake in the sanatorium series was, however, much more marked. It is of interest to consider why these increases in diet occurred. At the start of treatment the patients in both series were ill and suffering from toxæmia. There was a rapid reduction to toxæmia after the start of treatment and it is likely that the increase in food intake was due to the consequent increase in appetite. The sanatorium patients had, in addition, a well-balanced diet provided regularly. The domiciliary patients bought as rich a diet as they were able to afford, but because their purchasing capacity was low (Tuberculosis Chemotherapy Centre, 1959) this rarely gave them the same intake as was routinely available for the patients in sanatorium.

The response of the patients in the home series to a year's chemotherapy closely approached that

of the sanatorium patients to the same combination of drugs, even though the diet of the home series was much inferior. Thus, it is evident that none of the factors in the diet could have been important in the attainment of quiescence. This was investigated further by studying whether, within each series of patients, the intake of any of the main dietary factors was associated with the radiographic or bacteriological response. No associations were found. Thus, for example, considering total protein, 75% of 24 home patients who had less than 40 g a day had a favourable radiographic response, as compared with 67% of 24 home patients with an intake of 60 g or more a day. Similarly, 72% of 18 home patients with an intake of less than 10 g of fats had a favourable response, as compared with 74% of 31 home patients with an intake of 20 g or more a day.

There was, however, evidence that the sanatorium patients whose disease attained quiescence responded more rapidly bacteriologically than the corresponding home patients. This may have been due to the superior diet in sanatorium. Other factors which may have contributed are the greater rest which the sanatorium patients had and the supervised medicine administration in sanatorium, which ensured that the patients had their medicament regularly; there was evidence that a number of the home patients did not take the medicine regularly (Tuberculosis Chemotherapy Centre, 1959).

The weight changes in the 12-month period are of considerable interest. Both series gained weight, the average gain being considerably larger in the sanatorium patients than in the home patients. Thus, the average weight gain of home males was 10.7 lb and of sanatorium males 17.1 lb., and the corresponding gains in the females were 11.0 lb and 24.2 lb., respectively. The greater increase in weight in the sanatorium patients was not indicative of a more satisfactory therapeutic response. It presumably resulted from the larger dietary intake and the lesser degree of physical activity.

It has been shown in this study that the diet plays little, if any, part in the attainment of bacteriological quiescence at the end of a year in patients receiving standard combined chemotherapy. Since overcrowding has also been shown to be unimportant (Tuberculosis Chemotherapy Centre, 1959), it may be concluded that the successful treatment of patients in their homes in developing countries need not await an increase in the standard of living. Successful treatment of patients on a mass scale can begin as soon as adequate supplies of medicaments are

available, and as soon as the necessary supervision of the patients can be organized.

The study is continuing and the dietary intake is being assessed in a period of follow-up in order to

evaluate the role of diet in relation to the maintenance of bacteriological quiescence and in the occurrence of relapse. The findings will be the subject of a separate report.

IX. SUMMARY

1. A study was undertaken of the diet of 157 patients with pulmonary tuberculosis admitted to a controlled comparison of treatment with isoniazid plus PAS for a year at home with the same treatment in sanatorium.

2. The patients were drawn from a poverty-stricken section of the community living in overcrowded conditions in Madras City.

3. A comparison has been made of the dietary status of the home and the sanatorium patients before and during treatment, and the role of the diet in the attainment of bacteriological quiescence of the tuberculous disease has been evaluated.

4. The assessments of the dietary intake were made by the oral questionnaire method. In an analysis based on 45 patients it gave results similar to a dietary weighing technique.

5. The dietary intake before the start of treatment was assessed for all the 157 patients, and 112 of them had another assessment in the second six months of treatment; the remaining 45 patients were investigated at five set dates during treatment—namely, at six weeks, three months, six months, nine months and one year.

6. Before treatment the patients in both series had poor and similar diets.

7. During the early months of treatment, the dietary intake of the patients in both series increased.

However, the sanatorium patients received a clearly superior diet throughout the year in terms of total calories, fats, total and animal proteins, phosphorus and several of the vitamins.

8. The home patients were physically more active during treatment than the sanatorium patients, further accentuating the dietary disadvantage of the home series.

9. The home patients gained on the average 10.8 lb. in weight over the 12-month period, as compared with 19.8 lb. for the sanatorium patients. This greater weight gain among the sanatorium patients was not, however, indicative of superior clinical results.

10. The response to treatment (as measured by the radiographic and bacteriological progress) was not directly associated with the level of dietary intake of any of the food factors, either in the patients treated at home or in those treated in sanatorium.

11. It may be concluded that none of the dietary factors studied appears to have influenced the attainment of quiescent disease among tuberculous patients treated with an effective combination of antimicrobial drugs for a period of one year. The successful initial treatment of patients at home is therefore possible even if the levels of dietary intake are low.

RÉSUMÉ

On estimait naguère qu'une alimentation riche jouait un grand rôle dans le traitement de la tuberculose. La chimiothérapie a provoqué une telle révolution, qu'il fallait réexaminer également l'influence du facteur nutritionnel, considéré jusqu'ici comme un adjuvant précieux.

Au Centre de Madras, dans le cadre des études sur la chimiothérapie de la tuberculose, et la comparaison des résultats du traitement à domicile ou en sanatorium, le rôle de l'alimentation a pu être évalué, du fait que les malades hospitalisés en sanatorium étaient mieux nourris et moins actifs que ceux qui étaient soignés à domicile. Ayant mesuré les différences de régime en calories, protéines, graisses, hydrates de carbone, sels minéraux et

vitamines — qui étaient au détriment du groupe domestique — puis les variations de l'activité physique des deux groupes — les uns se reposant beaucoup tandis que les autres vavaient à certaines occupations — les auteurs concluent que l'alimentation n'a pas eu l'importance qu'on lui attribuait autrefois dans le succès du traitement. Aucun des éléments considérés ne paraît avoir influencé l'amélioration de l'état des patients, atteignant après une année de traitement, un stade de quiescence. Il semble donc que le traitement à domicile peut donner de bons résultats, même si l'alimentation est médiocre, tout au long de l'année de traitement par les médicaments anti-tuberculeux combinés.

REFERENCES

- Aykroyd, W.R., Patwardhan, V.N. & Ranganathan, S. (1951) The nutritive value of Indian foods and the planning of satisfactory diets, 4th ed., Health Bulletin, Simla, Government of India Press, p.5.
- Barlovatz, A. (1959) Trans. Roy. Soc. Trop. Med. Hyg., 53, 214.
- Chaudhuri, S. (1959) Lancet, 1, 144
- Dakshinamurti, K. & Devadatta, S. C. (1956) Proc. Indian Acad. Sci., 43, 121
- Davidson, S., Meiklejohn, A.P. & Passmore, R. (1959)
- Human nutrition and dietetics, Edinburgh & London, Livingstone, p. 662.
- Haddock, D.R.W. (1959) Trans. Roy. Soc. Trop. Med. Hyg., 53, 298
- Hudson, E.H. (1957) In: Heaf, F.R.G., ed., Symposium of tuberculosis, London, Cassell, p. 352
- India, Ministry of Commerce, Office of the Economic adviser (1949) Report on an enquiry into the family budgets of middle class employees of the Central Government, Simla, p.2.
- McLester, J.S. & Darby, W.J. (1952) Nutrition and diet in health and disease, Philadelphia & London, Saunders, p. 489
- Padmavati, S., Lakhanpal, R.K. & Gupta, S. (1958) Indian J. med. Res., 46, 834.
- Pagel, W., Simmonds, F.A.H. & Macdonald, N. (1953) Pulmonary tuberculosis, London, Oxford University Press, p. 438.
- Pasricha, S. (1958) Indian J. med. Res., 46, 605
- Pasricha, S. (1959) Indian J. med. Res., 47, 207
- Patwardhan, V.N. (1952) Indian J. med. Sci., 6, 139.
- Tuberculosis Chemotherapy Centre (1959) Bull. Wld Hlth Org. , 21 51.
- Venkatachalam, P.S., Srikantiah, S.G. & Gopalan, C., (1954) Indian J. med. Res., 42, 554.