Alimentary tract and pancreas

Low residue or normal diet in Crohn's disease: a prospective controlled study in Italian patients

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SUMMARY Seventy patients with non-stenosing Crohn's disease were randomly assigned to follow a low residue diet or a normal Italian diet for a mean of 29 months. The two groups were comparable at the onset in various measures of disease severity and diet. Patients complied well with the diet prescriptions, the low residue group eating a mean of 8·1 portions a week of fibre containing foods and the liberalised group a mean of 26·6 portions ($p<0·005$). There was no difference in outcome between the two groups, including symptoms, need for hospitalisation, need for surgery, new complications, nutritional status, or postoperative recurrence. Eighty six per cent of patients eating *ad libitum* and 65% of patients who avoided roughage eliminated one or more permitted foods because of subjective intolerance. Lifting of dietary restrictions, which results in a more appetising and nutritious diet, does not cause symptomatic deterioration or precipitate intestinal obstruction in Crohn's disease.

Standard treatment for patients with Crohn's disease (CD) includes the prescription of a low fibre diet.[1] This traditional precept has never been scientifically demonstrated, however, and there have always been what Spiro calls a numberless legion of cynics who ignore it in practice.[2] With the current surge of interest in the salutary effects of dietary fibre the doubters have increased; the single published study, which used historical controls, suggested a high residue diet might even be beneficial.[3] We prospectively compared patients with Crohn's disease who had been randomised to a low residue or a normal Italian diet, in order to determine whether diet liberalisation altered nutritional status or syptoms; whether it affected the rates of disease flares, partial obstruction, or surgery; and how well the two diets were tolerated by the patients.

Methods

PATIENT SELECTION
Eighty five patients with a diagnosis of Crohn's disease attending our Inflammatory Bowel Disease Clinic between March and December 1981 were screened for participation in the study. All patients (except five who had been newly diagnosed) were

considered by their physicians to be following a low residue diet as defined below. After eliminating four patients with frank roentgenographic strictures, we explained the motivation and the design of the research to 81 patients and asked if they would be willing to follow a randomly assigned diet for a period of approximately two years. Ten declined to participate, seven because they admitted they would not adhere to a low residue diet, and three because they were afraid to risk eating the foods they had always been forbidden.

The remaining 71 patients were randomised either to continue on a low residue control diet (36 patients) or to gradually normalise their diet (35 patients). The diagnosis of one patient in the experimental group was subsequently changed and he was dropped from the study, leaving 70 subjects for follow up. Of these, 58 had active Crohn's disease, while 12 (six randomised to each group) were free of radiological or clinical evidence of recurrence after intestinal resection. Enrolment of the latter patients was curtailed after the first three months, both because they were observed to adhere poorly to low residue diets and because the probability of affecting disease recurrence was felt to be too slim to justify restricting the dietary habits of patients who were, by all reasonable criteria, well.

DIETS
Items specifically forbidden on the low residue diet

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were legumes, whole grains, nuts, and all fruits and vegetables with the exception of ripe bananas and skinned potatoes. Patients were encouraged to buy a centrifuge in order to prepare solid free extracts of fruits and vegetables, while ordinary juices (containing some pulp) were not allowed.

Handouts were used to reinforce the verbal explanation of both diets by the research physician (SL), included a graded plan of gradual fibre reintroduction for patients previously following a low residue diet. Patients in both groups were encouraged to try all permitted foods; experimental patients were not, however, specifically urged to eat whole grains or any other foodstuffs. All randomised patients were advised to eliminate any foods that proved to cause pain or diarrhoea. Coffee, spices, simple sugars, alcohol, and dairy products were permitted to patients in both groups as tolerated. Restrictions on salt for cardiovascular disease and on ordinary fats for short bowel were maintained by the few patients who already observed them.

Non-dietary medical and surgical therapy, which was managed by two 'treating physicians' (CP, CL) kept blind to the diet assignment of each patient, was not affected by the study. A therapeutic multivitamin was prescribed by the research physician for patients in the control group. Patients were asked to discuss all questions concerning diet with the research physician only.

DATA COLLECTION
Among the information recorded on the day of randomisation were the gastrointestinal sites ever involved with disease, previous surgery, history of fistulas (anorectal, enterovisceral, enteroenteric, enterocutaneous), history of extra-intestinal complications (ankylosing spondylitis, iritis, dermatitis, arthritis, erythema nodosum), current therapy, the New Crohn's Disease Activity Index (NCDAI, an index developed by our group and incorporating diarrhoea, fever, fistulas, seromucoids, C-reactive protein, serum iron, and alpha-2 globulin),[4] and a Crohn's Disease Activity Index (CDAI) modified from Best[5] by the retrospective rather than prospective notation of symptoms. We looked up the random number used to assign diet for any given patient only after all data including diet history had been recorded.

The research physician and the dietician (AD) took all diet histories, using a one week recall method. Fibre consumption was then crudely quantified by counting the number of portions of fruit, vegetables, legumes, and whole grains eaten during the week. Portion size was disregarded. Each pear, apple, orange, tangerine, peach, or apricot was

counted as one portion, while ripe bananas, potatoes, and centrifuged fruit and vegetable extracts were not counted as 'fibre'.

As a measure of compliance, diet histories were repeated three to six months after randomisation in 22 unselected patients with active disease in each diet group, and in seven of 12 disease free after surgery.

All outcome criteria were evaluated by the two 'blinded' treating physicians, who rated pain and diarrhoea on a five point scale at each clinic visit. At least one year after enrolment (mean, 19 months), three final assessments were compiled on a five point scale from 'very poorly' to 'very well': one averaging the severity of diarrhoea during the study, one rating the severity of pain, and a global clinical assessment of how the patient had done since the time of randomisation. These three numbers were then added to yield an 'overall physician assessment' which could range from three (worst) to 15 (best). Other follow up parameters included serum albumin, body weight, mean NCDAI during the study period, the need for hospitalisation or prolonged bedrest, steroid therapy, and the new development of severe local complications including fistulae, definite inflammatory abdominal mass, and partial obstruction. Patients were also re-interviewed, when possible, regarding their experience with diet.

In November 1983, a mean of 29 months after randomisation (range, 23–34 months), the outcome status 'surgery *versus* no surgery' or 'recurrence *versus* no recurrence' was determined.

STATISTICAL ANALYSIS
Statistical significance was determined for both baseline and end point parameters using the χ^2 test for dichotomous variables and the Student's t test for continuous variables.

Results

PATIENTS WITH ACTIVE CROHN'S DISEASE
At randomisation, experimental and control groups were virtually identical in age, sex distribution, disease duration, history of fistulae, NCDAI, and previous adherence to a low residue diet (Table 1). There were minor differences between the rates of ileocolitis (more frequent among the experimental patients, p=0·10) and of history of extraintestinal complications (p=0·14), previous surgery, current steroid therapy, and CDAI (all somewhat less favourable among controls), but none reached statistical significance.

Repeat diet histories to assess compliance showed that experimental patients ate more than three times as many portions a week (mean, 26·6; range 6–67) of

Table 1 *Baseline characteristics of patients with active Crohn's disease*

	Low residue diet (n=30)	Liberalised diet (n=28)
Age at disease onset (yrs)	29·2	33·4
Age at enrolment	38·2	42·0
Previous intestinal resection	15 (50%)	11 (39·3%)
Men	20 (66·7%)	16 (57·1%)
History of ileocolitis	6 (20%)*	11 (39·3%)*
History of fistulas	14 (46·7%)	13 (46·4%)
Extra-intestinal complications	7 (23·3%)†	2 (7·1%)9†
Steroid therapy at enrolment	15 (50%)	11 (39·3%)
CDAI at enrolment	99·4	84·6
NCDAI at enrolment	35·2	36·0
Fibre portions/week at enrolment	13·7	12·8

* p=0·10. † p=0·14

fibre-containing foods than controls (mean, 8·1, range, 0–37); this difference was highly significant (p<0·005). Taking the complete diet histories into account, we estimate that total daily dietary fibre was 13 g in the experimental group and 3 g in controls, following Paul and Southgate's tables.[6] If one excludes the two least compliant control patients and the three least compliant experimental patients, there was no overlap between the ranges of the two groups. Two of the three 'non-compliant' experimental patients stated they avoided roughage not because of symptom exacerbation but mainly for fear that fibre could damage their intestines.

Follow up was complete, with all outcome measures obtained for 100% of subjects. There was no significant difference between the two groups in any of the parameters studied (Table 2). In particular, surgery was required within 30 months by 14·3% of experimental patients and 16·7% of controls. If to these are added the patients who did not arrive at

Table 2 *Outcome of all patients assigned to diets*

	Low residue diet (n=30)	Liberalised diet (n=28)
Fibre portions/week during study	8·1%	26·6%*
Mean NCDAI during study	33·7	33·1
Weight change (kg)	1.5†	−1·5
Serum albumin (g/l)	39	40
Overall physician assessment	10·6	10·0
Months on steroids in first year	5.7	4.8
Poor outcome		
Surgery	5 (16·7%)	4 (14·3%)
Other poor outcome†	6 (20·0%)	4 (14·3%)
Total	11 (36·7%)	8 (28·6%)

* p<0·005. † Hospitalisation, prolonged bedrest, partial obstruction, or new inflammatory mass

surgery but who developed severe flares, inflammatory masses, or partial obstruction, then 36·7% on a low residue diet had a poor outcome, and 28·6% on a liberalised diet. The mean overall physician assessment score was 10·0 for experimental and 10·6 for control patients, corresponding in both cases to having done somewhat better than 'so-so' but worse than 'well'. Further examination of these data showed that all 13 patients with a physician rating under nine (worse than 'so-so') had also been considered to have a 'poor outcome' on the independent basis of surgery or severe local disease.

There were two deaths, one a 58 year old man who succumbed to the complications of emergency bowel resection 11 months after being randomised to the restricted diet, and the other a 69 year old man in the experimental group who committed suicide one year after enrolment. Only the former was considered to have had a poor outcome for purposes of this study; as the latter was doing well medically at the time of his suicide, and had always had mild disease (at the time of randomisation he had a CDAI of 50 off all therapy), it was elected to consider his case a death from unrelated causes rather than a poor outcome.

Out of 22 experimental patients who were formally re-interviewed regarding subjective tolerance of the liberalised diet, 19 thought that some foods did cause pain or diarrhoea, although few named more than one or two specific items as responsible. Ten had milk intolerance, while six experienced symptoms associated with eating specific fruits, four with legumes, and 13 with one or more specific vegetables (most often spinach, even in puree). Among other foods blamed on occasion were coffee, chocolate, whisky, biscuits, clear broth, spices, fish, honey, and carrot juice. All but the two fearful patients were enthusiastic about the liberalised diet. While eating a low residue diet, on the other hand, 17 out of 26 control patients eliminated some permitted foods because of symptoms; in only five cases was this simply because of lactose intolerance.

In order to evaluate the possibility that poor compliance prevented a potential difference in outcome from being detected, we reanalysed the data after eliminating the three patients in each group who had departed most substantially from the prescribed diet; as noted previously, the reasons given for non-compliance by the patients were not related to the severity of symptoms. During the study, the 'compliant' experimental patients ate a mean of 33·6 portions of fibre a week (range, 20–67), while the compliant controls ate a mean of 4·7 portions (range, 0–16; p<0·001). There was again no significant difference in any outcome measures (Table 3).

Table 3   *Outcome of patients complying with diets*

	Low residue diet (n=30)	Liberalised diet (n=28)
Fibre portions/week during study	4·7*	33·6*
Mean NCDAI during study	33·8	33·0
Weight change (kg)	1.6	−1·0
Serum albumin (g/l)	38	40
Overall physician assessment	10·6	10·4
Months on steroids in first year	5.4	4.8
Poor outcome		
Surgery	5 (18·6%)	3 (12·0%)
Other poor outcome†	6 (22·2%)	4 (16·0%)
Total	11 (40·8%)	7 (28·0%)

* p<0·005.   † Hospitalisation, prolonged bedrest, partial obstruction, or new inflammatory mass

Dietary habits of the patients with 'poor outcome' were also analysed separately, to determine whether sicker patients had voluntarily restricted their fibre intake or whether, conversely, the were sicker because they had overindulged. There proved to be no significant difference in the number of portions of fibre eaten weekly during the study by experimental patients with (27·1 portions) and without (31·9 portions) a poor outcome, nor between residue free diet patients who did badly (6·1 portions) or well (9·2 portions).

POSTOPERATIVE PATIENTS IN REMISSION
Out of six patients randomised to each diet, two in each set had developed a preanastomatic recurrence by 26–30 months. Limited data show that adherence to the diet prescription was mediocre in this postoperative group (experimental patients, 24 portions per week; control patients, 11 portions), and the number of patients was in any case too limited for drawing conclusions.

Discussion

Several studies have suggested an aetiological role for refined sugars in Crohn's disease,[7–10] although the impairment in sweet taste detection which can develop secondary to zinc deficiency in this disease may be a confounding factor;[11] Crohn's disease may eventually be placed with ulcerative colitis among the 'diseases of westernisation'.[12]

Regarding the dietary management of Crohn's disease, fibre restriction,[1 2] fat restriction,[13] increased ratio of unrefined to refined carbohydrates,[3 14] and a normal diet[15] all have their recent proponents. Our own study was designed on the premise that patients should be offered a free choice of foods, barring good evidence that a normal diet

worsens the course of the disease, nutritional status, or symptoms. None of the parameters we used to gauge outcome proved to show any difference between a low residue and an unrestricted diet.

While our study period was brief in relation to the course of Crohn's disease, longer follow up would be unlikely to change our findings, because food residues have been thought rather to precipitate intestinal obstruction than to cause gradual worsening of bowel inflammation. The fact that disease flares and/or partial obstruction do not become more frequent on a normal diet does not contradict a limited role for low roughage diets, such as during episodes of acute inflammation with partial intestinal obstruciton or for patients with fixed radiological strictures.

We deliberately chose not to test a fibre enriched diet, particularly because the question of whether to forbid roughage to Crohn's disease patients should be settled before moving on to consider another, opposite departure from normal eating. Evidence in favour of fibre supplementation comes only from the study of Heaton et al,[3] which is seriously flawed by its use of historical controls and by the possible confounding effects of forbidding refined sugar. It should be observed, however, that, as our data confirm, the traditional Italian diet is rich in fruits, vegetables, and complex carbohydrates, and relatively low in sugar. Caution is therefore indicated in generalising from our findings, based on an unrestricted 'Mediterranean' diet, to northern European or other diets.

As expected, an *ad libitum* diet did not prove to be entirely normal; most subjects eliminated one or more foods because of presumed symptom exacerbation. Crohn's disease patients should therefore be warned of the possibility that they may have food intolerances, although our data suggest that food components other than fibre are most often responsible.

Any diet research carried out outside a metabolic unit assesses the efficiency of a diet as actually followed by the patient, rather than what its ideal efficacy could be in a controlled setting. Even under the extremely favourable circumstances of this study, where those who thought they would not follow a randomly assigned diet were strongly encouraged to refuse randomisation, five out of 58 active disease patients are known to have virtually ignored their instructions.

In conclusion, a balanced diet is more appetising and richer in vitamins than one free of fibre, which may be helpful in averting malnutrition among patients with a potentially debilitating intestinal disease. Italians in particular are enthusiastic consumers of fruits and vegetables and suffer greatly

from being deprived of them. It is important that physicians caring for patients with Crohn's disease should not place unnecessary restrictions on their patients' eating patterns.

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