PAPERS AND SHORT REPORTS

Are fibre supplements really necessary in diverticular disease of the colon? A controlled clinical trial

M H ORNSTEIN, E R LITTLEWOOD, I McLEAN BAIRD, J FOWLER, W R S NORTH, A G COX

Abstract

Fifty-eight patients with uncomplicated diverticular disease of the colon took bran crispbread, ispaghula drink, and placebo for four months each in a randomised, cross-over, double-blind controlled trial. Assessments were made subjectively, using a monthly self-administered questionnaire, and objectively, by examining a seven-day stool collection at the end of each treatment period. In terms of a pain score, lower bowel symptom score (the pain score and sensation of incomplete emptying, straining, stool consistency, flatus, and aperients taken), and total symptom score (belching, nausea, vomiting, dyspepsia, and abdominal distension) fibre supplementation conferred no benefit. Symptoms of constipation, however, when assessed alone, were significantly relieved. Both fibre regimens produced the expected changes in stool weight, consistency, and frequency.

It is concluded that dietary fibre supplements in the commonly used doses do no more than relieve constipation. Perhaps the impression that fibre helps diverticular disease is simply a manifestation of Western civilisation's obsession with the need for regular frequent defecation.

Department of Surgery, Northwick Park Hospital, Harrow, Middlesex HA1 3UJ

M H ORNSTEIN, MB, FRCS, honorary senior registrar (present appointment: senior registrar, Ashford Hospital, Ashford, Middlesex TW15 3AA)

A G COX, MD, FRCS, consultant surgeon

MRC Epidemiology and Medical Care Unit, Northwick Park Hospital, Harrow, Middlesex HA1 3UJ

W R S NORTH, MA, PHD, statistician

Department of Medicine, West Middlesex University Hospital, Isleworth, Middlesex TW7 6AF

E R LITTLEWOOD, MB, MRCP, honorary senior registrar

J FOWLER, SRN, research assistant

I McLEAN BAIRD, MD, FRCP, consultant physician

Introduction

Diverticular disease of the colon is the first of the "diseases of Western civilisation" ascribed to inadequate fibre intake,[1] and the medical profession has been quick to extrapolate from hypothesis to treatment. Today there is a strong clinical impression that increased dietary fibre intake will relieve the symptoms of diverticular disease, but this was equally true of the low-fibre diets previously recommended for nearly 50 years.

Of the many clinical studies of the effect of increased dietary fibre intake,[2-10] only three have been controlled trials,[8-10] and these reached conflicting conclusions. Furthermore, only short-term fibre supplementation has been examined. We compared the effects of two forms of dietary fibre supplement and placebo in patients with uncomplicated, symptomatic diverticular disease.

Patients and methods

Patients—The trial was carried out, with the approval of the ethical committees, in two hospitals. All patients in whom uncomplicated *symptomatic* diverticular disease had been diagnosed recently by clinicians independent of this trial were eligible for entry. All had radiological evidence of diverticular disease with a minimum of six (usually many more) diverticula in the left colon. We excluded patients with coexistent gastrointestinal disorders, a history of intestinal operations, or any complication of diverticular disease. Each patient gave informed consent and was interviewed by one clinician (MHO or ERL) throughout the trial.

Treatment—We compared the effects of two forms of dietary fibre supplement and two placebos. The active treatments were bran biscuits (Energen bran crispbread) and a drink made from powdered ispaghula husk (Fybogel). The placebos for these were Energen wheat crispbread and a placebo powder prepared from highly refined wheat. These were provided in identical unmarked packages and combined to make three apparently similar treatments (table I). The placebo supplements provided a small quantity of fibre (largely pentose), and the active supplements differed both in total fibre content and in polysaccharide composition (D A T Southgate, personal communication). Each treatment was taken for 16 weeks. Treatment order was randomised and a month's supplements given at each of 12 visits; neither physician nor patient knew the order of treatment, and patients were unaware of the cross-over dates. Compliance was

assessed by asking patients to return unused packages at each visit. A qualified dietitian assessed each patient's basal fibre intake at the start and end of the trial using the dietary history method[11] and standard food-table values.[12] Patients took their usual diets throughout the study and were instructed not to add fibre apart from our supplements.

Subjective assessment—Before starting treatment and at each monthly visit patients completed a self-administered symptom questionnaire. This contained 12 questions, most of which had four possible answers —for example, the first question, "In the last week how often have you had tummy pains ?" had the possible answers not at all, a few times, many times, and nearly all the time. The scores were weighted according to scales decided before the start of the trial (see table V for the range for each question). The outcome was assessed by three composite scores. The pain score comprised the frequency and severity of abdominal pain; the lower bowel symptom score comprised the pain score and questions about stool consistency, straining, incomplete emptying sensation on defecation, flatus, and whether aperients were taken; and the general symptom score comprised nausea, vomiting, dyspepsia, abdominal distension, and flatulence.

Objective assessment—At the end of each treatment period the patients made a seven-day faecal collection. Stools were collected individually as described,[13] and we used an adaptation of the continuous marker method of Cummings *et al*[14] to estimate oroanal transit time. Stool consistency was assessed independently by a single observer (JF) on a five-point scale, and stool weight and frequency were recorded.

Statistical analysis—The results are expressed as means and SD for each treatment period, and we assessed the significance of differences by analysis of variance. The tables also show the standard errors of the mean differences between each active period's symptom scores and the placebo scores. Because the distributions of the symptom scores were not Gaussian we also used the Wilcoxon matched-pairs signed-ranks sum test (with the same results).

TABLE I—*Composition of the three dietary supplements (g) each taken for 16 weeks by 58 patients with diverticular disease (mean basal dietary fibre intake 15·2 (SD 5·8) g daily)*

	Bran period*		Ispaghula period†		Placebo period‡	
Non-cellulosic polysaccharides		5·51		8·50		1·91
Hexose	1·43		2·09		0·68	
Pentose	3·58		5·94		1·03	
Uronic acid	0·50		0·47		0·20	
Cellulose		1·45		0·52		0·40
Lignin		0·03		0·02		0·03
Total dietary fibre		6·99		9·04		2·34

*Eight bran biscuits and two sachets of placebo powder daily.
†Eight placebo biscuits and two sachets of ispaghula powder daily.
‡Eight placebo biscuits and two sachets of placebo powder daily.

TABLE II—*Reasons why 18 patients did not enter trial and 18 were withdrawn from it out of the 94 patients interviewed who had uncomplicated, symptomatic diverticular disease*

	Patients not entered	Patients withdrawn during each treatment period		
		Bran	Ispaghula	Placebo
Unable to comply:				
"Social" reasons	14	4	3	2
Unrelated disease	2	1	1	1
Anxiety over questionnaire	1			
Diarrhoea	1		2	1
Constipation				1
Acute diverticulitis		1		1
Total	18	6	6	6

Results

Ninety-four patients were interviewed, of whom 18 declined to enter the trial and a further 18 withdrew (table II). Twenty-two men and 36 women completed the trial (median age 64 years, range 43-78 years). The mean basal intake of dietary fibre was 15·2 (SD 5·8) g daily.

As there were no major differences between the two hospitals in any of the assessments made we combined the results for statistical analysis. Only minor trends occurred within each period, so we grouped the four monthly scores for each treatment and regarded them as replicates to estimate within-patient variance. The order of the three periods had no significant effect on the results. Compliance was good, a maximum of three and a half days' supplements being returned each month, and there was no measurable preference for a particular supplement.

Table III summarises the objective changes. A highly significant increase in wet stool weight occurred with both active treatments; stool frequency showed the expected increase and consistency the expected softening. All these changes were greater during the ispaghula period than the bran period. The effect on oroanal transit time was variable: results were available for 39 patients, of whom 23

TABLE III—*Objective changes shown by patients each taking three dietary supplements for 16 weeks in random order*

	No of patients	Treatment period						Standard error of difference between either bran or ispaghula mean and placebo mean
		Bran		Ispaghula		Placebo		
		Mean	SD	Mean	SD	Mean	SD	
Daily wet stool weight (g)	57	136·5 p<0·001	49·9	161·0 p<0·001	59·8	118·8	48·2	5·4
Weekly stool frequency	58	10·34 p<0·001	3·0	11·19 p<0·001	3·4	9·55	2·9	0·18
Stool consistency score*	58	3·79 p<0·001	0·83	4·08 p<0·001	0·76	3·56	0·94	0·052
Transit time (hours)	39	45·3 NS	22·4	46·9 NS	22·9	49·9	24·4	2·3

*1 = Very hard; 3 = "normal"; 5 = very soft.
Significance of differences between placebo period and active treatment periods assessed by analysis of variance.

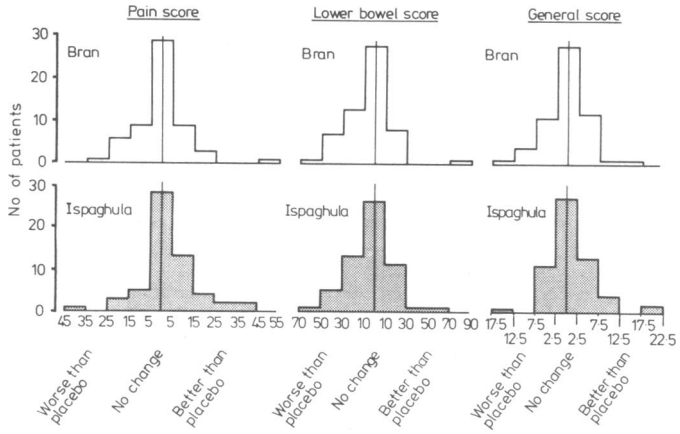
TABLE IV—*Composite symptom scores at start of trial and for each of the three random 16-week treatment periods in 58 patients*

	Initial score		Treatment period						Standard error of difference between either bran or ispaghula mean and placebo mean
			Bran		Ispaghula		Placebo		
	Mean	SD	Mean*	SD	Mean*	SD	Mean	SD	
Pain score	22·6	27·3	15·2	16·9	19·5	18·4	17·5	15·6	1·72
Lower bowel symptom score	47·4	39·6	39·7	27·4	41·3	27·4	45·0	28·3	2·59
General symptom score	9·7	9·1	6·7	5·9	8·1	6·7	7·6	7·3	0·69

*Differences between the active and placebo periods were not significant, as assessed by analysis of variance and Wilcoxon matched-pairs signed-ranks sum test.

showed no measurable change in transit time; in the remaining 16 both active treatments decreased transit time in 11 and increased it in five.

Table IV shows the mean composite symptom scores initially (before treatment) and during each treatment period, and the figure shows the frequency distributions of the differences in scores between each period of active treatment and the placebo period. All three



Frequency distribution of mean changes in composite symptom scores between bran and placebo and between ispaghula and placebo treatment periods. (Ranges are: for pain score 0-100, for lower bowel symptom score 0-110, and for general symptom score 0-55.)

treatment regimens caused an improvement from the initial scores, but there were no significant differences in composite scores between the active and placebo periods, and the number of patients who improved with the active supplement was matched by the number who did not improve. The sensitivity (type II error) varied between symptom scores: we had an 80% chance of detecting a true difference of about six in the pain score, seven in the lower bowel score, and two in the general score at the 5% significance level.

When each symptom was considered separately (table V) straining was significantly reduced with the fibre supplements ($p < 0.01$). This was reflected in the objective changes and in the score for stool consistency, the faeces being softer with the active supplements. Flatus may have increased ($p < 0.05$) with the ispaghula supplement, but there were no other significant differences in the symptom scores.

Discussion

The results of this trial cast doubt on today's enthusiasm for dietary fibre treatment of diverticular disease. Management of this condition has changed radically in the past 10 years, but studies are difficult[15] because symptoms are intermittent and many patients with gastrointestinal disorders respond to placebo. This cross-over trial was designed to overcome these difficulties, since a large number of patients were studied for 12 months. It should be contrasted with Brodribb's study,[8] in which only 18 patients were investigated for three months without a cross-over design. They received, daily, nine of the same crispbreads (active and placebo) that we used, and a significant symptomatic improvement was found with bran. Ispaghula was not tested.

We cannot explain why these two trials yielded such different results, although the longer duration, larger number of patients, and design of our trial will have given greater precision. We set out to test the usual therapeutic dose of bran and ispaghula supplements (equivalent to two tablespoons of natural bran[16] and increasing our patients' intakes by 50-70%) rather than the very large quantities used by others.[2-4] Any criticism that we gave insufficient fibre would also apply to Brodribb's trial and is answered by our findings of the expected objective effects of dietary fibre on stool weight,[17] frequency, and consistency[18 19] and some subjective effects. The increase in stool bulk per gram of fibre added to the diet (4·2 g with bran and 6·7 g with ispaghula) was similar to that found by Cummings *et al*[20] in normal volunteers.

Our subjective findings are contrary to current clinical opinion. Because of this we looked more closely at the scores by analysing each symptom individually. Apart from straining, the individual symptom scores, like the composite scores, showed improvements from the initial assessments but no differences between the three regimens. Dietary fibre has a well-known and considerable effect on constipation,[21] which varies with different types of fibre.[17 19] Like Eastwood *et al*[7] we found that ispaghula has a greater effect than bran. The difference between the active preparations is further shown by differences in stool fibre content.[22] Despite this, both preparations show a remarkably similar lack of effect on the other scores. The remaining two published controlled trials also failed to show an unequivocal advantage for dietary fibre in diverticular disease: Devroede *et al*[9] tested six therapeutic regimens in a large trial with results that do not show a clear-cut advantage for high-fibre diets, and Hodgson[10] found that dietary fibre has only a placebo effect. Trials that have suggested that dietary fibre is effective have, apart from that of Brodribb, been uncontrolled and may represent merely a comparison with the previously poor results obtained with low-fibre diets.

It is unlikely that our placebo supplement of 2-3 g dietary fibre daily could relieve symptoms while producing fewer objective changes than bran or ispaghula. Therefore we believe that, unless the patient's symptoms are largely those of constipation, dietary fibre supplements are unnecessary in the long-

TABLE V—*Individual symptom scores at start of trial and for each of the three random 16-week treatment periods in 58 patients*

	Range†	Initial score		Treatment period						Standard error of difference between two treatment means
				Bran		Ispaghula		Placebo		
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	
				Pain score						
Frequency of abdominal pain	0-50	12·6	16·6	8·5	10·1	10·9	10·7	9·7	9·2	0·90
Severity of abdominal pain	0-50	10·0	12·3	6·6	8·1	8·7	9·2	7·8	7·9	0·99
				Lower bowel symptom score‡						
Sensation of incomplete emptying	0-30	13·6	8·9	10·9	7·6	10·5	6·9	11·9	8·2	0·74
Straining	0-30	9·7	8·2	8·8**	6·7	6·9***	6·2	10·6	8·4	0·68
Stool consistency	0-10	2·5	4·1	1·5	1·6	1·2*	1·4	1·9	2·3	0·30
Aperients taken	0-30	10·5	2·6	1·0	2·4	0·5	1·2	1·3	2·9	0·36
Flatus	0-10	3·0	3·5	2·4	2·7	2·7*	2·6	1·9	2·1	0·32
				General score						
Belching	0-10	1·6	2·9	1·4	2·3	1·2	2·0	1·1	2·1	0·22
Nausea	0-15	0·9	1·9	0·7	1·5	1·5	2·7	1·0	1·4	0·30
Vomiting (days per week)		0·1	0·4	0·1	0·2	0·1	0·2	0·1	0·2	0·03
Dyspepsia	0-15	2·2	4·0	1·2	2·0	1·7	2·7	1·6	2·6	0·26
Abdominal distension	0-15	4·7	4·5	3·3	2·9	3·6	3·2	3·8	3·4	0·29

†Range is from never or none to continuously or worst possible.
‡Lower bowel symptom score includes pain score.
Significance of differences (assessed by analysis of variance) between active treatment periods and placebo period: *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

term management of uncomplicated diverticular disease of the colon.

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STINKING GLADWIN is one of the kinds of Flower-de-luce, having divers leaves arising from the roots, very like a Flower-de-luce, but that they are sharp-edged on both sides, and thicker in the middle, of a deeper green colour narrower and sharper pointed, and a strong ill-scent, if they be bruised between the fingers. In the middle rises up a reasonably strong stalk, a yard high at least, bearing three or four flowers at the top, made somewhat like the flowers of the Flower-de-luce, with three upright leaves, of a dead purplish ash-colour, with some veins discoloured in them; the other three do not fall down, nor are the three other small ones so arched, nor cover the lower leaves as the Flower-de-luce doth, but stand loose or asunder from them. After they are past, there come up three square hard husks, opening wide into three parts when they are ripe, wherein lie reddish seed, turns black when it hath abiden long. The root is like that of the Flower-de-luce, but reddish on the outside, and whitish within, very sharp and hot in the taste, of as evil a scent as the leaves.

This grows as well in upland grounds, as in moist places, woods, and shadowy places by the sea-side in many places of this land, and is usually nursed up in gardens. It flowers not until July, and the seed is ripe in August or September, yet the husks after they are ripe, opening themselves, will hold their seed with them for two or three months, and not shed them.

It is supposed to be under the dominion of Saturn. It is used by many country people to purge corrupt phlegm and choler, which they do by drinking the decoction of the roots; and some to make it more gentle, do but infuse the sliced roots in ale; and some take the leaves, which serve well for the weaker stomach: The juice hereof put up, or snuffed up the nose, causes sneezing, and draws from the head much corruption; and the powder thereof doth the same. The powder thereof drank in wine, helps those that are troubled with the cramps and convulsions, or with the gout and sciatica, and gives ease to those that have griping pains in their body and belly, and helps those that have the stranguary. It is given with much profit to those that have had long fluxes by the sharp and evil quality of humours, which it stays, having first cleansed and purged them by the drying and binding property therein. The root boiled in wine and drank, doth effectually procure women's courses, and used as a pessary, works the same effect, but causes abortion in women with child. Half a dram of the seed beaten to powder, and taken in wine, doth speedily cause one to make water abundantly. The same taken with vinegar, dissolves the hardness and swellings of the spleen. The root is very effectual in all wounds, especially of the head; as also to draw forth any splinters, thorns, or broken bones, or any other thing sticking in the flesh, without causing pains, being used with a little verdigrease and honey, and the great Centaury root. The same boiled in vinegar, and laid upon an eruption or swelling, doth very effectually dissolve and consume them; yea, even the swellings of the throat called the king's evil; the juice of the leaves or roots heals the itch, and all running or spreading scabs, sores, blemishes, or scars in the skin, wheresoever they be. (Nicholas Culpeper (1616-54) *The Complete Herbal*, 1850.)

CARDUUS BENEDICTUS is called Carduus Benedictus, or Blessed Thistle, or Holy Thistle. I suppose the name was put upon it by some that had little holiness themselves.

I shall spare a labour in writing a description of this as almost every one that can but write at all, may describe them from his own knowledge. They flower in August, and seed not long after.

It is an herb of Mars, and under the sign of Aries. Now, in handling this herb, I shall give you a rational pattern of all the rest; and if you please to view them throughout the book, you shall, to your content, find it true. It helps swimming and giddiness of the head, or the disease called vertigo, because Aries is in the house of Mars. It is an excellent remedy against the yellow jaundice and other infirmities of the gall, because Mars governs choler. It strengthens the attractive faculty in man, and clarifies the blood, because the one is ruled by Mars. The continual drinking the decoction of it, helps red faces, tetters, and ring-worms, because Mars causes them. It helps the plague, sores, boils, and itch, the bitings of mad dogs and venomous beasts, all which infirmities are under Mars; thus you see what it doth by sympathy.

By antipathy to other planets it cures the French pox. By antipathy to Venus, who governs it, it strengthens the memory, and cures deafness by antipathy to Saturn, who has his fall in Aries, which rules the head. It cures quartan agues, and other diseases of melancholy, and adust choler, by sympathy to Saturn, Mars being exalted in Capricorn. Also provokes urine, the stopping of which is usually caused by Mars or the Moon. (Nicholas Culpeper (1616-54) *The Complete Herbal*, 1850.)