What is the benefit of coarse wheat bran in patients with irritable bowel syndrome?

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SUMMARY The effect of open treatment with coarse wheat bran was compared with response to placebo, given in the form of a double blind, cross over drug trial, in patients with irritable bowel syndrome. Both bran and placebo significantly reduced the severity of most of the symptoms. Constipation was the only symptom that improved significantly with bran, but not with placebo, and was the only symptom that predicted a successful outcome with bran. Diarrhoea did not improve with bran. In fact, stools became less formed in patients presenting with this symptom. The incidence of pain and urgency was significantly more frequent on bran compared with placebo. Compared with a baseline period, bran treatment resulted in an acceleration of whole gut transit time ($p < 0.05$) increases in daily stool weight ($p < 0.01$) and the proportion of unformed stools ($p < 0.01$) but no change in stool frequency. Coarse wheat bran was no better than placebo for most symptoms in irritable bowel syndrome, although its efficacy in constipation was confirmed.

Dietary supplementation with wheat bran has been widely advocated^{1,2} and adopted³ as a first line treatment of patients with irritable bowel syndrome although its efficacy has never been properly established. Only two controlled studies of the effects of wheat bran in irritable bowel syndrome have been published. The first of these⁴ did not support the use of bran in a mixed group, including patients with diverticular disease and patients taking laxatives, whereas the second paper⁵ showed a significant reduction in abdominal pain and 'improvement in bowel habit' on bran, in a group of 14 patients with irritable bowel syndrome. In the first study,⁴ the effect of biscuits containing bran was compared with biscuits without bran. No baseline period was incorporated to enable the recognition of a placebo response and some patients were not able to take the bran biscuits because 'they were too hard to chew'. In the second study,⁵ the control group merely excluded wholegrain cereal products usually involving little or no change to the diet and hence were likely to have a placebo response only in as much that they were receiving attention and reassurance. Neither of the studies used a crossover

trial, nor did they detail whether any of the hospital outpatients had been previous 'bran failures'.³ Both studies used an inflexible dosage regime of bran; 30 g and 20 g daily respectively. No details of the spectrum of symptoms presented by the patients were given in either case and symptomatic response referred largely to abdominal pain.

We have now carried out a trial on 38 carefully selected subjects, none of whom had previously experienced bran treatment. This study compares the effects of coarse bran on an extensive range of symptoms and physiological measurements with both placebo treatment and no treatment. Coarse bran was administered in a flexible dose regime but no attempt was made to carry out a 'blinded' assessment as coarse bran is so obvious to the patient and cannot easily be concealed.

Placebo was given to the same group of patients, in the form of tablets, as part of a double blind, cross over drug trial. We believe that this approach has several important advantages compared with other studies.

Methods

SUBJECTS

All had complained of abdominal pain and disturbance in bowel habit for at least six months

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occurring at least three days per week. Organic disease was excluded by sigmoidoscopy and an extensive series of screening investigations (Table 1). None of the patients had undergone previous gastrointestinal surgery (excluding appendicectomy). Patients who had previously undertaken a trial of bran or a high fibre diet were excluded from this trial.

Eighty four patients considered to have irritable bowel syndrome after satisfying these selection criteria, were subjected to the screening programme shown in Table 1. Ten of these patients (12%) were found to have demonstrable pathology (three had diverticular disease, one coeliac disease, one non-specific proctitis, one unexplained steatorrhoea, one cholelithiasis, one giardiasis, one bacterial overgrowth in the small bowel and one lactose malabsorption). Of the remaining 74 patients, 60 were willing to undergo further study. Twenty two of the latter group had already tried bran treatment and were not given bran again. This left the 38 patients who entered the bran study. (31 women, seven men; median age 32 years, range 19-61 years).

STUDY DESIGN

The first part of our study considered the response of 11 separate symptoms to an individually tailored dose of open bran treatment. This serves as a guide to the clinician as to the response he can expect when using this treatment in the surgery or clinic. Secondly, the subsequent response to a placebo in the same patients was compared with their response to bran.

The bran study consisted of a three week baseline period, during which patients ate their usual diet and received no treatment. This was followed by a four week period, during which their diet was

supplemented with coarse wheat bran (Healthlife Products, Bradford) and finally by a double blind cross over trial, which incorporated a five week period on placebo and another on an active drug, given in random order. The active drug was either loperamide or domperidone. In the case of domperidone, the active drug and placebo periods were separated by a two week long 'wash-out' phase. Patients were issued with 750 g of bran and a pot which measured out 10 g of bran. They were given every reason to think that bran would be a useful treatment and a simple explanation of how it is thought to help patients with irritable bowel syndrome. Great stress was laid on the importance of taking the right type of bran (coarse) in the right way (building up from a small dose) and no mention was made at that time of the subsequent drug trial.

Bran was taken in whatever manner or form, was most palatable. The daily dose was 10 g for the first week. Thereafter patients were instructed to increase the dose by 10 g at weekly intervals to a maximum of 30 g per day, stopping at whatever dose they felt had relieved their symptoms or returning to a lower dose if their symptoms had deteriorated. In this way, patients determined their optimal daily dose of bran between 10 to 30 g daily by the end of the three weeks and maintained this for the fourth week. The doses of bran, taken each day, were recorded by the patients on diary cards, and all unused bran was weighed at the end of the four week period to confirm that patients had taken the recorded dose. No bran was taken by the patients during the drug trial and an interval of at least one week on no treatment separated bran treatment from placebo. No medication whatsoever was taken during the baseline, bran or placebo periods of the study.

MEASUREMENTS

The daily frequency and consistency of stools (formed or unformed) and the occurrence of three symptoms (urgency, pain, and distension) were recorded on diary cards by the patients. Symptom questionnaires, in which patients were to rate each symptom on a scale from 1 (well) to 5 (incapacitating), were administered during the baseline period, and at the end of the final weeks of the bran and placebo periods. At the end of the bran period, patients were asked to rate their overall response to treatment as better, worse or unchanged.

Measurements of stool weight and whole gut transit time were carried out at the same times as the symptom questionnaires. Patients were asked to ingest 50 radio-opaque plastic pellets (3x2 mm) with their breakfasts and to collect the contents of

Table 1 Screening investigations

Full blood count + ESR
Plasma urea/electrolytes/calcium
Liver function tests
Rectal biopsy
Stool microscopy + culture
Barium meal + follow through
Barium enema
Thyroid function test
* Faecal fat excretion
* Serum folate + vitamin B12
* Schilling test
* ¹⁴ C-Glycocholate breath test
* Lactose tolerance test
* Urinary 5-hydroxy-indole acetic acid

* indicates those investigations carried out only on the patients who complained of diarrhoea.

every bowel movement for at least the next three days in individual plastic bags labelled with the time and the date.⁶ Whole gut transit time was defined as the time taken to void 50% of the markers and the mean daily stool weight was calculated from the total weight passed during the 72 hour period immediately after ingestion of the markers.

ETHICAL CONSIDERATIONS

Approval for this study was granted by the ethical subcommittee of the Sheffield Area Health Authority (Teaching) in November 1980. Patients gave their written informed consent for the trial to be carried out.

STATISTICAL METHODS

Measurements of whole gut transit time, stool weight, and stool frequency appeared to be normally distributed and differences were assessed using Student's paired or unpaired *t* test as appropriate. Proportions of stools reported as formed or unformed and proportions of patients reporting symptoms at different grades of severity were compared using the χ^2 test. Changes in individual symptom scores between treatments were compared using the Wilcoxon's (paired) signed rank sum test.

Results

OPEN TREATMENT WITH BRAN

At the end of four weeks of bran treatment 18/38 patients (47%) considered that they had improved overall on bran (success group). The remaining 20 patients (53%) (failure group) either felt that their condition was unchanged (11 patients [29%]) or had deteriorated (nine patients [24%]) while taking bran. Two of the latter group were only able to take bran for six and 10 days respectively. The symptom scores from these two patients were included in the analysis, but not the amounts of bran consumed and no transit measurements were available for the bran period.

Despite a measure of overall improvement in some patients, 28 were still so disappointed with their symptoms while on bran as to warrant inclusion in the double blind cross over drug trial. Only five of the 10 patients who did not proceed were completely satisfied with their response to bran. Three of the other patients were worse overall on bran and the remaining two patients noticed no change.

The median dose of bran during the fourth week was 20 g daily (range 9 to 38 g). The failure group took significantly more bran during the final week than the success group (medians = 24 vs 14 g daily;

$p<0.05$). Over the whole four week period, the median total weight of bran consumed by the failure group did not differ significantly from the success group (medians = 430 vs 350 g; $p>0.1$).

COMPARISON OF BRAN WITH PLACEBO FOR TRANSIT MEASUREMENTS AND STOOL DATA (Table 2)

Bran accelerated whole gut transit time ($p<0.05$), increased daily stool weight ($p<0.01$), and the proportion of unformed stools ($p<0.01$) but did not change stool frequency. Placebo treatment had no significant effect on any of these measurements.

SYMPTOMS

Figure 1 shows the mean symptom scores for all symptoms rated as 'moderate', 'severe' or 'incapacitating' during the baseline period, at each stage of the study. In spite of a smaller group and the loss of five 'bran responders', the mean scores, calculated as above, during both baseline and bran treatments for the group who underwent the placebo trial were virtually identical to those for the whole group (Fig. 2) suggesting that the results from the former group can be regarded as representative of the whole group. There was a significant improvement in the severity of all symptoms apart from diarrhoea, distension, flatulence and heartburn during treatment with bran compared with the preceding baseline period. All of the symptoms that improved with bran, with the addition of diarrhoea and the exception of constipation, however, also improved, to at least the same degree, with placebo compared with the baseline period. (Fig. 1). Constipation was the only symptom that was significantly better on bran but not on placebo.

It was also possible to assess the mean incidence of pain, urgency, and distension from the diary cards. Pain was less frequent on placebo compared with both bran (3.7 vs 4.1 days per week; $p<0.05$)

Table 2 Results for whole gut transit time and stool weight, frequency and consistency for the whole group of 38 patients during the baseline and after four weeks bran treatment and for the sub-group of 28 patients after placebo treatment

	Baseline (n=38)	Bran (n=38)	Placebo (n=28)
Daily stool frequency	1.8±0.2	1.8±0.2	1.8±0.2
Whole gut transit time (50% markers hours)	56±5	42±4*	50±6
Stool weight (grams/24 hours)	116±15	155±12*	126±14
% Unformed stools (median)	55	79*	52

* Significant difference from baseline ($p<0.05$).
(Mean values are shown ± SEM).

Fig. 1 Mean symptom scores are shown during baseline (■) and placebo (□) periods for sub-group of 28 patients who went on to 'blinded' placebo treatment. For each symptom only those patients reporting the symptom as 'moderate', 'severe' or 'incapacitating' during the baseline were included for analysis of that symptom response. Boxed number above each symptom indicates number of patients within whole subgroup included in the analysis.

○ – Significant difference from baseline period ($p < 0.05$).

and baseline (3.7 vs 4.0 days per week; $p < 0.05$) periods: urgency was more frequent during bran, compared with the baseline, (2.3 vs 1.9 days per week; $p < 0.05$) but the same during placebo (1.8 vs 1.9 days per week): the incidence of distension was unaffected by bran and placebo.

COMPARISON OF SUCCESS AND FAILURE GROUPS
The only symptom which was more common in

Fig. 2 Mean symptom scores are shown during A baseline and B bran treatment periods for whole group of 38 patients (■) and subgroup of 28 patients who went on to 'blinded' placebo treatment (□).

those who responded to bran was constipation ($p < 0.01$). These patients also had slower whole gut transit ($p < 0.001$) and lower stool weights ($p < 0.05$), stool frequencies ($p < 0.05$) and proportions of unformed stools ($p < 0.001$) during the baseline period (Table 3).

RESPONSE OF DIARRHOEA AND CONSTIPATION TO BRAN (Table 4)

Seventeen patients reported constipation as moderate, severe or incapacitating during the baseline period and 18 patients reported diarrhoea as the same order of severity. The results from the two subgroups were analysed separately in order to identify the effect of bran treatment on these two symptoms in particular. In patients complaining of diarrhoea, bran had no effect on whole gut transit time or stool weight or stool frequency, although there was an increased proportion of unformed stools ($p < 0.001$).

In the group complaining of constipation, bran produced an increase in stool weight ($p < 0.05$) and the proportion of unformed stools ($p < 0.001$).

Discussion

The present study has several advantages compared with other studies.^{4,5} Firstly, our patients were more extensively screened for organic disease and were selected for study only if their symptoms were long standing and persistent. Secondly, none of our patients were previous 'bran failures'³ and our use of coarse rather than fine bran, on a flexible, small dose – increasing if required – basis, follows currently recommended practice.^{7,8} The incorporation of a preceding baseline period was very important as it allowed us to assess and compare the response to both bran and placebo in the same patients. Finally, our more detailed assessment of a

Table 3 Results for whole gut transit time and stool weight, frequency and consistency during the baseline period from those patients ultimately deriving benefit from bran treatment, compared with those reporting no benefit, or deterioration

	Success (n=18)	Failure (n=20)
Daily stool frequency	1.3±0.2	2.2±0.3*
Whole gut transit time (50% markers – hours)	78±8	42±4*
Stool weight (grams/24 hours)	73±19	144±19*
% Unformed stools (median)	29	73*

* Significant difference between sub-groups ($p < 0.05$). Mean values are shown ± SEM.

Table 4 *Response of whole gut transit time and stool weight, frequency and consistency to bran treatment in those patients with predominant constipation at presentation and those with predominant diarrhoea*

	Constipation (n=17)		Diarrhoea (n=18)	
	Baseline	Bran	Baseline	Bran
% patients with improvement in symptom		71		28
% patients with deterioration in symptom		12		17
Daily stool frequency	1.1±0.2	1.2±0.1	2.2±0.3	2.2±0.3
Whole gut transit time (50% markers hours)	74±8	52±8	39±6	41±6
Stool weight (grams/24 hours)	76±24	135±19*	168±22	170±19
% unformed stools (median)	39	69*	69	94*

* Significant difference from baseline ($p<0.05$).

Mean values are shown ± SEM.

range of symptoms, physiological measurements, and stool indices enabled a closer definition of the patient and the response.

Several aspects of our own study, however, require comment. The bran period always preceded the placebo period as the authors felt that only those patients who had failed to respond to simple reassurance and dietary change should be considered for drug therapy. In approximately half the patients who entered the drug trial, the placebo period was separated from the bran period by treatment with an active drug – domperidone or loperamide. While it could be argued that these treatments had a ‘hang-over’ beneficial effect persisting throughout the subsequent placebo period, in the case of domperidone there was a two week ‘wash-out’ period between treatments. The effect of placebo was the same, irrespective of the active drug taken and the order of treatments. It is possible that a ‘placebo effect’ might have been made prominent as part of the mystique of a double blind trial compared with an open dietary treatment. It is equally likely, however, that the initial reassurance by explanation and extensive negative screening (Table 1), together with the psychological build-up given to the bran also had a powerful ‘placebo effect’ which may have contributed to the apparent efficacy of bran.

With respect to the screening, our experience from this study has been that patients are greatly

reassured to know that the search for an underlying organic basis for their symptoms has been thorough and are then more willing to accept simple symptomatic treatment and reassurance. After applying this screening (Table 1) to 84 patients considered to have irritable bowel syndrome clinically only 10 (12%) were found to have demonstrable pathology, which may or may not have been related to their symptoms. It would, therefore, be difficult to justify this practice outside the context of a scientific study.

Our initial impression was in line with current clinical opinion in that bran appeared to benefit many of the symptoms of irritable bowel syndrome. The analysis of the subsequent placebo period, however, suggested that most of the benefit of bran could be ascribed to placebo response. In fact the only symptom that showed a statistically and clinically significant response to bran and not to placebo was constipation. Constipation was also the only symptom that was significantly more common during the baseline period in patients, who subsequently said that they had improved on bran compared with those who had not. Placebo appeared to be at least as effective as bran for reducing the severity of every symptom, apart from constipation (Fig. 1). Indeed, placebo treatment was significantly better than bran in terms of reducing the incidence of pain, and bran increased the incidence of urgency, unlike placebo.

Previous studies have reported that bran may be of use in patients complaining of diarrhoea.^{5,9} We could not confirm a symptomatic improvement in patients with irritable bowel syndrome. In fact, stools in patients with diarrhoea became less formed. It is important to note that different patients mean different things when describing symptoms. ‘Diarrhoea’ may mean frequent, large volume stools or perhaps occasional loose stools with a sense of urgency. Similarly, ‘constipation’ may be used by the patient to describe infrequent bowel movements or regular bowel movements associated with discomfort or straining. In order to clarify this without introducing too many subgroups, which might tend to confuse, we have used these terms which are those used by patients, but also given stool data and transit measurements and have considered the symptom of urgency separately. We feel that this is preferable to the use of terms such as ‘bowel dysfunction’ and ‘improvement in bowel habit’, which have been used in other studies.^{5,10}

Despite the fact that 18/38 of our patients reported an overall improvement on bran, albeit probably because of a placebo effect, only five of these actually wanted to continue on bran therapy. This was partly due to the lack of improvement or

even deterioration of many symptoms and partly to its unpalatability, which might be avoided by the use of other foods as a source of dietary fibre. In this context, other workers have shown Ispaghula husk to be superior to both placebo and bran in irritable bowel syndrome and to be synergistic with other agents.^{11 12} Some workers have advocated that fair assessment of the efficacy of bran in diverticular disease should be made over a three month period to give patients time to get used to it.¹⁰ Inspection of the data from these studies, however, shows that two thirds of the improvement in pain and one half of the improvement in stool consistency is achieved in the first month.¹⁰ In our study, the final dose of bran was taken for only one to three weeks before symptomatic and physiological assessments were carried out. Thus, it is conceivable that with more prolonged treatment, a more beneficial effect could be obtained. We found, however, that it was difficult to persuade patients to keep taking the bran for a month, if there was no improvement even when the doses were initially low, built up slowly and taken in the manner that the patient found most palatable.

Our findings correspond with our clinical experience in that many patients are referred to clinic having failed to respond, or maintain a response to bran and we believe that the results of this study cast serious doubts on the value of coarse, wheat bran for most symptoms in irritable bowel syndrome, although its efficacy in constipation is confirmed.

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