For Debate . . .

Is bran useful in diverticular disease?

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It is a painful truth that controlled clinical trials are difficult and tedious to carry out but, when at last they are published, they are easy to criticise. This is well illustrated in the recent challenging report by M H Ornstein and his colleagues (25 April, p 1353), which concluded that bran is no better than a placebo in relieving the symptoms of uncomplicated diverticular disease, and by the spate of critical letters that followed it (9 May, p 1546; 30 May, p 1792; 11 July, p 140). This controversy follows a decade in which bran has become universally accepted in Britain as the first line of treatment. The basis of this belief in bran was a series of uncontrolled trials¹⁻³ and two placebo-controlled trials,^{4,5} backed up by evidence that bran lowers the pressure within the sigmoid colon in man^{2,6-8} and animals.⁹ Bran treatment seems logical since there is much epidemiological and some experimental evidence to implicate a low-residue diet in the aetiology of diverticular disease.¹⁰⁻¹² So why did the Ornstein study come up with a negative result? In many ways it is the best study. It included a large number of patients, studied them for a long time (eight months), and had an impeccable randomised, cross-over design. All the same, it has been dismissed as "meaningless" and the report itself as "sweeping overstatement" (30 May, p 1792). Similar criticisms have been made when the study has been presented at national scientific meetings.

The *BMJ* was aware of these criticisms but decided to publish the paper because it was thought to contribute considerably to our knowledge of bran and its role in clinical practice. And so it does, but mainly by focusing attention on dosage and the selection of patients for treatment.

Patients

The patients enrolled in the Ornstein study had mild symptoms. In particular, to judge by their average scores for abdominal pain (10 or 12 out of a possible 50), their pains were mild and infrequent. This contrasts with the patients in other published trials. In Brodribb's controlled trial,⁴ which showed bran to be so much better than placebo that the trial had to be stopped, the average pain score was 11 or 12 out of 24 and other symptoms were described as severe. In a study⁷ that showed bran tablets to be better than a sterculia preparation many of the patients had been so ill they had been admitted to hospital. It is the general impression of gastroenterologists that bran is highly effective in the patient with severe lower abdominal colics, especially when these are associated with hard stools or alternating constipation and diarrhoea. Such patients must have been in a minority in the Ornstein study. It is a phenomenon well known to clinical trialists that when they go out of their way to find patients for a study they end up with many mild or

borderline cases. In this trial the patients seem to have had mostly the minor symptoms of the irritable bowel syndrome. Such patients are well known to have high indices of neuroticism and to be responsive to placebos.

The suspicion that the patients were atypical is strengthened by their stool weights and transit times. On the placebo their stools averaged 119 g/day, which is close to the stool weights of healthy people on an ordinary British diet.^{6,13-16} In other series of untreated patients with symptomatic diverticular disease stool weights have averaged 66-84 g/day.^{2,6,7} Similarly, the patients' intestinal transit time was near normal at 50 hours. If colonic function is practically normal to start with, little can be expected from a treatment that aims to restore normal function.

It may be that patients with symptomatic diverticular disease need to have a low stool weight and a prolonged transit time to respond to bran. This is not to say, however, that bran "does no more than relieve constipation." Relief of abdominal pain has been the most impressive effect of bran in all other studies and in many people's clinical experience. Another symptom that is usually relieved is the feeling of incomplete evacuation.^{1,2} This symptom is present in most people who strain at stool and may be regarded as part of the constipation syndrome.¹⁷ The failure of Ornstein *et al* to remove this symptom confirms that they did not give a constipation-relieving dose of bran.

Daily intake

The main criticism that has been levelled at this study is that there was too little difference in the daily intake of fibre between the bran and placebo periods. This difference amounted to 4.6 g/day, which is equivalent to only 10 g or one tablespoon of bran or to one-and-a-half slices of wholemeal bread. There was indeed a similar difference in Brodribb's study,⁴ but his patients had more severe symptoms and so were possibly more bran sensitive. It must be conceded that Ornstein *et al* did not achieve anything approaching a high fibre intake nor even the "standard" dose of 20 g bran daily.

It is true that, in practice, some patients find bran difficult to take in this dosage. The wise clinician, however, does not limit his recommendations to the unpalatable dry flakes of millers' bran or to cardboard-like biscuits. Wholemeal bread is rich in bran and far more palatable. Eating five or six slices of wholemeal bread a day would double most people's intake of dietary fibre. There are also palatable breakfast cereals consisting mainly of bran.

Dilemma of the trialist

A problem with all controlled trials of bran is that the use of a standardised dose ignores the pronounced variability in people's response to bran and prevents the investigator from treating each patient as an individual, which is how he is treated in clinical practice. This epitomises the dilemma of the trialist. It is holy

writ that, in any experiment, as many variables as possible should be controlled, but it is also a fact that the more narrow a treatment protocol the less validly can its results be applied to real clinical practice.

Had Ornstein and his co-workers been more reserved in their conclusions and more modest in their choice of title their paper might have escaped condemnation. It does allow a conclusion to be drawn but it is a modest one—namely, that if you take a patient with mild irritable-bowel-type symptoms and diverticula on his barium enema and give him a small dose of bran in biscuit form he is unlikely to be cured. Such a conclusion will surprise few experienced physicians. And most will go on giving bran in individually tailored amounts to their patients with typical severe symptomatic diverticular disease. It will need a different study from the Ornstein one to change this practice.

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Doubts about diverticular disease

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"It is what we think we know already that often prevents us from learning"—CLAUDE BERNARD¹

The treatment of diverticular disease of the colon exemplifies the capricious nature of medical fashion. Before the 1920s dietary fibre (known as roughage, crude fibre, or fibre) was popular; there then followed a vogue for fibre-free, so-called "soft" diets, which lasted until the late 1960s. Fashion has now turned full circle and, apart from the occasional voice of caution,²⁻⁴ dietary fibre is becoming increasingly popular. This trend has followed two separate paths: the "fibre hypothesis" of Cleave⁵ and others⁶ (concerning fibre depletion as the cause of such diverse conditions as carcinoma of the colon and ischaemic heart disease) should not be confused with the present debate concerning the therapeutic role of dietary fibre in established diverticular disease. The former is difficult to test in a clinical study but the latter should be amenable to scientific inquiry.

For this reason a working party of the Medical Research Council asked us to investigate what many colleagues had come to accept on the evidence of uncontrolled observations—that bran was an effective treatment for diverticular disease. The subject is more complex than it at first appears because bran is only one mixture of a group of substances called dietary fibre with differing physiological properties. We therefore included ispaghula, another fibre preparation widely used in Britain, in our trial.

We are pleased that Dr Heaton complimented the design of our study. Nevertheless, all controlled studies are easy to criticise, and the same exacting standards should be applied to studies giving different results.

Selection of patients

Uncontrolled studies (including Taylor's study of bran tablets⁷) are little better than clinical impression, and there have been only four placebo-controlled trials. Two do not support the argument that dietary fibre is effective treatment (though one is only reported in abstract⁸ and the other used methylcellulose tablets⁹). One of the remaining two has been reported only in the discussion periods of symposia on dietary fibre¹⁰ and cannot be properly assessed—indeed, several questions need to be answered before this study can be accepted. The other is the Oxford study by Brodribb,¹¹ which we have already criticised (11 July 1981, p 140). Fortunately this study and ours used biscuits from an identical source so that direct comparison is unfettered by arguments about the quantity (the apparent discrepancy is made clear in our letter) and quality of fibre given. The scoring system, selection of patients, intake of basal fibre, etc, are not fully described, but we understand that Mr

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