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The need for confidence intervals in reporting clinical trials

SIR,—At first glance Lucey *et al*'s randomised controlled trial of bran in irritable bowel syndrome (*Gut* 1987; **28**: 221–5) appears to show that this treatment amounts to no more than trial by bran. Before accepting their conclusion that the beneficial effects of bran are due to a placebo response, however, it is instructive to calculate the confidence interval on which they base this conclusion.

According to Figure 1 of their paper, 10 (70%) of 14 patients had a reduction in symptom score of greater than 2 after three months on bran biscuits, compared with 8 (57%) of 14 patients on placebo biscuits for three months. Using conventional methods for calculating the standard error of the difference between two sample proportions, the 95% confidence interval around the 14% difference in response, runs from –20% to +50%.^{1,2} In other words, the trial result is compatible with the true proportion of subjects responding to bran being 50% more than the proportion responding to placebo. This is a difference I think most clinicians would regard as worth obtaining. Indeed, considering the lack of efficacy of drugs and other measures in irritable bowel syndrome, a difference of only 20% might be regarded as worth obtaining.

Similar considerations apply to Chapman *et al*'s trial of metronidazole in acute ulcerative colitis (*Gut* 1986; **27**: 1210–2). In that study 14 (74%) of 19 patients receiving metronidazole recovered without colectomy compared with 14 (70%) of 20 patients not receiving metronidazole. The 95% confidence interval on this difference extends from –24% to +32%. Again, this interval includes a potential benefit many clinicians might regard as worth having, as well as the potential for harm.

The authors of both these papers may well be right about their conclusions, but equally, these two small trials are open to considerable risk of Type 2 errors – that is, they may falsely accept the null hypothesis of there being no difference when important clinical differences do exist.³ Some may argue as to whether a 50% benefit from taking bran or a 32% benefit from metronidazole are clinically important but at least by stating a confidence interval, referees and readers can judge for themselves. Surely *Gut* should now adopt the policy of other leading journals and ask authors to state the relevant confidence intervals?

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Reply

SIR,—Thank you for the opportunity to respond to Dr Logan's letter. In our study of the efficacy of bran in irritable bowel syndrome, on comparing the initial response to bran or to placebo in two groups of 14 subjects; or on comparing in a crossover fashion the responses to bran and placebo in all 28 subjects; or finally on stratifying the subjects according to the effect of bran on stool weight, no therapeutic advantage of bran over placebo could be demonstrated.¹ Thus we could not reject the null hypothesis that bran and placebo are similar. The possibility of a Type 2 error exists in any study which does not reject the null hypothesis. In studies such as ours, however, given the relatively small numbers, a confidence interval based on either data from the initial treatment period or the crossover analysis is likely to contain zero, be fairly wide and include both positive and negative values. Therefore this is not an appropriate setting for this form of analysis as the result always will be too diffuse to be meaningful. Confidence intervals are of value in larger studies in which the null hypothesis is rejected because they allow the reader to judge whether a statistical significant observation is of clinical significance.²

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