

Reviewer's report

Title: Concentrated oat beta-glucan, a fermentable fiber, lowers serum cholesterol in a randomized controlled trial

Version: 1 **Date:** 6 December 2006

Reviewer: Kenneth J Mukamal

Reviewer's report:

General

This manuscript describes a feeding study of 75 adults with mildly elevated cholesterol levels who were randomized to oat b-glucan or dextrose for 6 weeks. A particularly novel aspect is attention to colonic fermentation, although it was not directly related to the feeding study itself. The authors find lower levels of LDL-cholesterol (but less of a decrease in levels of TG) among b-glucan supplemented participants. No clear effects on other CV markers were identified.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Three issues may require some revision to my eye:

1. The manuscript fairly liberally refers to dietary fiber when soluble fiber is meant. It also discusses health effects attributed to dietary fiber intake that may or may not be related to soluble fiber intake. For example, page 4, the hypothesis that dietary fiber lowers blood cholesterol levels appears to be a discussion of soluble fiber effects, and the review of mechanisms in the Discussion does not make this distinction either. More careful attention to this would help eliminate confusion.
2. The higher TG in the supplemented group is not discussed. This is a surprising finding and, while possibly a chance result, is just as statistically strong as the LDL-C finding.
3. I am troubled by the exclusion of 15 subjects post-randomization, as this invalidates the intention-to-treat approach. Unless the authors' hypothesis is that b-glucan only lowers LDL-C among hypercholesterolemic individuals, which is relatively implausible, it is hard to justify this exclusion, especially because such individuals apparently had a qualifying cholesterol level at at least one point in time. As it appears that such individuals were followed and only excluded at the final analysis stage, additional analyses that include all randomized participants with complete information should be provided or described.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. Title and abstract. Should probably include reference to the fact that only hypercholesterolemic individuals were studied. Also, the abstract should indicate that the fecal inoculum was from subjects unrelated to this trial.
2. Pg 4. Total fat intake is generally not considered a major CVD risk factor; should clarify to indicate saturated and trans fat if the authors mean that.
3. Pg 4. A citation for the lower CVD risk associated with oats and psyllium is needed.
4. Pg 4. "In rats" is superfluous; male Wistar rats are noted subsequently.
5. Pg 11. The significant difference between the change in triglycerides between b-glucan and control should be noted explicitly.
6. Pg 11. Table 4 is written instead of Table 3.
7. Pg 12. I found the description of Table 3 rather long and somewhat difficult to follow. Guar gum did not produce greater concentrations of TSCFA at all time points.
8. Pg 14. The Keys equation is described only in the Discussion with no data or description noted in the Methods or Results.
9. Pg 15. I found the second paragraph confusing. The authors show no effect on non-lipid CVD risk factors but later suggest that other mechanisms may be involved, but conclude that b-glucan may slow atherosclerosis progression by lowering LDL-C. These seem inconsistent and - at least regarding atherosclerosis - beyond the scope of the data.

Discretionary Revisions (which the author can choose to ignore)

The authors cite a 1994 review of previous trials and do not provide contrast with the many more recent trials (e.g., Naumann 2006, Chen 2006, Karmelly 2005, Jenkins 2002, Andersson 2002). These would be

particularly helpful in providing context for the observed effects on LDL-C and TG in terms of magnitude and direction.

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.