Article: In the Absence of Dietary Surveillance, Chitosan Does Not Reduce Plasma Lipids... (SC Ho, et al) (SMJ Vol 42 Issue 1 January 2001)

Dear Sir,

Most of the results did not show any statistically significant difference. Before one can conclude that it is so, we need to know the statistical power of the test. A quick calculation would show statistical power to be very low for most comparisons. In other words, the sample size was too small to detect a difference, even if it was present.

The conclusions were, therefore, incorrect.

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Reply From Authors

Dear Editor,

We will like to reiterate that the objective to this study is to evaluate the effect of chitosan on weight, lipid profiles and other parameters in obese, hypercholesterolaemic subjects while not on dietary surveillance. Absorbitol, a salt of chitosan, was marketed at the time of study as an effective weight reducing agent. It can be bought over the counter and is frequently used by the general public without proper dietetic counselling, who are believed to have a more liberal caloric intake.

With respect to changes in weight, we based our sample size calculation on detection of 10% weight change. The female subjects had an average weight of ~ 60 kg with SD of 9 kg while the male subjects had an average ~ 75 kg with SD of 11 kg. To have power of 0.80 and detecting a 10% change (2-tailed) at p < 0.05, the calculated sample size required would have been 37 and 40 for the female and male cohorts respectively<sup>(1)</sup>.

Lifestyle and dietary changes are able to mediate a 10% reduction in total cholesterol while treatment with a first generation HMGCoA inhibitor can bring about 30% reduction<sup>(2.3)</sup>. A 20% reduction in total cholesterol level was chosen for calculation of sample size because on one hand, it is unrealistic to assume that Absorbitol can achieve as big a reduction in lipids as a statin while on the other, we are looking for changes higher than those achievable by non-pharmacological means. In the study, the mean total cholesterol level was ~ 6 mmol/l with SD of 1 mmol/l. A sample size of 12 would have been able to detect a 20% reduction (power = 0.8, p < 0.05, 2-tailed).

Therefore, based on the above calculations, the sample size of 88 recruited in the study is of sufficient power to detect physiologically significant changes in weight and total cholesterol level. Although it may be true that given the sample size, we cannot detect changes as small as  $\leq 10\%$ , the reductions may be statistically significant but physiologically inconsequential. In addition, such minute reductions can easily be achieved by lifestyle and dietary modifications and will not justify treatment with chitosan.

We hope we have answered the queries to your satisfaction.

Thank you.

Yours faithfully Dr Ho Su Chin et al.

## REFERENCES

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