

## Nutrition Discussion Forum

# Calcium, vitamin D and weight loss – reply by Tremblay and Major

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Blumsohn & Barker have raised some issues<sup>(1)</sup> relating to our paper published recently in the *British Journal of Nutrition*<sup>(2)</sup> and describing the impact of a Ca plus vitamin D supplementation on energy balance and fat mass in female very low Ca consumers who were subjected to a weight-reducing programme. This supplementation was found to accentuate body weight and fat loss by about 4 kg over the 15-week intervention. In addition, the results showed that variations in food intake were the main factor explaining the greater negative energy balance observed in supplemented subjects. Blumsohn & Barker<sup>(1)</sup> express some reservations and criticisms about certain aspects of the methodology of this study. In this regard, the main purpose of this response is to present clarifications and additional justifications about relevant issues.

The first issue to discuss is the placebo used in the trial. It is always a challenge to prepare the perfect placebo tablet which has the same appearance and weight as a tablet containing the active agent and which is totally free from potentially active ingredients. In the context of study, the funder, Wyeth Consumer Healthcare Inc., carefully designed placebo tablets which were similar to tablets supplemented with Ca and vitamin D. The ingredients of this placebo were carnauba wax, hypromellose, lactose monohydrate, light mineral oil, magnesium stearate, microcrystalline cellulose, polysorbate 80, sodium lauryl sulfate and titanium dioxide. The tablet weight was 1222 mg; microcrystalline cellulose accounted for 48.4% of the tablet weight (592 mg) and lactose monohydrate accounted for an additional 48% of the tablet weight (589 mg). None of these ingredients has documented properties which could confer to the placebo a confounding effect on the outcome of our study. We are confident that the study products and procedures allowed a good comparison between the experimental and the control groups.

The second issue to discuss is the potential impact of Ca supplementation on digestion.

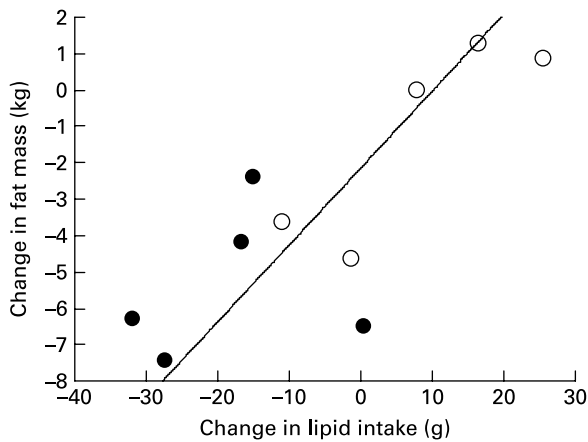
Recent literature demonstrates that Ca and dairy food can modify every component of energy and fat balance. With respect to digestion, both animal and human studies show that Ca/dairy supplementation promotes faecal fat loss to an extent that can significantly change energy balance. In a recent meta-analysis of available literature, we examined the effect of Ca from dietary supplements and dairy products on faecal fat excretion<sup>(3)</sup>. The most consistent results pertained to the effect of dairy supplementation which has been shown to induce an additional faecal fat loss ranging between 1.6 and 8.8 g/d, with a mean value of 5.2 g/d. As explained in the discussion of our recent paper<sup>(2)</sup>, this effect was taken

into consideration in our calculations. We used the data of Jacobsen *et al.*<sup>(4)</sup> to estimate the potential 'indigestion' effect of Ca in our study. Jacobsen *et al.* reported an additional faecal fat loss of 8.3 g/d in their study (a loss that is at the upper level of currently reported values), which led us to assume that this effect potentially accounted for an energy loss of 350 kJ/d in our supplemented subjects. If this estimate represents an overestimation, it is likely that variations attributable to food intake might have been slightly greater than what we proposed in the paper, and thus Ca supplementation could be more effective than we concluded.

The third point to discuss is our choice of the 'cut-off' of <600 mg Ca intake per d.

The choice of the appropriate criteria to classify subjects or patients is a delicate task for the clinical trial dietitians, since they have to rely on literature and clinical tools that present limitations. In this particular study<sup>(2)</sup>, a 'cut-off' of 600 mg Ca/d was used to determine very low intakes of Ca. In our first study in this field, we had found that women who reported (3 d dietary record) habitual Ca intake of <600 mg/d were characterised by a significantly greater percentage of body fat<sup>(5)</sup>. Since this relationship was less clear in men, we wanted to test the hypothesis that supplementing Ca in the diet would improve the response of low Ca-intake consumers to a weight-reducing programme, particularly in overweight and obese women. This is the evidence on which we based the choice of our subject sample and the cut-off point used to classify subjects on the basis of their habitual Ca intake.

Being aware of the usefulness but also the limitations of the 3 d dietary record<sup>(6)</sup>, we used a two-step strategy for the recruitment of our subjects, as explained in the Methods section of our paper<sup>(2)</sup>. In step 1, a questionnaire was used during a telephone interview to evaluate the amount of food high in Ca consumed by responders. On the basis of the quantitative importance of the reported consumption of Ca-containing food, the recruitment process was either interrupted or carried on to step 2. Thus, the 3 d dietary record that was used as a tool at step 2 was only completed by individuals who were classified as low consumers of Ca-containing food at step 1. To our knowledge, this is one of the most rigorous classification processes that has been used in this type of study. With respect to this marker, the mean reported daily Ca intake before the study was 542.0 and 525.6 mg/d for the placebo and supplemented groups, respectively. Accordingly, at baseline when supplementation was initiated, daily Ca intake was 542.0 and 1725.6 mg in these subjects. It is then obvious that the between-group



**Fig. 1.** Correlation between changes in lipid intake during the *ad libitum* buffet and in fat mass in very low-Ca consumers (habitual Ca intake <600 mg/d) receiving Ca plus vitamin D (●) or placebo (○) ( $r$  0.80;  $P=0.005$ ).

difference in Ca intake during the study protocol was attributable to the supplementation. In order to provide further clarification on the relationship between Ca intake and body-weight loss, we republish Fig. 1 of our paper<sup>(2)</sup>. With this new version of Fig. 1, it is possible to more easily distinguish between individuals who received the Ca plus vitamin D supplement and lost the greatest amount of fat mass (and also had the larger decrease in lipid intake) and those who received the placebo and experienced a lower decrease in fat mass.

Our screening procedure along with the relevance of the <600 mg Ca/d cut-off were clearly set as criteria up-front in the study protocol, and were followed during study execution to maintain adherence to good clinical practices. This allowed us to assess the relevance of Ca and vitamin D

supplementation to fat mass loss in overweight and obese women with habitual very-low Ca intake.

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