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Digesting research on preoperative nutrition in Crohn's disease

Dear Sir

We read with interest the recent article by Yamamoto et al on the role of pre-operative enteral nutrition and its role in reducing complications following surgery¹. Whilst the study provides interesting information, we have some comments.

Matching: We would be interested to know why the authors selected the reported variables for matching as this does not seem to be mentioned in the dataset. The split of </>40 years of age seems somewhat arbitrary. No attempt was made to match for use of anti-Tumour necrosis factor agents, which might be relevant given the ongoing uncertainty around their association with complications². As CDAI was collected, we wonder why subjects were not matched for this factor? We also note high CRP values, and no comment is made as to whether these patients received antibiotic therapy for conditions such as abscess prior to surgery, or whether this was related to disease activity alone.

Statistical analysis: We also suspect the authors are asking a lot from their data. The ability of such a small sample size to detect a change as small as 0.1mg/dL change in albumin is surprising. For this to be plausible, the standard deviation of the population would need to be quite small to detect this. The standard deviation of the population is not presented in tables so this cannot be explored by the reader. In addition, rules of thumb for logistic regression modelling recommend 10 events per variable³. There were 12 complications in this study, meaning that regression analysis was probably not feasible. This is reflected in the wide confidence intervals (e.g. 1.2-174.6 for the case of penetrating disease and association with complications). The authors do acknowledge that sample size is small for the analysis type and gives rise to a high risk of type I and II error, given this acknowledgment, and that it's not clear there was a pre-determined statistical analysis plan, what was the justification for conducting this regression analysis?

With the above two points, it is probable that neither the matching nor the model include key factors to explain all potential variation, and that the sample size is too small to adequately assess the population of interest. This leaves us without a clear answer on the issue. This study does serve to highlight the need for a large randomised controlled trial to identify the true effect of this intervention in a well described population.

Yours faithfully

Matthew J Lee, Steven R Brown.

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