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TITLE PAGE

Title: VSL#3 in Post-operative Crohn's Disease.

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Abbreviations: RCT randomized controlled trial

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Sirs;

We read the study by Fedorak et al.¹ with interest. Although there have been several randomized controlled trials (RCTs) evaluating the efficacy of VSL#3 in ulcerative colitis, the only previous study in Crohn's disease post-surgery is the small study by Campieri et al.² The optimal management of Crohn's disease post-operatively remains unclear, with conflicting evidence for the use of 5-aminosalicylates, and immunomodulator therapies, and few data for biological therapies. (Ford AC, Am J Gastro 2011;106:413-420, Doherty G, Cochrane Database Syst Rev 2009;7(4):CD006873, Regueiro M Gastroenterology 2009;136:441-450, Savarino E, Am J Gastro 2013;108:1731-1742). High quality RCTs examining the efficacy of probiotics in this situation are therefore welcome.

Unfortunately, the study failed to demonstrate a significant difference between VSL#3 and placebo, in terms of severe endoscopic recurrence, or endoscopic recurrence of any grade, 3 months post-randomization. Whether this was due to an underpowered study, or subtle differences in the study population compared with those recruited by Rutgeert's et al. in their 1995 paper³, on which their power calculation was based, is unclear. It is, however, interesting to note that fewer patients in the current study had undergone at least one previous surgical resection, compared with those in the aforementioned trial, suggesting a more severe disease spectrum.

Given the failure to show a significant difference in their primary endpoint, and the failure to demonstrate significant differences in 11 of the 13 mucosal cytokines studied, we were surprised by the provocative title of the article, which stated that VSL#3 could reduce endoscopic recurrence following surgery, and that the probiotic had anti-inflammatory effects. We suspect that further, larger, randomized controlled trials will be required before any firm conclusions about the efficacy of VSL#3 in this setting can be drawn.

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