2015. VSL3 postop

RCT/VSL3/CD/Postop

The Probiotic VSL#3 Has Anti-inflammatory Effects and Could Reduce Endoscopic Recurrence After Surgery for Crohn's Disease

Multicenter, randomized, double-blind, placebo-controlled trial. Patients with CD with ileocolonic resection and re-anastomosis were randomized within 30 days from surgery to: 1 sachet BD of VSL3 (900billion available bacteria) or placebo for 90 days. After day 90, open label study with those patients with no severe recurrence receiving VSL3 BD.

Primary endpoints: Severe endoscopic recurrence (Rutgeerts 3 or 4) at day 90.

Results:

- At day 90, severe endoscopic recurrence occurred in 9.3% VSL3 and 15.7% placebo, p=0.19
- At day 365, 10% in VSL3 and 26.7% in placebo had endoscopic recurrence of the patients with no-severe lesions at day 90, p=0.09
- Patients on VSL3 had reduced mucosal inflammation cytokine levels vs placebo at day 90, p<0.05.

Conclusion:

No differences in endoscopic recurrence rates at day 90 between VSL#3 and patients who received placebo. Lower mucosal levels of inflammatory cytokines and a lower rate of recurrence among patients who received early VSL#3 (for the entire 365 days) indicate that this probiotic should be further investigated for prevention of Crohn's disease recurrence

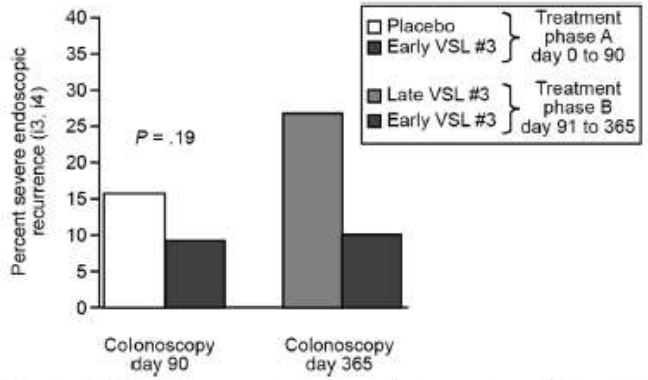

Figure 2. Percent severe endoscopic recurrence (Rutgeerts score i3, i4) at day 90 and day 365. Between day 0 and day 90, patients received either placebo (*open bar*) or early VSL#3 treatment (*black bar*). Between day 91 and day 365, all patients received VSL#3, defining a group who received early VSL#3 (early VSL#3 treatment group, *black bar*) and one who received VSL#3 late (ie, from days 91 to 365, late VSL#3 treatment group, *open hatched bar*). At day 90, the proportions of patients with severe endoscopic lesions did not differ significantly between VSL#3 and placebo. Similarly, the proportions of patients with non-severe lesions at day 90 who had severe endoscopic recurrence at day 365 were numerically but not statistically different in the early VSL#3 group (given VSL#3 for the entire 365 days) compared with the late VSL#3 group (given VSL#3 from days 90 through 365) ($P = .09$).

Fedorak RN et al. Clin Gastroenterol. Hepatol. 2015; 13:928-935