Budesonide MMX and Mesalamine to Induce Remission in Patients With Ulcerative Colitis

Dear Sir:

We read with interest about the randomized, controlled trial (RCT) by Sandborn et al,1 which deserve some comments concerning the methodology and the interpretation of the results.

First, the authors compared the efficacy of Budesonide MMX (9 and 6 mg/d) with mesalamine 2.4 g/d or placebo to induce remission in patients with active mild to moderate ulcerative colitis (UC). When a new drug must be evaluated versus an old treatment, the main rule is to choose the most appropriate dosage of the comparison drug. In 1987, Schroeder et al2 showed that oral 5-aminosalicylic acid therapy in a dosage of 4.8 g/d was an effective therapy to induce remission in active UC. Two successive metaanalyses of the all RCTs of mesalamine confirmed that doses of 3 g/d are needed to achieve the best result.3,4 Therefore, the comparison in this trial was not appropriate.

Second, the clinical and combined remission (clinical and endoscopic) data observed in this study with mesalamine tablets (34% and 12%, respectively) are at variance with those of published RCTs. Leifeld et al,5 in a pooled analysis of 4 RCTs of 3 g/d of mesalamine, showed that tablets were able to obtain a clinical remission in 71% and endoscopic remission in 48% of patients. In the discussion, the authors state that mesalamine 2.4 g/d is not more effective than placebo, when this statement seems debatable according to the analysis previously quoted.5

Considering that mesalamine is an effective drug in mild-to-moderate, active UC, before introducing budesonide MMX as a standard treatment for mild to moderate UC, it is advisable to design a trial which compare budesonide MMX with an effective dose of mesalamine.

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