**P056 NUMBER NEEDED TO TREAT WITH MMX MESALAZINE FOR ONE PATIENT WITH MILD-TO-MODERATE ULCERATIVE COLITIS TO ACHIEVE REMISSION**

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Introduction: The number needed to treat (NNT), which defines the treatment-specific effect of an intervention, is a valuable aid for evidence-based clinical decision making. In a previous randomised, double-blind, placebo-controlled, phase III trial (SPD476-302), MMX mesalazine, a high-strength (1.2g/tablet), once-daily 5-aminosalicylate, significantly improved remission rates versus placebo in patients with active, mild-to-moderate ulcerative colitis (UC). In this analysis of data from the same study, we evaluated the NNT associated with MMX mesalazine-related induction of remission. MMX and ASACOL are registered trademarks Methods: Patients enrolled in study SPD476-302 received MMX mesalazine 2.4g/d (once daily [QD]), MMX mesalazine 4.8g/d (QD), ASACOL (mesalazine) delayed-release tablets 2.4g/d (0.8g three times daily), or placebo. The primary endpoint was clinical and endoscopic remission (modified UC Disease Activity Index Score of no more than 1, with rectal bleeding and stool frequency scores of 0, no mucosal friability, and a 1-point reduction in sigmoidoscopy score from baseline) at week 8. The NNT for one patient to achieve remission versus placebo at week 8 was calculated for each active treatment.

Results: After 8 weeks, 40.5, 41.2, 32.6 and 22.1% of patients in the MMX mesalazine 2.4g/d, 4.8g/d, ASACOL 2.4g/d and placebo group, respectively, had achieved remission (p < 0.001 for all groups combined), logistic regression analysis of treatment versus placebo; p < 0.05 for ASACOL versus placebo). The NNT (95% confidence intervals) for one patient to achieve remission versus placebo at week 8 was 5.4 (3.1–21.3), 5.2 (3.1–21.3) and 9.6 (4.2–infinity) for MMX mesalazine 2.4g/d, 4.8g/d and ASACOL 2.4g/d, respectively.

Conclusion: For one patient to achieve clinical and endoscopic remission versus placebo at week 8, six patients need to be treated with MMX mesalazine (2.4g/d or 4.8g/d), whereas 10 patients need to be treated with ASACOL 2.4g/d.

**P057 MMX MESALAZINE IS AN EFFECTIVE TREATMENT FOR MEN AND WOMEN WITH MILD-TO-MODERATE, ACTIVE ULCERATIVE COLITIS**

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Introduction: An optimal therapy for ulcerative colitis (UC) should be effective irrespective of a patient’s gender or other demographic or personal characteristics. MMX mesalazine is a high-strength (1.2g/tablet) 5-aminosalicylic acid (5-ASA) formulation, utilising Multi Matrix System (MMX) technology designed to release 5-ASA throughout the colon. This analysis evaluated the effect of gender on the efficacy of MMX mesalazine in patients with active UC. MMX and MMX Multi Matrix System are registered trademarks.

Methods: Data were combined from two phase III, randomised, multicentre, double-blind, placebo-controlled studies involving patients with mild-to-moderate active UC (SPD476-301 and -302). Patients had received MMX mesalazine 2.4g/d (once daily [QD]) or 1.2g twice daily), MMX mesalazine 4.8g/d (QD), or placebo. The primary endpoint of both studies was clinical and endoscopic remission using stringent criteria (modified UC Disease Activity Index score of no more than 1, with rectal bleeding and stool frequency scores of 0, no mucosal friability and at least a 1-point reduction in sigmoidoscopy score from baseline) at week 8.

Results: In men (n=256), 8-week remission rates were significantly higher in patients taking MMX mesalazine 2.4g/d (29.4%) and 4.8g/d (28.7%), than in those taking placebo (14.3%). Similarly, a significantly higher proportion of women (n=261) receiving MMX mesalazine achieved remission compared with placebo (22.4g/d: 44.8% [p < 0.001]; 4.8g/d: 41.4% [p < 0.01]; placebo: 20.7%). Although gender significantly affected remission rates (p=0.008 for all groups combined), logistic regression analysis of treatment by gender interaction indicated that there was no difference in MMX mesalazine effect by gender (p=0.920).

Conclusions: MMX mesalazine effectively induces clinical and endoscopic remission of mild-to-moderate, active UC in both men and women.

**P058 LEVELS OF DEPRESSION AND ANXIETY IN THE PATIENTS WITH IBD**

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Background and Aim: Inflammatory bowel disease (IBD) is according to the biopsychosocial model multifactorial in etiology and results from the interaction of genetic, immune, social and psychological factors. The aim of our study was to investigate the presence and levels of depression and anxiety in the patients with IBD.

Patients and Methods: Sixty-five patients admitted to Outpatients Clinic of the Department of Gastroenterology at University Hospital Centre Rijeka, participated in our study. There were 30 patients with Crohn’s disease and 35 patients with ulcerative colitis, aged 19 to 63 (M=40.83; SD=12.42) who filled the questionnaires (Beck Depression Inventory, Spielbergers Trait-Anxiety Inventory).

Results: The mean total depression score was 8.47 (SD=7.04) which is within normal range, but among them 6 patients (9%) had depressive symptoms with a score of 18 or above, reflecting clinically relevant depression and 15 patients (23%) had depressive symptoms with score ranging from 10 to 18, reflecting mild depression. The mean total anxiety score was 32.83 (SD=12.16) in Twenty-five patients (40%) had anxiety score of 35 or above reflecting elevated anxiety.

Conclusions: Depression and anxiety score are elevated in certain number of IBD patients and should deserve more consideration in the clinical treatment of those patients.

**P059 MMX MESALAZINE IS AN EFFECTIVE TREATMENT FOR ACTIVE, MILD-TO-MODERATE UC REGARDLESS OF PRIOR 5-ASA USE: A POOLED ANALYSIS OF TWO PLACEBO-CONTROLLED, PHASE III TRIALS**

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Introduction: Although 5-aminosalicylates (5-ASA) provide effective treatment for ulcerative colitis (UC), some patients may not respond to a particular therapy. For these patients, a dose increase may improve efficacy. If there are concerns about tolerability, or non-compliance resulting from the increased pill burden, there is a rationale to change therapy. MMX mesalazine is a high-strength (1.2g/tablet), oral 5-ASA therapy utilising Multi Matrix System (MMX) technology to extend consistent release of mesalazine throughout the entire colon. This analysis assessed whether prior 5-ASA use could influence efficacy in UC patients changed to MMX mesalazine. MMX and MMX Multi Matrix System are registered trademarks.

Methods: This was a retrospective analysis of pooled data from two randomised, double-blind, placebo-controlled, phase III trials (SPD476-301 and -302). Patients with active, mild to moderate UC received MMX mesalazine 2.4g/d (once daily [QD]) or 1.2g twice daily), MMX mesalazine 4.8g/d (QD), or placebo. Clinical and endoscopic remission rates at week 8 were calculated for patients who had changed directly from prior low-dose, oral 5-ASA therapy (taking oral 5-ASA therapy [no more than 2g/d] during the 5 days prior to baseline) and ‘previously untreated or discontinued’ patients (no prior oral 5-ASA, or discontinued oral 5-ASA therapy [no more than 2g/d] > 5 days prior to baseline).

Results: For patients changed directly from low-dose 5-ASA therapy (n=259), 8 week remission rates (95% confidence intervals) were 31.8% (23.0–40.2), 37.5% (27.1–48.1) [p=0.05 vs placebo] and 20.9% (13.3–30.0) in the 2.4g/d, 4.8g/d and placebo groups, respectively. For previously untreated/discontinued patients (n=258), remission rates were 42.9% (32.7–53.7 [p=0.001 vs placebo]), 33.0% (24.6–43.8 [p=0.01 vs placebo]) and 13.8% (7.3–22.6), respectively.

Conclusions: MMX mesalazine is an effective treatment for active, mild-to-moderate UC, irrespective of whether patients have changed directly from other 5-ASA therapies or are previously untreated/discontinued.