internet before discussing their therapy of choice with the gastroenterologist. 7% told that due to their activity in the IBD patients organization they already made their mind about a particular therapy option which they proceeded to discuss with their gastroenterologist. 7% of patients told that they decided for another therapy option the one recommended by their gastroenterologist, and 5% of patients noted that their gastroenterologist provided them with several therapy options, but they thought it is upon the gastroenterologist to select the appropriate treatment. Older patients (≥55 years of age) were more likely to choose the option that was proposed by the gastroenterologist for the appropriate treatment when compared to younger patients (<55 years) (12.7% vs. 3.6%, p<0.001). The shorter the disease duration the more frequently patients followed the therapy recommendation provided by their gastroenterologist. Conclusions: Younger IBD patients tend to be more actively involved in therapy decision-making than older IBD patients. The knowledge of patient-specific information seeking behaviors may help gastroenterologists to improve adherence to medical treatments in the long-term run.

Tu1268

Effect of Vedolizumab on Health-Related Quality of Life in Patients With Crohn's Disease


Background Vedolizumab (VDZ) is an alpha-4beta7 integrin antagonist for the treatment of Crohn's disease (CD). In the placebo (P) controlled GEMINI 2 trial, VDZ resulted in statistically significant improvements in clinical endpoints compared with PBO. The present analyses investigate the effect of VDZ on health-related quality of life (HRQoL) at week (wk) 52 in the GEMINI 2 population and its relationship with response and remission. Methods: In GEMINI 2, patients who responded to VDZ induction therapy at wk 6 received maintenance therapy with PBO or VDZ every 8 or 4 weeks (Q8W or Q4W) (maintenance ITT population). Exploratory endpoints included the change from wk 0 to 52 in the European Quality of Life-5 Dimension (EQ-5D) visual analog scale (VAS), Inflammatory Bowel Disease Questionnaire (IBDQ), and 36-item Short-Form Health Survey (SF-36) physical/mental component score (PCS/MCS). In post hoc analyses, the mean changes from wk 0 to 52 were stratified by baseline disease severity and prior failure to tumor necrosis factor antagonist (anti-TNF) therapy. Percentages of patients with a clinically meaningful improvement (CMI) in VDZ total score (≥16-point increase from wk 0 or total score ≥170 and improvements in VDQl by responder (20% point reduction in C-Activity Index (CAI)) score from wk 0 and remission (CDAI score ≤150) status at wk 52 were also assessed. All patients in these analyses received 2 doses of VDZ (half-life 20 days) during induction. Results: The mean change in IBDQ total score and SF-36 PCS/MCS from wk 0 to 52 were numerically greater with VDZ than with PBO. EQ-5D VAS scores were significantly greater with VDZ (Figure 1A). Similar trends were observed in patients stratified by disease severity and prior failure to anti-TNF therapy. In patients with prior anti-TNF failure, the differences between VDZ Q8W and PBO in EQ-5D VAS, SF-36 PCS were statistically significant. Rates of CMI in IBDQ total scores and of IBDQ scores ≥210 were generally higher with VDZ than with PBO (CMI: 64% Q8W, 74% Q4W, 63% PBO and score ≥210: 39% Q8W, 48% Q4W, 35% PBO). Responders and remitters showed statistically significant improvements in all scores versus non-responders and non-remitters, respectively (Figure 1B,C). Conclusions: These findings indicate that HRQoL benefits accompanied the clinical improvement experienced by patients who received VDZ in GEMINI 2. Treatment in HRQoL appear modest because of VDZ exposure during induction and potential carryover effect of patients non-randomized to PBO during maintenance. Reference: 1. Sandborn WJ, et al. N Engl J Med. 2013;369:711-721. The clinical studies were funded by Millennium Pharmaceuticals, Inc. (now Takeda Pharmaceuticals International Inc.). Medical editing was provided by Invenio Medical Communications and supported by Takeda Pharmaceuticals International, Inc.

Tu1267

The Effects of Infliximab Treatment Failure on Health-Related Quality of Life and Work Productivity in Patients With Crohn's Disease

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Background: A notable portion of patients with Crohn's disease experience relapse of disease activity despite ongoing infliximab (IFX) therapy. While handling IFX treatment failure is clinically and financially demanding, little is known about the impact on health-related quality of life (HRQoL) and work productivity in this situation. Methods: Pre-defined analysis of a 20-week randomized controlled clinical trial where 69 Crohn's disease patients (55 luminal, 7 fistulizing, 7 both) with IFX treatment failure (CD Activity Index (CAI) ≥220 or ≥21% reduction from baseline CAI) had been randomized to intensified IFX regimen or personalized therapy determined by IFX and anti-IFX antibody levels. HRQoL was assessed using the Short Inflammatory Bowel Disease Questionnaire (IBDQ). Productivity was assessed using the Work Productivity and Activity Impairment Questionnaire for Crohn's disease (WPAI-CD). NC1008S1565. Results: The IBDQ score at manifestation of IFX treatment failure was median 40, and this concurred with impaired HRQOL. Patients with clinical response (CAI decrease of ≥20% or ≥25% reduction of active fistulas) had significant improvement in IBDQ scores at all study visits. IBDQ score increased median 11 at week 4 and 8, and 13 at week 12 and 20 (p<0.01). In contrast, non-responders had a modestly lower increase in IBDQ scores and only at week 12 and 20 (median 4 and 5, p=0.03). Among employed patients (35%), missed time on work due to Crohn's disease was very low both at time of manifestation of IFX treatment failure (median 0%) and throughout all subsequent study visits (all medians ≤0.03). Furthermore, absenteeism was not significantly influenced by clinical outcomes (p=0.05). On the other hand, impairment while working was relatively high at time of IFX failure (median 40%) and this figure decreased only among responders at subsequent study visits (week 4 median 25%, p=0.05; week 8 20%, p=0.05; week 12 30%, p=0.01; week 20 10%, p=0.01). The overall daily activity impairment, respectively of employment status, was high at IBDQ treatment failure (median 70%), and decreased over time in responders (median at week 4, 8, 12, 20 was 20%, 30%, 30%, and 20%; p<0.001), and to a lesser extent also in non-responders (30%; p=0.05, 55%; p=0.05, 30%; p=0.05, and 40%; p=0.05). Conclusion: Therapeutic failure of IFX immediately causes major impairment of HRQOL and daily activity status, but patients who regain clinical response recover rapidly. Even though employed patients comprise a robust subgroup with a high threshold for absenteeism, IFX failure results in substantially lowered work productivity. Indirect disease related costs should be taken into account when evaluating consequences of IFX failure. (1) Steenholdt et al. Gut 2014; 63:919-27.

Tu1269

Psychological Profiling in Crohn's Disease: Emotion Processing Distress and Body Connection Issues Are Dominant Coping Strategies in Severe Disease

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Background: There is debate whether psychological treatments would benefit patients with Crohn's disease (CD). Emotion processing and body connection are central psychological constructs affected by chronic diseases. Emotion processing distress disrupts the process of absorbing disturbing events, and is experienced in anxiety attacks, colorectal cancer and chronic back pain ailments. Body connection is awareness of body states and cues, and is