

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 than 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 it is upon the gastroenterologist to select 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 therapeutic decision making when compared to 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.

Tu1266

Response to the Specific Carbohydrate Diet Amongst Individuals With Inflammatory Bowel Disease - A Survey of 122 Patients

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Background: The relationship between nutrition and inflammatory bowel disease (IBD) is a complex one, and little is known about the clinical implications of dietary modulation. Despite this, dietary interventions are a focus of high interest among patients. The Specific Carbohydrate Diet (SCD) was first introduced in the 1950's, initially to treat celiac disease, but has gained increasing popularity among patients with IBD. However there remains very limited study of its benefit amongst patients. The aim of this study was to survey experience and perceptions of the SCD in a large patient cohort (www.Crohnology.com). **Methods:** A descriptive analysis of patient experience of the SCD using data collected through a cross-sectional web-based survey. 4000 individuals with a diagnosis of IBD who had expressed interest in internet surveys (approximately 60% of all Crohnology users), were invited to participate in the study. The survey was completed by 246 individuals, of whom 66 (26.83%) reported current, and 56 (22.76%) prior SCD use. 66.4% of SCD users had CD and 34.8% had ulcerative colitis. The mean age of current SCD users was 35.25 years (SD 12.61, range 18-62 years), and disease duration was 5.56 years (SD 1.43, 95% CI 5.21-5.91 years). 98 (83.05%) individuals who had ever tried the SCD were in North America and 77 (66.36%) had either pancolitis, ileocolitis or ileal disease. Concomitant medication with aminosalicylates, thiopurines and biologics were recorded in 36.36%, 6%, and 12% of all current SCD users. Duration on the SCD was ≤ 3 months, 4-6 months, 7-9 months, 10-12 months and > 1 year in 20.55%, 16.44%, 6.85%, 9.59% and 46.58% respectively, with 26.03% reporting adherence to the SCD for 3 or more years. 52/62 (83.87%) current SCD users and 72/113 (63.72%) ever SCD users reported improvement in their IBD symptoms. Diarrheal symptoms improved in 66% and energy levels in 51.5% of current users. Reasons for discontinuing the diet were too difficult to follow in 21 (38.18%), too restrictive with not enough food choices in 5 (9.09%) and no improvement in IBD symptoms in 16 (29.09%). The majority of patients (81.2%) told their GI physician that they were on the diet, but only 27.45% felt their physician supported this decision. 77/244 of all responders reported first learning about the SCD via the internet with only 3 individuals stating their GI physician as the primary source. **Conclusion:** As far as we are aware, this is the largest study to assess experience and perceptions of the SCD among IBD patients. Two thirds of individuals reported an improvement in IBD symptoms with the diet and long term adherence of greater than 3 years noted in 26%. Given the likelihood that the SCD will continue to gain popularity and awareness among patients and its reported benefit, more studies to explore its effect on biological mechanisms are needed.

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 proportion 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 (CDAI ≥ 220 or ≥ 1 draining perianal fistula) had been randomized to intensified IFX regimen or personalized therapy defined by IFX and anti-IFX antibody levels. (1) HRQOL was assessed using the Short Inflammatory Bowel Disease Questionnaire (IBDQ). Productivity was assessed by the Work Productivity and Activity Impairment Questionnaire for Crohn's disease (WPAI:CD). NCT00851565. **Results:** The IBDQ score at manifestation of IFX treatment failure was median 40, and this concurred with impaired HRQOL. Patients with clinical response (CDAI decrease of ≥ 70 or $\geq 50\%$ 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 ($p < 0.001$). In contrast, non-responders had a very modest increase in IBDQ scores and only at week 12 and 20 (median 4, $p < 0.05$). Among employed patients (55%), 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%, $p > 0.05$). 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 10%, $p < 0.05$; week 8 30%, $p > 0.05$; week 12 30%, $p < 0.01$; week 20 10%, $p < 0.01$). The overall daily activity impairment, irrespectively of employment status, was high at IFX 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 (50%, $p < 0.01$; 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.

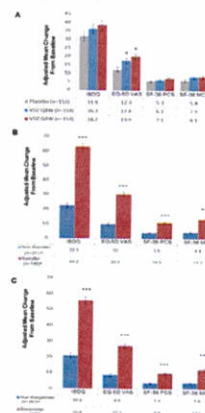
Tu1268

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

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Background: Vedolizumab (VDZ) is an $\alpha 4\beta 7$ integrin antagonist for the treatment of Crohn's disease (CD). In the placebo (PBO)-controlled GEMINI 2 trial,¹ 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 wks (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 IBDQ total score (≥ 16 -point increase from wk 0) or total score > 170 and improvements in HRQoL by responder (≥ 70 -point reduction in CD Activity Index [CDAI] 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 25 days) during induction. **Results:** The mean changes 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 by prior failure to anti-TNF therapy. In patients without prior anti-TNF failure, the differences between VDZ Q4W and PBO in IBDQ, EQ-5D VAS, and SF-36 PCS were statistically significant. Rates of CMI in IBDQ total scores and of IBDQ scores > 170 were generally higher with VDZ than with PBO (CMI: 64% Q8W, 74% Q4W, 63% PBO and score > 170 : 39% Q8W, 47% 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 differences in HRQoL appear modest because of VDZ exposure during induction and potential carryover effect in patients re-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. (d/b/a Takeda Pharmaceuticals International Co.). Medical editing was provided by inVentiv Medical Communications and supported by Takeda Pharmaceuticals International, Inc.

Figure 1: Mean change from baseline at week 52 (end of maintenance) in IBDQ, EQ-5D VAS, and SF-36 (PCS/MCS) scores (LOCF) in (A) all patients, (B) remitters, and (C) responders (maintenance ITT population)



Abbreviations: ANCOVA, analysis of covariance; CDAI, Crohn's Disease Activity Index; EQ-5D, European Quality of Life-5 Dimension; IBDQ, Inflammatory Bowel Disease Questionnaire; LOCF, last observation carried forward; MCS, mental component score; PCS, physical component score; Q4W, every 4 weeks; Q8W, every 8 weeks; SF-36, 36-item Short-Form Health Survey; VAS, visual analog scale; VDZ, vedolizumab.
* $p < 0.05$ vs PBO; ** $p < 0.01$ vs non-responder/non-remitters; *** $p < 0.001$ vs non-responder/non-remitters.
¹Data for EQ-5D VAS are for fewer patients: n=308 (non-remitters), 148 (remitters), 260 (non-responders), 196 (responders).
Remission status was defined by CDAI score ≤ 150 for remitters and ≤ 160 for non-remitters. Responder status was defined by ≥ 70 -point reduction in CDAI score from week 0 (responders) and ≥ 70 points (non-responders). Mean changes from baseline were adjusted using baseline scores as a covariate (ANCOVA, LOCF). Figure includes standard error bars.

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