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recorded. Each IBD pt with cancer (IBD-K) was matched with 2 IBD pts with no cancer (IBD-C) for IBD type (Crohn’s Disease, CD vs Ulcerative Colitis, UC), gender, age (±5 yrs). Statistical analysis: data expressed as median (range). Wilcoxon, Chi-squared, Fisher’s exact tests, multivariate logistic analysis were used.

Results: Incident cancer occurred in 236 IBD pts (IBD-K): 129 CD (CD-K), 107 UC (UC-K). The frequency of incident cancer was higher in CD vs UC (55% vs 45%; p=0.01). Incident cancers (n=236) included: digestive system (n=80; 34%), skin (n=32; 14%; 16 NMSC, 16 melanoma), urinary tract (n=25; 11%), lung (n=18; 8%), breast (10%; n=20), genital tract (6%; n=15), thyroid (n=8; 3%), lymphoma (n=10; 4%), others (n=24; 10%). Lymphoma (n=10) and small bowel cancers (n=8) occurred only in CD. Comparable cancer frequency in UC vs CD: digestive system (37% vs 31%; p=0.48); skin. (13% vs 15%; p=0.19); urinary tract (14% vs 9%; p=0.27). Colorectal cancer (CRC) frequency was higher in UC vs CD (32% vs 17%; p=0.02). Risk factors for any cancer considered: age (<40 vs ≥40 yrs), IBD duration (<10 vs ≥10 yrs), smoking (Y/N), ISS-anti-TNFs (Y/N), IBD-related surgery. UC extent, CD pattern (B3 vs B1, B2 vs B1), perianal CD. Significant risk factor for any cancer were UC-related surgery in UC [OR [95% CI]]: 5.78 [2.38–15.6I] and perforating pattern in CD: 1.72 [0.92–3.25I]. A higher proportion of pts with vs without cancer was considered as significant risk factors for incident cancer. Small bowel cancers and lymphoma occurred only in CD. A high frequency of second and third incident cancer was observed, thus supporting a higher cancer risk in subgroups of patients.

Conclusions: In a prospective, multicenter, nested-case control study, CD phenotype, penetrating CD and UC-related surgery were identified as significant risk factors for incident cancer. Small bowel cancers and lymphoma occurred only in CD. A high frequency of second and third incident cancer was observed, thus supporting a higher cancer risk in subgroups of patients.

OC.12.5
VEDOLIZUMAB TROUGH LEVELS AND CLINICAL OUTCOMES IN INFLAMMATORY BOWEL DISEASE
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Background and aim: Vedolizumab is an alpha4beta7 integrin antagonist for the treatment of inflammatory bowel disease (IBD). The role of drug monitoring, based on the assessment of Vedolizumab trough levels (VTL) and anti-Vedolizumab antibodies (AVA) has not been clarified.

Material and methods: Consecutive IBD patients who started therapy with Vedolizumab at our centre were prospectively enrolled. Each patient underwent 300 mg infusion at weeks 0, 2, 6 and 14; additional doses at week 10 and then every 4 weeks were given to non-responders at week 6. Clinical activity was evaluated by Harvey Bradshaw Index (HBI) and partial Mayo score (pMayo). Patients were followed up to a median of 36 months. VTL and AVA were assayed by ELISA (Theradiag) at weeks 6 and 14. Limits of detection for VTL and AVA were 2 μg/ml and 35 ng/ml, respectively. Clinical response was defined as at least 30% reduction of activity scores from baseline and remission was defined as HBI<5 or pMayo<2. Statistics was performed by Mann Whitney test, Spearman’s rho, ROC curve analysis.

Results: We included 66 patients (mean age 46.1 y; male 60%) with Crohn’s disease (CD, n=34) and Ulcerative colitis (UC, n=32). Median VTL measured at week 6 were significantly higher in clinical responders as compared to non-responders (41.3 vs 26.9 μg/ml, p=0.003), and in patients in clinical remission at week 14 (45.6 vs 27.9 μg/ml, p=0.03), at week 22 (46 vs 28.3 μg/ml, p=0.012) and at week 36 (40.2 vs 28.8 μg/ml, p=0.047) compared to non-remitters. By ROC curve analysis we identified a cut-off value for VTL of 40.3 μg/ml for clinical response at week 6 (AUC 0.714, sensitivity 51.6%, specificity 78.5%).