recorded. Each IBD pt with cancer (IBD-K) was matched with 2 IBD pts with no cancer (IBD-C) for:IBD type (Crohn's Disase, 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 tracts (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 observed penetrating CD (27% [35/129] vs 16% [41/258]; p=0.02) and in extensive UC (50% [53/107] vs 35% [75/213]; p=0.02). Second (n=11) or third incident cancers (n=2) occurred in 11 IBD pts.
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.12.4

PRIMARY SCLEROSING CHOLANGITIS ASSOCIATED WITH INFLAMMATORY BOWEL DISEASE: ANALYSIS OF INTESTINAL OUTCOME AFTER LIVER TRANSPLANTATION

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Background and aim: Primary sclerosing cholangitis (PSC) is a cholestatic disease frequently associated with inflammatory bowel disease (IBD), that often leads to orthotopic liver transplantation (OLT). Management of IBD before and after liver transplant for PSC can be challenging, as there are no official guidelines.
The aim of this study was to evaluate the differences of progression of intestinal disease between a group of transplanted and a group of non-transplanted IBD/PSC patients. Secondary objectives were to evaluate risk factors, including medical therapy, that could influence the IBD outcome, as well as the incidence of complications and mortality rates. Intestinal disease activity pre- and post-OLT was documented as well.
Material and methods: A retrospective analysis of 53 patients with a diagnosis of IBD/PSC was performed, with a total mean follow-up time of 18.4 years. The primary outcome was IBD activity, based on symptomatology, endoscopic assessment and drug use at the last follow-up examination, as well as anamnestic positivity criteria to a therapy non-responder disease (colectomy/intestinal resections, steroid dependency).
Results: During the follow-up period, 27 patients underwent liver transplant (22 UC,4 CD,1 IBDu); of them a total of 17 presented an unfavourable outcome of IBD, more than double the portion of non-transplanted patient (63% vs. 31%, P=0.04). Our analysis showed that poor IBD outcome can be associated with a tacrolimus-based immunosuppression (RR=2.15) more frequently than with other anti-rejection drugs (P=0.02); we found that an active IBD at the time of transplant (RR=2.05; P=0.05) or an earlier diagnosis of intestinal disease can be risk factors for a more aggressive IBD-course. Other possible risk factors for a poorer outcome are discontinuation of aminosalicylates after transplant, history of extraintestinal IBD manifestation or PSC complications and feminine gender. An increased risk of malignancy was detected, with a total of 13 people who developed colon dysplasia during follow-up (25% of total population), of whom 5 resulted in CRC (9%). Even if most of the analysed patient did not experience a change of disease activity after transplant, about 20% of the patients transplanted for PSC improved, whereas about 30% worsened.
Conclusions: Liver transplant, which is more common in UC patients due to the higher prevalence of PSC-related liver cirrhosis, seems to worsen the IBD natural history, although is not clear what are the mechanisms behind this increase in activity. The use of tacrolimus-based immunosuppression may be associated with an unfavourable outcome: in certain patients a shift from tacrolimus post-transplant maintenance treatment should be considered. Furthermore, OLT should be performed, when possible, on patients with non-active IBD at the time of transplant. This study also emphasises the importance of periodic endoscopic/histologic surveillance in IBD/PSC 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%,