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THERAPEUTIC STRATEGIES UTILIZATION AND RESOURCES CONSUMPTION IN PATIENTS AFFECTED BY CROHN DISEASE (CD) OR ULCERATIVE COLITIS (UC) IN AN ITALIAN REAL-WORLD SETTING, VENETO REGION

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OBJECTIVES: To analyze therapeutic strategies utilization and resources consumption in patients affected by Crohn Disease (CD) or Ulcerative Colitis (UC) in an Italian real-world setting, Veneto Region. **METHODS:** An observational retrospective cohort analysis of administrative databases of Veneto Region was performed. Patients with a hospitalization/discharge diagnosis of MC or UC (ICD-9-CM codes: 555-556) or exemption code for CD or UC (codes:009.555–009.556) from 01/01/2011 to 30/09/2016 (inclusion period) were included. The index-date (ID) was the 1st biologic agent prescription during the inclusion period. This study refers to patients naive to index biological agent during the inclusion period. All patients were characterized 12 months prior the ID and followed up after the ID for 9 months (Follow-up, F-up). **RESULTS:** We identified 18,133 patients with a diagnosis of MC or UC; mean age was 52.3 and 54.8% were males. CD and UC prevalence in the study population was estimated at 0.4% (denominator= 4,937,854). A total of 933 were naive to index biological agent; among them, 495 patients were treated with infliximab, 370 with adalimumab, 51 with golimumab and 17 with vedolizumab. It is important to mention that infliximab is tracked in our database starting from 2015 and vedolizumab starting from May 2016. The percentage of patients who required dose escalation, during F-up, was: 12.4% for adalimumab, 13.7% for golimumab, 7.3% for infliximab and none for vedolizumab. During the F-up, the percentage of patients who switched their ID therapy was: 5.7% for adalimumab, 15.7% for golimumab, 6.9% for infliximab and none for vedolizumab. Per patient disease cost at one year, was: €12,242 for adalimumab, €12,630 for golimumab, €10,203 for infliximab, €10,875 for vedolizumab. **CONCLUSIONS:** Our study is still ongoing. Given the limited patients in this early phase of study, the results are not conclusive yet. Final and detailed analysis will be presented at the end of the study.



GASTROINTESTINAL DISORDERS - Health Care Use & Policy Studies

PGI29

GENDER DIFFERENCES IN CLINICAL PROFILE AND HEALTHCARE UTILIZATION OF NON ALCOHOLIC FATTY LIVER PATIENTS

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OBJECTIVES: To compare the clinical profile and healthcare resource utilization of women vs. men with non-alcoholic fatty liver disease (NAFLD) in a large population-based study. **METHODS:** We identified NAFLD patients among 2.2 million people in the computerized database of a national payer-provider health fund in Israel using natural language processing of ultrasonography and dynamic imaging reports, diagnoses, fibrosis scores (>0.67) or consecutively elevated liver enzymes. Patients with viral hepatitis or alcoholism were excluded. Among active members on January 2017, NAFLD male patients were age-matched to female patients. Standardized mean differences (SMD) > 0.1 were regarded substantial. **RESULTS:** A total of 91,304 women and 102,243 men with NAFLD were identified, with a median age of 61 vs. 54 years old respectively. After age matching, the prevalence of cardiovascular disease was lower in women vs. men (17% vs. 29%, SMD=0.29) but similar for diabetes (30% vs. 33%), hypertension (51% vs. 50%), cancer (16% vs. 17%) and kidney disease (23% vs. 27%). Women exhibited higher median BMI (30.5 vs. 29.2, SMD=0.22), HDL and LDL (107 vs. 98), lower ALT (19 vs. 23, SMD=0.25), AST, triglycerides (127 vs. 131, SMD=0.10) and similar HbA1c. According to ultrasound, women had lower hepatic fat levels, with 59%, 23%, 18% vs. 49%, 27%, 24% for mild, moderate and high levels respectively. Women had more visits to primary care physicians (last 3 years) (median [IQR]: 29 [18-44] vs. 25 [14-39]) as well as nutritionists (34.3% vs. 29.0% with at least 1 visit, SMD=0.11), however, visits to gastroenterologists (37.9% vs. 35.3%) or hospitalizations (41.4% vs. 40.9%) were similar. **CONCLUSIONS:** This study provides a contemporary profile of gender-specific differences among NAFLD patients, which may shed light on possible genetic or behavioral differences and could be relevant for targeted screening and therapeutic considerations.



PGI30

POLISH THERAPEUTIC ALGORITHMS IN PATIENTS WITH COMPLEX PERIANAL FISTULAS IN CROHN'S DISEASE

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OBJECTIVES: Complex perianal fistula (CPF) is a chronic and relapsing disease representing a serious therapeutic challenge for both gastroenterologists and surgeons. Main reason for that is lack of any standardized treatment approach for about 12-14% of young patients with Crohn's disease (CD) who are affected by CPF. The aim of this study was to assess current therapeutic approach for the treatment of CPF in Poland. **METHODS:** The study was held from February to April 2018. It consisted of two parts: direct interviews with physicians (30 gastroenterologists and 15 surgeons) and medical records analysis including 75 patients with CPF who failed to respond to standard therapy. **RESULTS:** The management of patients



with CPF significantly differs depending on the experience of a medical center. The role of surgeon was differently perceived depending on the size and experience of the medical center, however the main approach was that gastroenterologists as physicians treating the underlying disease continue pharmacological treatment solely, whereas the surgeon is basically involved in treating complications specific to CPF that require surgical intervention. Among the analyzed 75 patients, in 41% pharmacological treatment solely was applied, whereas in 59% both pharmacological and surgical treatment was applied. The length of pharmacological therapy from the start to the decision to use the next line of treatment was 3 to 24 months. The time from the start of standard CPF treatment to the decision about surgical treatment was 10 to 18 weeks (only patients with surgical treatment analyzed) depending on the experience of the center. **CONCLUSIONS:** The study showed the lack of coordinated care of CPF patients in Poland, relevant differences in treatment patterns depending on the experience of the centers among medical centers and the necessity for extending the range and for improving collaboration between gastroenterologists and surgeons.

PGI31

PATTERNS OF ANTI-TNF ADOPTION AND DIFFUSION: REAL WORLD EVIDENCE FROM A 12-YEAR COHORT OF CROHN'S DISEASE AND ULCERATIVE COLITIS PATIENTS TREATED IN TERTIARY REFERRAL MEDICAL CENTERS IN ISRAEL

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OBJECTIVES: Anti-TNF drugs are widely used for treating various autoimmune diseases, but the existing knowledge on their adoption and long-term diffusion in clinical practice is scarce. We assessed the patterns of infliximab and adalimumab use in a cohort of Crohn's disease (CD) and Ulcerative colitis (UC) patients in Israel. **METHODS:** A list of patients with a confirmed IBD diagnosis was obtained from seven teaching hospitals participating in our study. Detailed information on infliximab and adalimumab prescription patterns over a 12-year period from 2003-2014 was provided by the patients' HMOs together with other health resource utilizations and patients' demographic data. The date when each of the drugs was covered and reimbursed in Israel for CD and UC was obtained from the Ministry of Health. We calculated the proportion of patients in which infliximab and adalimumab have been used throughout the study period. **RESULTS:** Our retrospective-cohort included 2,053 adult (18 years and older at the start of follow-up) IBD patients (1,333 CD, 720 UC) with a mean age of 38.9±14.9 years at the follow-up midpoint and a mean 8.7±3.5 years of follow-up. The proportion of patients treated with anti-TNFs increased substantially over the years from 4.0% in 2004 to 28.0% in 2014 in CD, and from 0.8% to 13.2% in UC. While the adoption and diffusion of both drugs follow a classical S-shaped curve, the proportion of patients treated with infliximab and adalimumab was similar in CD, but the use of infliximab for UC patients was two-fold higher. **CONCLUSIONS:** The use of infliximab and adalimumab increased substantially following their coverage and reimbursement in Israel with a growing proportion of patients treated with anti-TNFs over the study period. The difference in the use of infliximab and adalimumab may be a result of HMOs' policies regarding the drugs of choice, and physician or patient treatment preferences.



PGI33

URSODEOXYCHOLIC ACID TO GALLSTONE DISSOLUTION THERAPY IN ASYMPTOMATIC CHOLELITHIASIS PATIENTS: A SYSTEMATIC REVIEW OF THE EFFICACY AND SAFETY

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OBJECTIVES: Cholelithiasis is a disease that occurs in 80% of cases asymptomatic with incidental diagnosis made by other exams and may never evolve to the symptomatic form. However, has the risk of pancreatitis or cholangitis as complications. In Brazil, an oral treatment for gallstone dissolution has been a recurrent issue of judicialization. This study assessed evidence of the efficacy and safety of ursodeoxycholic acid (UDCA) to gallstone dissolution therapy in asymptomatic cholelithiasis patients. **METHODS:** Systematic searches for articles were conducted on electronic databases of MEDLINE, EMBASE and Cochrane Library. Searches strategies were constructed for each database using terms of interest and no filters. The Clinicaltrials.gov have also been searched for any published or unpublished study. Some of inclusion criteria were used and only Randomized Clinical Trials (RCT) and Systematic Reviews written in English, Portuguese or Spanish were selected. Data extraction was performed by two reviewers and verified by consensus. Quality assessment of evidence was based on GRADE system. **RESULTS:** Three RCT were elected from 25 full-text articles selected from 434 retrieved articles in electronic databases. These studies showed results favoring the UDCA when compared to placebo. However, the evidence quality of these 3 RCT was graduated as very low by GRADE criteria. This drug has been used for more than four decades and highlights the reduced amount of new studies about its effectiveness for biliary lithiasis. **CONCLUSIONS:** A very low evidence of these three studies, with small samples and drug doses heterogeneity, generates uncertainties about defined outcomes. Adverse events and long-term treatment with 50% of gallstone recurrence shows the need to careful recommendation for asymptomatic patients. Nevertheless, it would be an option for against indication to surgery or patients who need a solid organ transplant. Cholelithiasis has no indication for oral gallstone dissolution and the treatment should be surgical for the risk of pancreatitis.

