recognition that the severity of mucosa damage and its modification over time has strict implication with prognosis and management, should prompt the clinicians to a more extensive integration of CE in this field.

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Bile acid malabsorption incidence and diagnosis in clinical practice

B. Gros[1]*, L. Mena[2,3], J.M. Benítez[1,3], E. Carmona[2], S. Marín[1,3], F. Maza[2], R. Medina[3], V. García-Sánchez[1,3], E. Iglesias-Flores[1,3]
[1]*Reina Sofia University Hospital, Gastroenterology, Córdoba, Spain,* [2]*Reina Sofia University Hospital, Nuclear Medicine, Córdoba, Spain,* [3]*Instituto Maimónides de Investigación Biomédica de Córdoba, Córdoba, Spain*

Background: Bile Acid Malabsorption (BAM) is a well-known disorder whose understanding is increasingly recognised. Proper diagnostic methods and treatments are emerging in the last decades leading to a bigger relevance in clinical practice, although nowadays it is still underdiagnosed. The diagnostic challenge behind diarrhoea symptom carries an important economic expense. 75SeHCAT test is the current gold standard in Europe for diagnosing BAM. BAM is classified into type 1: secondary to ileal resection or disease; type 2 idiopathic; type 3 secondary to various gastrointestinal diseases (cholecystectomy, vagotomy, celiac disease, etc.). The aim of this study was to investigate the frequency of BAM with 75SeHCAT scanning among patients suffering from chronic watery diarrhoea and to compare the incidence in Crohn's disease (CD) patients with non CD.
Methods: We analysed retrospectively 81 patients with chronic diarrhoea, between August 2015 and October 2017. We included patients with inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), cholecystectomy, chronic pancreatitis among others. No patients had received treatment with bile acid sequestrants (Cholestyramine) before. We perform the test after the ingestion of a 75SeHCAT capsule (0.37 MBq) prior fasting the night before. Seven-day measurements were compared with 3 h activity to calculate the abdominal retention percentage. The interpretation of the retention results was ≥10% BA is consistent with a normal result. Mild BAM 7–10%, moderate 4–7% and severe <4% retention.
Results: We studied 51 women and 30 men, mean age 46.3. 40 suffered from Crohn's disease (CD), 2 ulcerative colitis (UC), 4 ileal resection due to neoplasia, 11 cholecystectomies, 1 Meckel diverticulum, 1 primary sclerosing cholangitis (PSC), 1 appendectomy, 2 IBS-Diarrhoea, 1 chronic pancreatitis, 1 eosinophilic colitis, 17 diarrhoea with no diagnosis. After performing 75SeHCAT scan, 75.3% had abnormal values. 80.3% severe malabsorption, 11.5% moderate and 8.2% mild malabsorption. When considering the classification of BAM, 54.3% were type 1, 25.9% type 2 and 19.8% type 3. Regarding to patients with ileal disease o ileal resection, 95.5% presented BAM (type 1). 39 were CD patients, 84.6% presenting intestinal resection. The rest of patients of our cohort presented 42.9% type 2-BAM and 62.5%-type 3.
Conclusions: A higher than expected incidence was found among the different groups. CD with chronic diarrhoea present high incidence of BAM when activity of their disease is discarded. According to BAM type 2 we found a higher number affected than those described in the literature. When studying diarrhoea as a symptom, BAM should be considered in the differential diagnosis.

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Predictive factors of a clinical severe course of Crohn's disease: A monocentric study

K. Agar*, L. Hamzaoui, S. Jardak, M. Medhioub, A. Khsiba, M.M. Azzouz
Med Taher Maamouri Hospital, GastroEnterology department, Nabeul, Tunisia

Background: Crohn's disease (CD) is a heterogeneous entity with an unpredictable course. Categorising patients into high and low risk of severe course of CD would enable clinicians to adapt treatment strategy (top-down or step-up) for a better outcome. The aim of this study was to assess the predictive factors of severe disease at presentation.
Methods: A retrospective study, including all patients diagnosed with CD in our Gastro-Enterology department between January 2007 and June 2017. A severe disease was defined by: three or more moderate to severe flares per year necessitating oral or intravenous corticosteroid therapy, need for surgery for a complication after diagnosis (ileocaecal resection for localised non-complicated disease was excluded) and presence of perianal disease at diagnosis.
Results: One hundred and twelve patients with CD were enrolled. Mean age of our patients was 42 years old (17–52). Fifty-one patients (45%) had non-stricturing non penetrating disease, 31 (28%) had stricturing disease, 20 (18%) patients had fistulising disease and 10 (9%) had stricturing and penetrating disease. Eighty-five patients (76%) presented with no severe disease and 27 (24%) had a severe course of CD. Patients with severe course of the disease had younger age at first diagnosis ($p = 0.02$). In univariate analysis, independent predictive risk factors for a severe course of CD were: complicated disease at diagnosis (stricturing or fistulising) ($p = 0.01$), active smoking ($p = 0.012$), disease extent at diagnosis > 50 cm ($p = 0.04$) and severe flare inaugurating the disease ($p = 0.04$). Nineteen patients (70%) with severe disease had surgery after a mean follow-up of 22.4 months and they all had an age < 30 years old with at least one of the four independent risk factors of severe disease.
Conclusions: Our study confirms that the course of CD might be predicted. Thus, treatment strategy can be adapted to the severity of the disease. Independent risk factors of an aggressive disease at diagnosis were: complicated disease at diagnosis, active smoking, disease extent at diagnosis > 50 cm and severe flare inaugurating the disease.

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Predictors of health-related quality of life in patients with newly diagnosed moderate to severe ulcerative colitis: Results from the MOSAIC cohort in Korea

Y.M. Park[1]*, C.K. Lee[1], S.N. Hong[2], J.P. Im[3], B.D. Ye[4], J.M. Cha[1], J.M. Cha[1], S.-A. Jung[5], K.-M. Lee[6], D.I. Park[7], Y.T. Jeen[8], Y.S. Park[9], J.H. Cheon[10], H.-S. Kim[11], Y. Kim[11], H.J. Kim[1]
[1]*Kyung Hee University, School of Medicine, Seoul, South Korea,* [2]*Sungkyunkwan University, School of Medicine, Seoul, South Korea,* [3]*Seoul National University, College of Medicine, Seoul, South Korea,* [4]*University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea,* [5]*Ewha Womans University, School of Medicine, Seoul, South Korea,* [6]*St. Vincent's Hospital, The Catholic University, Seoul, South Korea,* [7]*Kangbuk Samsung Hospital Sungkyunkwan University, Department of Internal Medicine,*

Seoul, South Korea, [8]Korea University, College of Medicine, Seoul, South Korea, [9]Eulji University, College of Medicine, Seoul, South Korea, [10]Yonsei University, College of Medicine, Seoul, South Korea, [11]Janssen Korea, Medical affairs, Seoul, South Korea

Background: There are limited data regarding disease burden and patient-reported outcomes (PROs) of inflammatory bowel disease in non-Western countries. The MOSAIK cohort is a Korean nation-wide, multi-centre, hospital-based inception cohort to reveal disease behaviour and long-term outcome in patients with newly diagnosed moderate to severe ulcerative colitis (UC) (ClinicalTrials.gov id: NCT02229344). We aimed to identify predictors of health-related quality of life (HRQoL) and to document burden of psychosocial distress shortly after disease onset in patients affiliated with the MOSAIK cohort.

Methods: Between August 2014 and March 2017, 355 consecutive patients were enrolled to the MOSAIK cohort. All patients were requested to complete four self-questionnaires within the first 4 weeks of diagnosis, including (1) 12-item short-form health survey (SF-12) and Inflammatory Bowel Disease Questionnaire (IBDQ) for HRQoL, (2) work productivity and activity impairment (WPAI) questionnaire for work disability, and (3) Hospital Anxiety and Depression scale (HADS) for emotional health. Linear regression analysis was used to evaluate predictive factors of HRQoL. Another logistic regression model was used to evaluate predictors of poor disease-specific QoL defined as total IBDQ score <170.

Results: In total, 59.2% (210/355) were male and the mean age was 37.6 years. Disease severity and extent were found to be major determinants of HRQoL in the linear regression. Severe disease was associated with poor social function and low total IBDQ score as well as low mental health score of the SF-12 (all $p < 0.05$). Extensive disease was associated with low levels of all domains of the IBDQ (excluding bowel system) and low mental/physical health scores of the SF-12 (all $p < 0.05$). When using predefined criteria (total IBDQ score <170), 78.1% (274/351) of patients was reported as having poor disease-specific QoL. Substantial numbers of patients have significant mood disorders as 16.7% for anxiety and 20.6% for depression (≥11 by HADS). About half of patients have severe work disability as work impairment for 46.2% and social activity impairment for 53.5% (≥50% by WPAI). Higher disease activity was a significant predictor of poor disease-specific QoL: odds ratio 1.50, 95% confidence interval 1.228–1.841 in the logistic regression.

Conclusions: Patients with newly diagnosed moderate-to-severe UC have a significant burden of poor QoL, psychological comorbidity and work disability within the first 4 weeks of their diagnosis. Disease severity and extent are useful predictors of HRQoL in these patients. Our results suggest that it is required to integrate HRQoL and other PRO measures into the routine initial assessment.

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Efficacy and safety of upadacitinib maintenance treatment for moderate to severe Crohn's disease: Results from the CELEST study

J. Panes[1]*, W.J. Sandborn[2], E.V. Loftus Jr.[3], G. Van Assche[4], S. Ghosh[5], Q. Zhou[6], S. Goteti[6], J.V. Enejosa[6], A.L. Pangan[6], A.P. Lacerda[6]

[1]Hospital Clínic Barcelona, IDIBAPS, CIBERehd, Barcelona, Spain, [2]University of California San Diego, La Jolla, USA, [3]Mayo Clinic, Division of Gastroenterology and Hepatology, Rochester, USA, [4]University Hospitals Leuven, Leuven, Belgium, [5]University of Birmingham, Birmingham, UK, [6]AbbVie Inc., North Chicago, USA

Background: The efficacy and safety of upadacitinib (UPA), an oral selective JAK1 inhibitor, as induction therapy were reported in patients with moderate to severe Crohn's disease (CD) who had inadequate response/intolerance to an immunomodulator or tumour necrosis factor antagonist. [1] Results from the extension phase of the CELEST study are described.

Methods: All patients who completed the 16-week induction phase were re-randomised 1:1:1 to receive double-blind immediate release formulation of UPA at 3 mg twice daily (BID), 12 mg BID or 24 mg daily (QD) for 36 weeks. The 24 mg QD arm was later stopped and a 6 mg BID arm was initiated to evaluate an intermediate maintenance dose. Clinical remission, modified clinical remission, clinical response, endoscopic remission, endoscopic response (all defined in Table), CDAI <150, and change from BL in C-reactive protein (hsCRP) and faecal calprotectin (FC) were analysed at week 52 in patients who received UPA induction therapy and achieved clinical response with or without endoscopic response at week 16. Non-responder imputation was applied to patients who received open label UPA, prematurely discontinued prior to week 52 or initiated corticosteroid or received dose higher than BL. Last observation carried forward was used for missing post-BL hsCRP and FC data. Adverse events (AEs) were collected throughout the study up to 30 days after the last UPA dose.

Results: A total of 153 patients who received UPA induction therapy were analysed for efficacy endpoints among 180 patients re-randomised at Week 16. Dose-dependent increases in rates of modified clinical remission and endoscopic remission were observed with the 3, 6, and 12 mg BID arms (Table). Rates of clinical, enhanced clinical, and endoscopic responses were generally higher in the 6 and 12 mg BID arms. In the safety population (n = 178), no dose-dependent effect was observed in UPA at 3, 6, 12 mg BID and 24 mg QD for AEs (45/60 [75.0%], 14/23 [60.9%], 43/59 [72.9%] , and 23/36 [63.9%]), serious AEs (15 [25%], 2 [8.7%], 5 [8.5%], 4 [11.1%]) and infections (22 [36.7%], 6 [26.1%], 22 [37.3%], and 10 [27.8%]). Two malignancies (Hodgkin's disease and malignant neoplasm of thymus) occurred in the 12 mg BID arm. No deaths occurred.

Table. Clinical and endoscopic endpoints[a] at Week 52 in the CELEST study.

Endpoint at Week 52	UPA 3 mg BID	UPA 6 mg BID	UPA 12 mg BID	UPA 24 mg QD
Among patients who achieved clinical response and endoscopic response at Week 16				
Modified clinical remission, n/N (%)	7/17 (41.2)	5/8 (62.5)	11/15 (73.3)	4/10 (40.0)
Endoscopic remission, n/N (%)	5/20 (25.0)	2/8 (25.0)	6/16 (37.5)	1/10 (10.0)
Endoscopic response, n/N (%)	10/20 (50.0)	4/8 (50.0)	11/16 (68.8)	3/10 (30.0)
Among patients who achieved clinical response at Week 16				
Modified clinical remission, n/N (%)	8/28 (28.6)	6/14 (42.9)	14/27 (51.9)	7/18 (38.9)
Clinical remission, n/N (%)	8/32 (25.0)	4/14 (28.6)	12/29 (41.4)	6/19 (31.6)
CDAI <150, n/N (%)	14/32 (43.8)	7/14 (50.0)	16/29 (55.2)	7/19 (36.8)
Enhanced clinical response, n/N (%)	15/32 (46.9)	10/14 (71.4)	18/29 (62.1)	8/19 (42.1)
Clinical response, n/n (%)	16/32 (50.0)	10/14 (71.4)	18/29 (62.1)	8/19 (42.1)
Endoscopic remission, n/N (%)	5/32 (15.6)	3/14 (21.4)	7/29 (24.1)	5/19 (26.3)
Endoscopic response, n/N (%)	11/32 (34.4)	5/14 (35.7)	13/29 (44.8)	7/19 (36.8)
Mean change from BL in hsCRP ± SD, mg/L	-2.8 ± 18.9 n=30	-2.1 ± 18.4 n=14	-13.9 ± 37.1 n=28	10.2 ± 55.7 n=17
Mean change from BL in FC ± SD, µg/g	1.0 ± 2457.2 n=26	-239.3 ± 1443.1 n=12	-2617.4 ± 3232.0 n=18	-1510.3 ± 2773.9 n=10

[a]Endoscopies were evaluated at BL, 12 or 16 (per randomization schedule), and 52 weeks by a central reader.

Modified clinical remission: SF ≤2.8 and AP ≤1.0, both not worse than BL in patients with SF≥4 or AP≥2.0 at BL.
Clinical remission: SF ≤1.5 and AP ≤1.0 and both not worse than induction BL.
Enhanced clinical response: ≥60% reduction from induction BL in SF or ≥35% reduction from induction BL in AP and both not worse than BL or modified clinical remission.
Clinical response: ≥30% reduction from BL in SF or ≥30% reduction from BL in AP and both not worse than BL.
Endoscopic remission: SES-CD ≤ 4 and at least 2-point reduction from BL and no subscore >1.
Endoscopic response: SES-CD reduction >50% from BL or endoscopic remission.

Conclusions: Dose-dependent improvements in clinical and endoscopic outcomes and markers of inflammation with UPA were observed with 36-week treatment in patients who responded to a 16-week induction regimen. The overall safety profile of UPA is consistent with other studies in rheumatoid arthritis.