

with reduced rates of gallstones. Niacin may interact with other sex-specific risk factors affecting lipids namely hormone replacement therapy (HRT) and parity. This epidemiological study investigated whether dietary niacin reduces the risk of developing symptomatic gallstones (SGs), for the first time using 7-day food diaries (7-DFDs), the most accurate dietary assessment method in large prospective studies.

Methods 25,639 participants (54.7% women), aged 40–74 years, enrolled in the European Prospective Investigation into Cancer-Norfolk (EPIC-Norfolk). At recruitment, participants completed 7-DFDs which recorded 1 week's diet including information on recipes, brands, and portion sizes. Nutrient intakes were calculated using a computer program containing nutrient information on 11,000 foods. The cohort was monitored for 14 years to identify participants developing SGs. Cox proportional hazards regression models estimated the sex-specific hazard ratios (HRs), for SGs for quartiles of niacin intake, adjusted for covariates. Binary analyses were performed using the UK reference nutrient intake (RNI) for niacin, and in sensitivity analyses according to HRT use and parity.

Results SGs developed in 200 women (mean time to diagnosis=6.0 years SD=2.9 years) and 95 men (mean time to diagnosis=5.9 years SD=3.0 years), and 10.3% of diagnoses were AP. In women, total dietary niacin was associated with a reduced risk of SGs (highest vs lowest quartile HR=0.59 95% CI=0.39–0.91; HR trend=0.85 95% CI=0.74–0.98 p=0.022). The population attributable fraction for niacin intake was 16.3%. Eating the UK RNI for niacin was inversely associated with the risk of SGs in parous women (HR=0.63 95% CI=0.45–0.89 p=0.009), but not in nulliparous women (HR=1.65 95% CI=0.45–6.00 p=0.447). Meeting the UK RNI for niacin was inversely associated with the risk of SGs in women who had never used HRT (HR=0.53 95% CI=0.35–0.81 p=0.003), but not in previous or current users. In men, there were no significant associations for niacin (HR trend=0.92 95% CI=0.75–1.13 p=0.430).

Conclusions This data supports a role for dietary deficiencies of niacin in the development of SGs in women, but not men, with effect modification according to HRT use and parity. If further epidemiological studies confirm our findings, then dietary recommendations to increase niacin intake may help prevent the complications of gallstones, including AP.

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A REAL WORLD SINGLE CENTRE EXPERIENCE OF SERUM IGG4 TESTING AND CORRELATION WITH CLINICAL OUTCOMES

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Introduction Immunoglobulin G4 related disease (IgG4-RD) is a rare, multi-system, fibroinflammatory condition that is increasingly recognised but proves a significant diagnostic challenge. In recent years more reliable diagnostic criteria based on clinical, biochemical, radiological and histological findings have set out to improve differentiating IgG4-RD from non IgG4-RD. Elevated serum IgG4 is not specific for the disease but is often the first investigation when there is suspicion of IgG4-RD. With the increasing use of serum IgG4, the aim of this study was to assess its real world utilisation and describe

the diagnostic approach in those with raised levels in a non-specialist centre.

Methods All measurements of serum IgG4 performed in a district general hospital in South Wales (UK) over 5 years were evaluated. In this retrospective observational study those individuals with raised levels were further analysed to assess demographics, clinical presentation, diagnostics and eventual diagnosis. In those with a diagnosis of IgG4-RD, both treatment and response were reviewed.

Results 655 serum IgG4 measurements were performed on 560 patients. Of the 560 patients, serum IgG4 was raised ($\geq 1.35 \text{ g l}^{-1}$) in 81 (14.5%) and only 13 (2.3%) had a final diagnosis of IgG4-RD. In those with elevated serum IgG4 59 (72.8%) patients were tested for the purpose of differentiating IgG4-RD and non IgG4-RD. The median serum IgG4 in those diagnosed with IgG4-RD was 3.4 g l^{-1} ; this was 2.2 g l^{-1} in those with raised levels in non-IgG4-RD. Of the 13 patients diagnosed with IgG4-RD the majority had pancreatobiliary disease; 4 patients with pancreatitis and 3 with sclerosing cholangitis. 11 patients with IgG4-RD were treated with corticosteroids at diagnosis with initial clinical response in all. Long term treatment included corticosteroids, azathioprine, methotrexate and mycophenolate with 3 patients on dual therapy.

Conclusion Awareness of IgG4-RD is increasing and serological tests are requested with increasing frequency. However, only a small minority of patients found to have elevated serum IgG4 turn out to have IgG4-RD. The lack of specificity of raised serum IgG4 levels and the variable presentation of disease reinforce the importance of collecting data of patients found to have IgG4-RD. Given that not all cases of IgG4 RD have elevated levels, systematic review and clinical follow up of patients with suspected disease is necessary.

P257

REAL WORLD EXPERIENCE OF THE NEW ACR-EULAR CLASSIFICATION CRITERIA FOR IGG4-RELATED DISEASE

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Introduction IgG4-related hepatopancreatobiliary disease (IgG4-HPB) is part of a complex fibro-inflammatory systemic condition. It is critical to distinguish IgG4-HPB from malignant and inflammatory disease mimics to guide long-term management. The 2019 ACR/EULAR Classification Criteria for IgG4-related disease (IgG4-RD) were developed and validated in a large international cohort and reported to have excellent diagnostic specificity.¹ We sought to evaluate this in real-world clinical practice through our supra-regional Oxford-London IgG4-RD multi-disciplinary meeting (MDM).

Methods We prospectively collected data on 153 patients referred to our IgG4-RD MDM over 4-years with suspected IgG4-RD (Clin Med, Jan 2020 *in press*). Each was classified as definite, possible or not IgG4-RD based on existing diagnostic criteria (HISORT, CDC, Boston Histopathology) and speciality experience. We retrospectively applied the ACR-EULAR classification criteria to this cohort to assess concordance with MDM outcomes.

Results All cases considered not IgG4-RD in the MDM (n=52) similarly did not meet ACR/EULAR criteria. Of those considered definite IgG4-RD (n=63) in the MDM, only half (33;52%) met ACR/EULAR criteria. In those with definite HPB involvement (n=48) in the MDM, just over half (27;56%) met ACR-EULAR criteria. Most of the IgG4-HPB patients not meeting ACR/EULAR criteria scored insufficient diagnostic points (n=17) due to reliance on pancreatic imaging characteristics; diffuse swelling and pseudocapsule, with no points awarded for cholangiopathy without pancreatic involvement, atrophy, or focal enlargement of the gland. Small and unrepresentative biopsies were an additional challenge. Specific exclusions were absence of glucocorticoid response in advanced (fibrotic) cholangiopathy, and Crohn's disease or ulcerative colitis in isolated HPB involvement.

Conclusions The ACR-EULAR classification demonstrated excellent specificity (100%) and will be an invaluable tool for clinical trials. Disparity between diagnosis according to our IgG4-RD MDM and the ACR/EULAR criteria are explained by specific pancreatic imaging characteristics, absence of cholangiopathy/hepatopathy as a unique entity, and the necessity for steroid responsiveness even if presenting with advanced cholangiopathy.

REFERENCE

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P258 IS REPEATING FAECAL ELASTASE WORTHWHILE?

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Background Faecal elastase-1 (FE1) is the only widely available test for pancreatic exocrine insufficiency (PEI). However, FE1 is thought to misclassify approximately 10% of patients. False negatives delay treatment with pancreatic enzyme replacement therapy (PERT). False positives expose patients to unnecessary intervention, and the NHS to unnecessary costs. We studied the practice of repeating FE1 at our trust, its impact on being treated, and the predictors of reclassification of PEI diagnosis on repeat testing.

Methods We carried out a retrospective study at a London teaching hospital. All outpatients investigated with FE1 between 2012 and 2018 were identified. Demographic and clinical information was retrieved from the electronic medical record. PEI was defined as FE1 <200 µg/g. Where FE1 had been repeated, any change to PEI diagnosis was recorded. Univariable logistic regression was used to explore the dependence of having FE1 repeated and reclassification of PEI diagnosis on age, sex, ethnicity, presenting symptoms, comorbidities, and the initial FE1 result (grouped into FE1<100 µg/g, 100–199 µg/g, 200–299 µg/g and ≥300 µg/g). Exposure variables with significant associations (p<0.05) in the univariable analysis were incorporated into a multivariable logistic regression model. Univariable logistic regression was used to explore the association between having more than one positive FE1 result and being prescribed PERT. Firth's method of penalized likelihood was used to reduce bias in cases of

complete separation. Complete case analysis was used where any data were missing.

Results 1027 patients were included; mean age 53 years; 42.5% male; 54.5% white ethnicity. In total, 124 patients (12.1%) had their FE1 repeated. The median time to repeat FE1 was 5.4 months. 39 patients (31.5%) had their PEI status reclassified on repeat FE1; 28 patients from PEI to no PEI, and 11 from no PEI to PEI. On univariable analysis, diabetes mellitus, chronic pancreatitis and initial FE1 result were associated with having FE1 repeated. In the multivariable analysis, only initial FE1 result remained a significant predictor of having FE1 repeated (FE1 <100 µg/g: OR 4.66, 95% CI 2.76–7.87; FE1 100–199 µg/g: OR 7.26, 95% CI 4.21–12.5; FE1 200–299 µg/g: OR 3.53, 95% CI 1.88–6.61; all p<0.001). Initial FE1 100–200 µg/g was the only significant predictor of reclassification of PEI diagnosis on repeat testing (OR 6.91, 95% CI 2.39–19.95; p=0.007). Patients with more than one positive FE1 result were almost four times more likely to receive PERT than patients with a single positive result (OR 3.82, 95% CI 1.5–9.75; p=0.005).

Conclusions False positive and false negative FE1 results are common, and clinicians might be reluctant to prescribe PERT after one positive result. We recommend repeating FE1 routinely in all patients with FE1 <300 µg/g.

P259 ABNORMAL PANCREATIC IMAGING AND NUTRITION BIOCHEMISTRY PREDICT RESPONSE TO PANCREATIC ENZYME REPLACEMENT THERAPY

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Background Pancreatic enzyme replacement therapy (PERT) is a safe and effective treatment for pancreatic exocrine insufficiency (PEI). Approximately 80% of patients report symptomatic improvement with treatment, however the predictors of clinical response are unknown. We examined the investigation and management of patients with PEI at our trust, and studied the associations with clinical response to PERT.

Methods We carried out a retrospective study at a London teaching hospital. All outpatients diagnosed with PEI, defined as FE1<200 µg/g, between 2012 and 2018 were identified. Demographic and clinical information was retrieved from the electronic medical record. Patients with a positive followed by a negative FE1 were excluded. We noted the proportion of patients investigated with pancreatic imaging and nutritional blood tests within 6 months of diagnosis. Nutritional blood tests were defined as ≥3 of serum ferritin, folate, vitamin B12, vitamin D, magnesium and albumin. In addition, we noted the proportion of patients prescribed PERT, the initial dose, referral to dietetics and clinical response to treatment. Binary logistic regression was used to study the dependence of clinical response to PERT on PEI severity, initial dose prescribed, referral to dietetics, abnormal pancreatic imaging and abnormal nutritional blood tests. Complete case analysis was used where data were missing.

Results 182 patients were diagnosed with PEI; 60.4% severe (FE1<100 µg/g); mean age 56.4 years; 51.1% male; 47.8% white ethnicity. 149 patients (81.9%) underwent pancreatic imaging, with ultrasound (23.5%), CT (60.4%), MRI (15.4%) or EUS (0.7%). Poor views of the pancreas were reported in