

(mean  $\pm$  ds 25  $\pm$ 32mcg/ml vs 34  $\pm$ 27 mcg/ml respectively,  $p=0.22$ ). In the UC group we found a statistically significant correlation of both calprotectin and S100A12 with CRP ( $r=0.253$ ,  $p=0.044$  and  $r=0.252$ ,  $p=0.040$ , respectively). In CD group we found that both calprotectin and S100A12 correlated with hemoglobin ( $r=-0.343$ ,  $p=0.024$ ;  $r=-0.401$ ,  $p=0.008$  respectively), hematocrit ( $r=-0.361$ ,  $p=0.046$ ;  $r=-0.434$ ,  $p=0.015$ , respectively), fibrinogen ( $r=0.499$ ,  $p<0.001$ ;  $r=0.325$ ,  $p=0.038$ , respectively), and white blood cells count ( $r=0.309$ ,  $p=0.044$ ;  $r=0.394$ ,  $p=0.021$ , respectively). Moreover, in CD group, FC correlated with CRP ( $r=0.431$ ,  $p=0.004$ ) and erythrocyte sedimentation rate ( $r=0.430$ ,  $p=0.004$ ). Finally, S100A12 correlated with platelet count both in CD and UC group ( $r=0.351$ ,  $p=0.021$  and  $r=0.254$ ,  $p=0.038$ , respectively) IBD children in clinical relapse had higher values of S100A12 and FC than patients in remission ( $66\pm47$  mcg/ml vs  $43\pm42$  mcg/ml,  $p=0.05$  and  $260\pm192$  mg/Kg vs  $166\pm169$  mg/Kg,  $p=0.046$ , respectively)

**Conclusion:** Our preliminary data show that both faecal S100A12 and FC are useful non-invasive biomarkers which reflect inflammatory activity of IBD children. Our future aim is to evaluate the correlation of S100A12 and endoscopic finding in order to further clarify its role in the diagnosis and the management of pediatric IBD.

## P215

### Blood-based prognostic biomarkers in Crohn's patients treated with biologics: a new promising tool to predict endoscopic outcomes

M. Grova<sup>\*1,2</sup>, F. Crispino<sup>1,2</sup>, M. Maida<sup>3</sup>, S. Renna<sup>1</sup>, F. Mocciano<sup>4</sup>, A. Casà<sup>1</sup>, G. Rizzuto<sup>1</sup>, D. Scimeca<sup>4</sup>, R. Di Mitri<sup>4</sup>, F.S. Macaluso<sup>1</sup>, A. Orlando<sup>1</sup>

<sup>1</sup>A.O.O.R. Villa Sofia-Cervello, Inflammatory Bowel Disease Unit, Palermo, Italy, <sup>2</sup>University of Palermo, Department of Health Promotion Sciences Maternal and Infant Care- Section of Gastroenterology & Hepatology- Internal Medicine and Medical Specialties PROMISE, Palermo, Italy, <sup>3</sup>S.Elia-Raimondi Hospital, Section of Gastroenterology, Caltanissetta, Italy, <sup>4</sup>ARNAS Civico - Di Cristina - Benfratelli Hospital, Gastroenterology and Endoscopy Unit, Palermo, Italy

**Background:** There is a growing need for biomarkers of inflammation to monitor and predict therapeutic outcome in Crohn's disease (CD) patients. We aimed to evaluate whether the level of circulating blood cells, expressed as ratios (NLR, neutrophil-to-lymphocyte ratio; PLR, platelet-to-lymphocyte ratio; ELR, eosinophil-to-lymphocyte ratio and ENLR, eosinophil\*neutrophil-to-lymphocyte ratio), could be used as early prognostic biomarker of endoscopic response (ER) in patients starting biological therapy with infliximab, adalimumab, vedolizumab and ustekinumab. Association with steroid-free clinical remission at week 54 and endoscopic disease activity at baseline, as well as other variables related with ER were also evaluated as secondary outcomes.

**Methods:** Consecutive patients with CD who started biological therapy between June 2016 and July 2019 in two Italian tertiary centers were enrolled. We used multivariate analysis to evaluate whether NLR, PLR, ELR and ENLR at baseline and after 12 weeks of treatment could predict ER (SES-CD  $\leq 2$  or SES-CD  $\leq 2$  and Rutgeerts score i0-i1) after 54 weeks of treatment. Receiver operating characteristic (ROC) curves were generated to identify the area under the curve (AUC) and find the best cut-off values of NLR, PLR, ELR and ENLR for the prediction of ER. To enhance the diagnostic

performance, these ratios were combined with baseline Harvey Bradshaw Index (HBI) in a prognostic model.

**Results:** 107 patients were included. Patients who achieved ER had significantly lower baseline NLR ( $p=0.025$ ), ELR ( $p=0.013$ ) and ENLR ( $p=0.021$ ) compared with those without ER; similar results were confirmed after 12 weeks of treatment for ELR ( $p=0.006$ ) and ENLR ( $p=0.026$ ). AUC was 0.64 ( $p=0.003$ ), 0.67 ( $p=0.006$ ) and 0.65 ( $p=0.014$ ) for NLR, ELR and ENLR, respectively. The best cut-offs values were included in the HBI-based prognostic model: 81.8% of patients with HBI  $\geq 5$  and higher ratios did not achieve ER, while all patients with HBI  $< 5$  and lower ratios reached ER. Interestingly, ENLR was found to be linearly associated with SES-CD at baseline ( $p=0.035$ ).

**Conclusion:** To the best of our knowledge, this is the first study assessing NLR, ELR and ENLR as predictive markers of therapeutic response in CD patients. Low levels of these ratios can predict endoscopic response and could be used in clinical practice for a better management of CD patients needing biological therapy. Further prospective studies are needed to confirm these results in larger cohorts.

## P216

### Comparative Assessment C-reactive Protein Between a Point-of-Care Testing and Current Standard of Care (Immunonephelometric testing)

G. Lorenzon<sup>1</sup>, I. Marsilio<sup>1</sup>, D. Maniero<sup>1</sup>, A. Rigo<sup>1</sup>, B. Barberio<sup>1</sup>, F. Zingone<sup>1</sup>, B. Bahur<sup>2</sup>, K.R. Bray<sup>3</sup>, E.V. Savarino<sup>\*1</sup>

<sup>1</sup>Padua University Hospital, Department of Surgery- Oncology and Gastroenterology, Padua, Italy, <sup>2</sup>ProciseDx, Department of Clinical Trials, San Diego, United States, <sup>3</sup>ProciseDx, Department of Clinical Development and Medical Affairs, San Diego, United States

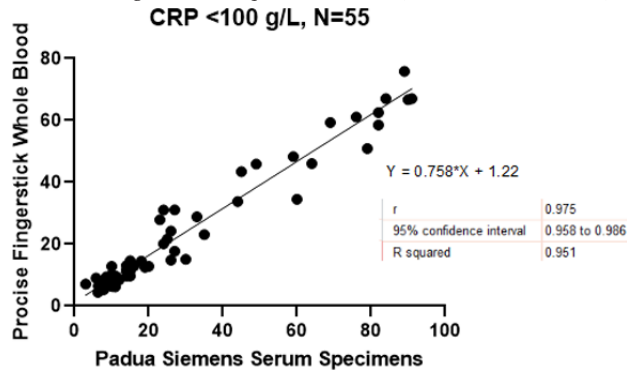
**Background:** C-reactive protein (CRP) is widely used as a biomarker of inflammatory disease activity in hospitalized and non-hospitalized patients. In particular, CRP is commonly used in patients suspected to have an inflammatory bowel disease (IBD) or with a confirmed diagnosis of IBD diagnosis in order to drive the diagnostic approach, to monitor disease activity and to guide therapeutic adjustments. However, standard laboratory CRP testing (Immunonephelometric assays) present some drawbacks, including a turnaround time of 1–2 hours, and the need of specialized equipment, offices and laboratory personnel. Because of that, point-of care testing (POCT) was recently developed in order to provide results within 2 minutes from blood collection, enabling a rapid response to clinical condition.

**Aim:** To determine the degree of analytical correlation between a recently developed POCT (ProciseDx) using capillary whole blood and the comparative Immunonephelometric assay using serum samples.

**Methods:** From October to November 2020, consecutive patients hospitalized at Gastroenterology Unit, Padua University Hospital, aged  $> 18$  years and with clinical evidence of active inflammatory disease or infection, who underwent to a standard of care CRP test (Dimension Vista – Siemens Healthineers) were included in the study (range 2.9–340 g/L). Within 1 hour from blood collection, in each patient, CRP quantitation from capillary whole blood collected by finger stick was performed using the ProciseDx CRP assay, with reportable range between 3.6–100 g/L. A Deming regression test was used to identify the correlation between the two methods.

**Results:** Eighty-three patients were enrolled (62.5% males with mean age  $\pm$  SD: 60 $\pm$ 18). The most common indications for hospitalisation were liver disease (34.9%), pancreatic disturbance (27.7%)

and suspicious or recurrence of IBD (16.7%). ProciseDx POCT with finger prick samples required a turnaround time of  $2\pm 0.2$  minutes, whereas serum samples analyzed in clinical laboratory with the reference method required a turnaround time of about  $180\pm 15$  minutes ( $p<0.001$ ). Overall, the correlation between the two tests was high (R squared of 0.899 (95% CI 0.916–0.968)). In particular, the correlation between the methods was even higher with CRP values between 0–100 g/L with R squared of 0.961 (95% CI 0.958–0.986).



**Conclusion:** The ProciseDx POCT allows a more rapid and comparable accuracy of CRP assessment in hospitalized patients as compared to the standard laboratory measurement. Moreover, the ProciseDx POCT does not require specialised personnel to be performed. The use of ProciseDx POCT may improve and accelerate the decision-making approach, further reducing the resources required for CRP assessment.

## P217

### Clostridium Difficile Infection as a cause of severe outcomes in patients with Inflammatory Bowel Disease

N. Fadeeva\*<sup>1</sup>, O. Knyazev<sup>1</sup>, A. Parfenov<sup>1</sup>, A. Kagramanova<sup>1</sup>, A. Lishinskaya<sup>1</sup>, A. Babayan<sup>1</sup>, M. Danilov<sup>1</sup>, I. Dolgopyatov<sup>1</sup>  
<sup>1</sup>A.S. Loginov Moscow Clinical Scientific Center, Department for IBD, Moscow, Russian Federation

**Background:** The prevalence of Clostridium difficile infection (CDI) in patients with inflammatory bowel disease (IBD) is higher than in general population. CDI may produce a negative effect on the clinical course of IBD. The aim of the study was to define the frequency of CDI in patients with IBD and to study risk factors that predict severe outcomes associated with CDI in IBD patients.

**Methods:** 1278 medical records were analyzed in a retrospective study of patients with IBD, of which 808 patients met the inclusion criteria. Patients were divided into 2 groups based on the presence of a preliminary diagnosis of CDI. Our primary outcome was time to total colectomy or death with follow-up censored at 180 days after CDI. Statistical analysis was carried out using Pearson Chi-square and two-sample t-test.

**Results:** The frequency of CDI in patients with IBD was 17.6%. The mean age of occurrence of CDI in patients with IBD was  $37.8\pm 12.9$ . The first group included 143 patients CDI+IBD, and the second group - 665 patients IBD without CDI. In the first group C-reactive protein, erythrocyte sedimentation rate and fecal calprotectin levels were significantly higher and albumin level was lower than in the second group ( $p<0.05$ ). The average albumin level in the first group was  $20.8\pm 1.83$  mg/l, in the second group -  $38.7\pm 2.36$  mg/l ( $p<0.05$ ).

Only 25.3% of all patients with CDI had a history of antibiotic use, and 30.4% had previously used steroids. Long-term immunosuppressive therapy in patients with IBD has an impact on the development of CDI: among patients with CDI 48.7% long-term received azathioprine/6-mercaptopurine, in patients without IBD - 18.3% ( $p<0.001$ ). Only 19% of patients with CDI had control of the disease with salicylate therapy, while 62% of patients without CDI achieved remission by taking salicylates ( $p<0.05$ ). Of these, 7 patients (4.9%) met our primary outcome (1 death, 6 colectomy) at a median of 21 days. On multivariate analysis, serum albumin  $<22$  mg/L (HR 7.93, 95% CI 1.006–62.57), was independent predictors of our primary outcome.

**Conclusion:** The frequency of CDI in patients with IBD was 17.6%. The study shows that patients with IBD are more sensitive to the development of CDI at a young age, while not having such traditional risk factors as recent hospitalization or antibiotic use. Patients with IBD with CDI in history often noted the ineffectiveness of therapy with salicylates; often require the assignment of biological therapy. IBD patients with CDI have a lower average albumin, and a higher activity of the inflammatory process ( $p<0.05$ ). Serum albumin  $<22$  mg/L was independent predictors of severe outcomes in hospitalized IBD patients with CDI.

## P218

### Assessment of the degree of intestinal destruction in Crohn's disease at the time of diagnosis

A. Hassine\*<sup>1</sup>, I. Akkari<sup>1</sup>, S. Mrabet<sup>1</sup>, E. Ben Jazia<sup>1</sup>  
<sup>1</sup>Hôpital universitaire Farhat Hached, service de gastro-entérologie, Sousse, Tunisia

**Background:** Certainly the presence of advanced intestinal lesions in Crohn's disease (CD) is associated with a more frequent recourse to surgical resection. However, in general, the degree of intestinal destruction in patients with CD is not assessed at the time of diagnosis, and the natural history of CD may differ phenotypically from patient to patient. The aim of this study was to assess the degree of intestinal destruction in patients with CD at the time of diagnosis, using the Lemann Index (LI), and to identify the associated factors.

**Methods:** A retrospective study was conducted involving all patients with CD followed in our center over a period of 4 years (2016-2020), and who were evaluated by endoscopy and MRI at baseline. The Lemann Index is a score that measures cumulative damage to digestive tissue from entero-MRI and endoscopy data. A LI score  $> 2.0$  was set as a cutoff to define advanced bowel injury. Hypothesis tests were applied to identify associations.

**Results:** 112 patients with CD were included in this study, of which 53.6% were female. The mean age at diagnosis was 33.29 years [15–63]. Regarding the localization of CD, it was ileal, colonic, and ileocolonic in respectively 16.1%, 42.9% and 41%. The disease phenotype was inflammatory in 60.7%, stricturing in 21.42%, and penetrating in 17.85%. The initial flare was judged to be severe in 33.9%, moderate in 55.4% and mild in 10.7% of cases, with a mean CDAI of 305.21 [115–493]. 12 patients had already undergone bowel resection. As for the biological data, the mean value of C-Reactive Protein (CRP) at the time of diagnosis was  $74.08 \pm 54.05$  mg/l, and that of the sedimentation rate (ESR) was  $62, 13 \pm 36.49$  (the 1st hour). The mean LI was  $3.14 (\pm 2.28)$  with 64 patients (57.1%) presenting an LI score indicating advanced bowel injury at