Methods: The ability of point-of-care users to obtain correct results was evaluated by testing result agreement between users’ Quantum Blue® fCAL extended POC measurements and laboratory reference values (BÜHLMANN fCAL® ELISA) for a set of 40 clinical stool samples. To demonstrate the ease-of-use of the test for non-laboratory professionals, the performance of the users was compared with that of laboratory personnel at BÜHLMANN who performed the same measurements with the Quantum Blue® system. Test robustness, ease and comfort of use as well as the clearness of the given instructions was further assessed in a questionnaire. Three point-of-care sites, in three geographically distinct locations participated in this study. Operators were non-laboratory medical personnel such as nurses, medical practice assistants or physicians. Two operators were recruited per site. Sites: (a) Hôpital Cantonal Fribourg, Fribourg, Switzerland, (b) Wielospecjalistyczny Szpital Wojewódzki, Gorzów Wlkp, Poland, (c) Kantonsspital Baselland, Liestal, Switzerland. Stool sample extractions were performed using the CALEX® Cap device.

Results: None of the six non-laboratory professionals’ of the three POC sites, received a false-positive or false-negative result, fulfilling the established acceptance criterion. Overall, non-laboratory professionals at the POC sites received comparable or even better results than laboratory professionals at BÜHLMANN. Bias at 100 µg/g and 300 µg/g clinical decision points for IBD monitoring, when compared with laboratory reference values, was determined as 1.2 % and −1.7 % for (a) site, 7.5 % and 6.5 % for (b) and −4.5 % and 3.5 % for (c). The total agreement of non-laboratory professionals’ results with reference calprotectin values was on average 80.5 % (a) 82.5 %, (b) 81.5 %, (c) 77.5 %. Overall the non-laboratory professionals’ assessment of the POC assay in terms of the robustness, ease and comfort of use was very positive.

Conclusions: The outcome of this study suggests that the Quantum Blue® fCAL extended POC test, which determines concentrations of a calprotectin in a complex stool specimen matrix, is easy-to-use and the given instructions are comprehensive and results are comparable between different sites and laboratories.

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Extended enoxaparin venous thromboembolism prophylaxis after surgery for inflammatory bowel disease: A cost-based decision-analysis

S. Holubar*, P. Dulač, B. Piazik, S. Finlayson, B. Udeh
1Cleveland Clinic, Department of Colon and Rectal Surgery, Cleveland, USA, 2University of California San Diego, Medicine, San Diego, USA, 3Eliot Health Systems, Manchester, USA, 4University of Utah, Surgery, Salt Lake City, USA, 5Cleveland Clinic, Clinical Transformation, Cleveland, USA

Background: Patients undergoing surgery for inflammatory bowel disease (IBD) are at an increased risk of venous thromboembolism (VTE) during their hospital stay and post-discharge. Optimal VTE prophylaxis, however, is not well defined in this population. In abdominopelvic surgery cancer patients, randomised trials showed extended enoxaparin (eENOX) prophylaxis was efficacious while decision-analytic study suggested extended heparin (eSQH) had greater economic efficiency but did not include patient adherence, and was prior to the availability of lower cost generic ENOX. This study used a cost-minimisation decision analysis to determine the optimal VTE prophylaxis strategy after surgery for IBD, addressing patient adherence and updated costs.

Methods: A cost minimisation decision model was constructed comparing four strategies of VTE prophylaxis after surgery for IBD: (1) inpatient SQH 5000 units TID 10 days; (2) inpatient Enox 40 mg daily 10 days; (3) eSQH 5000 units TID 30 total days (10 inpatient, 20 outpatient days) (eSQH); (4) eENOX 40 mg daily 30 total days
(10 inpatient, 20 outpatient days). Model assumptions included: no prior history of VTE; only major bleeding required intervention; 90% of major bleeds were treated medically with transfusion of 2 units PRBC and 10% reoperation rate; and heparin-induced thrombocytopenia (HIT) occurred within 10 days of exposure. Rates of inpatient and outpatient VTE, adherence to outpatient treatment, and strategy specific complications including HIT and major bleeding for each strategy, and costs ($US) were abstracted from primary and secondary data sources. Deterministic and probabilistic sensitivity analysis were conducted to assess the robustness of the results to changes in model and parameter uncertainty.

**Results:** At base case analysis, eENOX was the optimal strategy at $2,385/patient; eSQH was next strategy choice, incremental cost of $201 ($2768). Choice of optimal strategy was sensitive to VTE rates, HIT rates and drug costs. Sensitivity analysis demonstrated that eSQH was the optimal strategy when VTE rates with eENOX were >6.5% (vs. 5.7% in base case) and costs of eENOX were >$712 (vs. $528 in base case). eSQH became the optimal strategy when patient adherence rates were >85% (vs. 65% in the base case). Probabilistic sensitivity analysis determined the proportion of iterations that a strategy was the optimal choice.

**Conclusions:** After surgery for IBD, extended ENOX was the optimal strategy (least cost). This is likely due to the availability of generic ENOX, reduced HIT risk, and increased adherence with eENOX resulting in greater VTE prevention relative to eSQH. The robustness of these results suggest a change in the standard of care for IBD VTE post-operative prophylaxis is indicated.

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**Hyponatremia in patients with inflammatory bowel disease after intravenous iron infusion: One centre prospective study**

E. Tulewicz-Marti1*, A. Moniuszko1, T. Korcz1, G. Rydzewska12
1Clinical Hospital of Ministry of Interior Affairs and Administration, Department of General Medicine and Gastroenterology with Inflammatory Bowel Disease Subdivision, Warsaw, Poland, 2Jan Kochanowski University, Faculty of Medicine and Health Science, Kielce, Poland

**Background:** inflammatory bowel diseases (IBD) such as Crohn’s disease (CD) and ulcerative colitis (UC) may affect bone metabolism and are frequently associated with osteopenia and osteoporosis. There is growing body of evidence that intravenous iron infusions may lead to hyponatremia and thus contribute to skeletal abnormalities in IBD. Our objective was to prospectively determine the frequency and factors associated with hyponatremia in IBD patients with iron deficiency anaemia who received parenteral iron infusion (ferric carboxymaltose and iron isomaltoside). Potential changes in fibroblast growth factor 23 (FGF23) and 1,25-dihydroxyvitamin D (1,25 (OH)2D) levels were also included in the analysis.

**Methods:** In total, 27 patients with IBD who received iv iron isomaltoside or ferric carboxymaltose were prospectively recruited. Plasma phosphate, 1,25 (OH)2D, FGF23 and urinary level of phosphate were measured prior to iron administration and after 28 days, in some patients also after 7 and 120 days.

**Results:** Out of 27 patients with IBD (17 with CD and 10 with UC) 9 were women. The average haemoglobin level was 11.7 g/dl, MCV 83.5fl and after 120 days 13.4 g/dl, MCV 89.8 fl. The total phosphate level was 3.2 at the baseline and after 28 days 3.0 (p < 0.05). Total FGF23 level was 6.2 and after 28 days 2.6 (p < 0.01). Total level of dihydroxyvitamin D was 52.5 (±16.7) and after 28 days decreased to 45.8 (±13.1, p < 0.05), and a similar decrease was observed in the subgroup of patients after 7 and 120 days.

**Conclusions:** Parenteral iron may cause hyponatremia, probably mediated by an increase of FGF23. Serum phosphate levels should be monitored after administration of parenteral iron, especially in IBD patients.

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**Can we predict mucosal inflammation in children with inflammatory bowel disease without colonoscopy?**

M. Meglicka1*, M. Szczepanski, M. Dadalski, J. Kierkus
The Children’s Memorial Health Institute, Department of Gastroenterology, Hepatology, Feeding Disorders and Pediatrics, Warsaw, Poland

**Background:** Faecal calprotectin (FC) is a good marker in monitoring mucosal healing in adults with inflammatory bowel disease (IBD). Its concentrations in faeces is related to state of mucosa observed in endoscopy. Only few studies in paediatric IBD patients concern the role of FC in mucosa status assessment.

**Methods:** In total, 167 patients with IBD (F 73, M 94), of which 97 had ulcerative colitis (UC) and 70 had Crohn’s disease (CD) were involved to the study. All had colonoscopy performed and FC level within a week before endoscopy measured. Mucosa status was assessed with Mayo score for UC and Simple Endoscopic Score for CD (SES-CD). We have identified three subgroups: those with mucosal healing and Mayo score 0 or SES-CD 0-2, patients with mild inflammation in gut mucosa defined as Mayo score 1 or SES-CD 3-6, those with moderate inflammation described as Mayo score 2 or SES-CD 7-15 and finally those with severe disease with Mayo score 3 or SES-CD >15. The ROC was used as a statistical method to establish cut-off points. The AUC assesses the differentiation quality of the study group. We also analysed other laboratory, clinical or demographic data to established their impact on state of mucosa.

**Results:** Strong significant positive correlation between Mayo score or SES-CD and FC was found with r = 0.66. We also found low positive significant correlation between endoscopy findings and C-reactive protein (r = 0.38), platelets (r = 0.38) and erythrocyte sedimentation rate (r = 0.27) and low negative significant correlation with inflammation degree and haematocrit (r = 0.36) and body mass index (r = 0.22). AUC for FC in differentiation between mucosal healing and mild disease was 0.73, between mild and moderate inflammation was 0.75, whereas between moderate and severe endoscopy findings was 0.67. The optimal cut-off levels of FC of discrimination between subgroup with mucosal healing and low disease activity, low and moderate inflammation, finally moderate and severe disease was: 77 µg/L with sensitivity 0.56 and specificity 0.81, 367 µg/L with sensitivity 0.67 and specificity 0.81 and 1214 µg/L with sensitivity 0.58 and specificity 0.80, respectively.

**Conclusions:** FC is a good marker of mucosal healing in children with IBD and it is closely related to endoscopy findings. Using FC we can predict degree of inflammation in paediatric patients, however discrimination between patients with moderate and severe lesions is not satisfactory. Further efforts are needed to find more effectiveness model or marker, that determine degree of endoscopic activity in children with IBD.