CERTOLIZUMAB PEGOL IMPROVES WORK PRODUCTIVITY AND THE ABILITY TO PERFORM DAILY ACTIVITIES IN PATIENTS WITH CROHN’S DISEASE: DATA FROM PRECISE 2

B. Feagan1, M. Brown2, L. Gerlier3, S. Schreiber4. 1Robarts Research Institute, London, Canada; 2UCB Celltech, Celltech Antibody Centre of Excellence, Antibody Biology, Slough, UK; 3Reynus Biopharma, Levallois-Perret, France; 4Christian-Albrechts University, Kiel, Germany

Introduction: Potential benefits on work productivity of biological therapies for Crohn’s disease (CD) have not been thoroughly assessed. Certolizumab pegol is a Fab’ fragment of a humanised anti-TNF monoclonal antibody, currently in development for the treatment of CD and other autoimmune diseases. The PRECISE 2 maintenance trial reported good efficacy and tolerability for certolizumab pegol 400mg in CD compared with placebo. This analysis investigated the effect of certolizumab pegol on work productivity and daily activity impairment in patients with CD during PRECISE 2.

Methods: Patients with active CD (CD Activity Index [CDAI] score of 220-450 points) who demonstrated a clinical response to induction therapy (subcutaneous certolizumab pegol 400mg, Weeks 0, 2 and 4) at Week 6 were subsequently randomised to receive certolizumab pegol 400mg or placebo every 4 weeks from Week 8 to 24. The work productivity and activity impairment (WPAI) questionnaire, a validated instrument that evaluates four dimensions of work productivity and activity impairment, was administered at Weeks 0 and 26. The mean percentage change from Weeks 0 to 26 was calculated for each dimension and compared across treatment groups using Student’s t-test.

Results: Patients receiving certolizumab pegol experienced significantly greater improvement in WPAI scores, for all four dimensions, than those receiving placebo. Impairment due to CD while working decreased on average by 17.9% in the certolizumab group, compared with only 2.5% in the placebo group (p<0.001). It is also notable that patients assigned to active treatment missed, on average, 9.9% less work due to CD than those who received placebo (p=0.030).

Conclusions: Certolizumab pegol therapy improved both work productivity and the ability to carry out daily activities of patients with active CD in PRECISE 2. Assuming such benefits persist, treatment with certolizumab pegol may result in an important reduction in absenteeism and improved work-place productivity.

CD-68 POSITIVE CELLS IN BUCAL MUCOSA AS DIAGNOSTIC MARKER FOR IBD

B. Mijandrusic-Sinic1, M. Ilic-Tomas2, D. Kovac3, M. Juretic4, M. Belusic-Gobic1, A. Lekic5, R. Cerovic4, D. Stimac1.

1Department of Maxillofacial and Oral Surgery, University Hospital Centre Rijeka; 2Department of Pathology, Medical Faculty, University of Rijeka; 3Department of Physiology and Immunology, Medical Faculty, University of Rijeka; 4Department of Pathology, Medical Faculty, University of Rijeka; 5Department of Physics, Medical Faculty, University of Rijeka

Introduction: It is well known that Crohn’s disease (CD) may involve any part of gastrointestinal tract, including oral cavity. The aim of this study, was to determine if there are some microbiological and/or pathohistological changes in apparently normal buccal mucosa that can be a reliable marker for differentiating patients with inflammatory bowel disease (IBD) from healthy population and CD from ulcerative colitis (UC).

Methods: The presence of microaggregates of CD-68 positive cells (immunostained macrophages) at the section from buccal mucosa was investigated (picture 1.). We involved 52 patients with previously clinical and pathological diagnosed IBD (30 with CD and 22 patients with UC). The control group was matched for sex and age against IBD patients who were hospitalized for trauma in maxillofacial region and needed surgical approach thru oral cavity.

Results: The microaggregates of immunostained macrophages in buccal mucosa were found in 17 patients with CD and in 4 patients with UC (p=0.0121). In controls there were 3 positive for the respective findings (p=0.0241). The counts of bacteria in saliva or in smear of oral cavity were also measured. There was neither statistic difference in Candida albicans positive between IBD patients and controls nor CD vs. UC patients.

Conclusion: The microaggregates of macrophages were detected in apparently normal buccal mucosa more frequently in patients with CD than in patients with UC and controls. The finding leads us to conclusion that CD-68 positive cells can be helpful marker that can make difference between CD and UC patients, but further studies are necessary.

ESOPHAGEAL STRICTURES IN EOSINOPHILIC ESOPHAGITIS: DILATION IS AN EFFECTIVE AND SAFE ALTERNATIVE AFTER FAILURE OF TOPICAL CORTICOSTEROIDS

A. Schoepfer1, J. Gschossmann1, F. Seibold1, U. Scherer1, A. Struempfl2, 1Department of Gastroenterology, Inselhospital/University of Bern; 2Department of Gastroenterology, Kantonsspital Olten

Background: Esophageal strictures are a well known complication of Eosinophilic Esophagitis (EE). So far the efficacy and safety of topical corticosteroids and of dilation in the treatment of EE-associated strictures are not well defined.

Aim: to analyze the efficacy and safety of esophageal dilation in patients with symptomatic EE-strictures refractory to topical corticosteroids.

Methods: Chart review of 10 EE patients suffering from symptomatic esophageal strictures refractory to topical corticosteroids. Strictures were classified as high-grade (passage of 6 mm endoscope not possible), intermediate (between 7 and 10mm) and low grade (11-13mm, passage of the standard endoscope with elevated pressure).

Results: Location of strictures: 1 in the proximal, 4 in the middle and 3 in the distal third of the esophagus, two patients had 2 respectively 3 strictures in the middle and distal third of the esophagus. Mean length of strainedi strecture was 2.1cm (range 1-6cm). 2 patients had high-grade, 4 had intermediate and 4 had low grade strictures. Symptoms persisted in all patients despite topical steroids (swallowed fluticasone-propionate, daily dose of 1 to 2mg). All patients were gently dilated (Savary-bougies, mean diameter 16mm, range 13 to 19, mean 2 dilations). The procedures led to prompt symptom relief. Apart from post procedure retrosternal pain, no complications occurred (no perforation, no major bleeding), all procedures were carried out in an outpatient setting. Topical corticosteroids were continued after bougienage in 7 patients. During the follow-up (mean 6 months, range 2-11) all patients remained symptom-free.

Conclusions: In patients with symptomatic esophageal strictures due to EE, refractory to therapy with topical corticosteroids, gentle dilation leads to prompt and long lasting symptom relief and can be safely performed. However, the underlying inflammation is not influenced by dilation. The role of anti-inflammatory drugs in primary and secondary prevention of stricture formation needs to be further determined.