Conclusions: On the basis of this observational experience, granulocyteapheresis appears effective and well tolerated for the treatment of IBD patients. These preliminary findings may suggest the conduction of further randomized multicenter trials, in order to shed new lights on the use of granulocyteapheresis for the treatment of IBD.

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Concordance in IBD endoscopic scoring requires expertise and training: Preliminary results of an ongoing IG-IBD study

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Background: Endoscopic scoring is an essential tool required for clinical trials and probably for routine practice. As multicenter studies increasingly include endoscopic evaluation as relevant end-point, reliability of endoscopic scoring may become an issue. Aim of this multicenter IG-IBD study was to explore reproducibility of endoscopic scoring in the setting of dedicated IBD endoscopist, and to evaluate the effectiveness of a dedicated training program in amelioration of basal agreement.

Methods: 13 expert endoscopists reviewed endoscopic video-clips (6 ulcerative colitis clips, 5 post-surgical Crohn clips and 5 luminal Crohn clips), and blindly assigned endoscopic scores:
- Mayo endoscopic subscore for ulcerative colitis
- Rutgeerts’ score for post-surgical Crohn’s disease
- CDEIS and SES-CD for luminal Crohn’s disease

At the end of every score assessment, discussion was allowed and reference score was voted unanimously for every clip. The study is still ongoing with a validation phase and an educational program will start early in 2012.

Results: 78 combinations were available for every score (based on 13 observers’ scores). Median kappa values were normally distributed (p = 0.1962 and p = 0.0672 for Mayo and Rutgeerts’score, respectively). Median Kappa values for Mayo scores and for Rutgeerts’ score were rather unsatisfactory: 0.4405 (95%CI 0.3750-0.5026) and 0.3750 (95%CI 0.2860-0.4440) respectively. Intraclass correlation coefficients for total CDEIS and SES-CD attributed and computed by the same 13 observers were on the opposite highly significant and reached excellence: 0.8349 (95%CI 0.5414-0.9951) and 0.9287 (95%CI 0.7572-0.9981), respectively.

A second meeting is planned and scores will be re-attributed in a blinded fashion, educational material for increasing endoscopic scoring concordance will be produced at the end of the standardization process.

Conclusions: Endoscopic scoring is relevant for clinical trials, and the use of scores in clinical practice was advocated in order to better identify relevant changes in endoscopic disease activity. In this preliminary experience, simpler endoscopic scores (Mayo and Rutgeerts’ score) seem to require a larger amount of education in order to reach adequate agreement, while for more detailed and complex scores (CDEIS and SES-CD) agreement between observers is very high. Reproducibility of endoscopic scores cannot be assumed to be very high, and educational programs aimed to maximize agreement in scoring are mandatory.

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Infliximab drug levels in Crohn’s disease responding to the treatment

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Background: Though many studies have investigated antibody formation against Infliximab (IFX) demonstrating poor association to therapeutic effects less, is known about IFX serum levels in successfully treated patients with Crohn’s disease (CD).

Methods: Consecutive patients (n = 22) with CD under a scheduled (infusions every 8 weeks) treatment with IFX (5 mg/kg body weight) were recruited. Inclusion criterion was known clinical response to IFX. During the 8 weeks treatment interval IFX serum levels, CRP and Harvey-Bradshaw Index (HBI) were repeatedly determined. IFX serum levels were measured by using an immuno-competitive assay (Immundiagnostik AG, Bensheim, Germany). Clinical: Therapy and observation S125

Results: Serum levels of IFX between before and one week after infusion showed a dramatic increase (13.1±9.87 μg/ml trough level and 101.6±47.54 μg/ml one week later; mean ± SD). Despite all patients were clinical responders the range of IFX peak levels varied widely (27.6–201 μg/ml). As figure 1 depicts there exists an apparent association between courses of IFX drug levels, CRP and HBI. Mean CRP levels increased beyond 5 mg/l between week 5 and 6 while HBI increased during the same time from 3 to 4. In contrast, at week 4 mean serum levels of IFX decreased below 31 μg/ml, which may be a critical serum level of the clinical response.

Figure 1.

Conclusions: IFX serum levels in clinically responding patients with CD increase after IFX infusions significantly but show high interindividual variance in peak concentrations and decay. There is apparent association between the drop of serum IFX levels and increase of CRP, and HBI, where a level of 31 μg/ml may be critical. Worsening of clinical symptoms and CRP is associated to ineffective IFX serum levels and should lead to an adaption of the individual IFX treatment.

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