GO-CARE: A prospective multi-centre observational study of golimumab effectiveness and quality of life in a real-life UC patient population in Italy

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Background: The ultimate treatment target in UC must be the restoration of patient (PT) Quality of Life (QoL). The aim of the study was to identify predictors of QoL improvement measured by Inflammatory Bowel Disease Questionnaire (IBDQ) after 8 and 56 weeks of treatment with Golimumab (GLM) and to investigate other effectiveness outcomes in a real-life setting.

Methods: Responders to GLM induction therapy (by Partial Mayo Score (PMS) at 8 weeks after the start of GLM) were enrolled and clinical-demographic characteristics at start of GLM were collected. An interim analysis was conducted 18 months after the start of the study to evaluate predictors of IBDQ increase (≥1 point in rectal bleeding) and clinical remission (PMS ≤2 with no ≥1 point in rectal bleeding) and clinical remission (PMS ≤2 with no sub-score >1) achieved after 8 weeks of GLM treatment compared to baseline (primary endpoint). Mean change in IBDQ after 8 and 32 weeks of GLM treatment, clinical response (decrease ≥2 points or ≥30% of the PMS and decrease ≥1 point in rectal bleeding) and clinical remission (PMS ≤2 with no sub-score >1) at week 32 were also assessed (secondary endpoints).

Results: In total, 83 and 38 patients completed 8 and 32 weeks of treatment and were included in the interim analysis. Mean age was 43 years (57 males) and mean disease duration was 9.5 years. 80.7% of patients were steroid-dependent, 47% had pancolitis and 49.4% had left-sided colitis. 75.9% of patients had moderate disease activity (median PMS 6) and comorbidities occurred in 19.3%. Moderate endoscopic activity (Mayo 2) was reported in 68.7% of patients. 27.7% of patients were previously treated with anti-TNF. Baseline concomitant therapies were: 25.3% of patients treated with CS, 15.7% AZA, 75.9% oral 5-ASA. Mean (range) baseline IBDQ was 139 (54–214). By univariate analysis of predictors of IBDQ increase (age, gender, weight, height, BMI, smoking status, comorbidities, disease duration and localisation, concomitant therapy (CS, AZA, 6MP, 5-ASA), previous therapy (CS, AZA, 6MP, anti-TNFα), CS dependence, FMS, PMS, endoscopic score, CRP and ESR), oral 5-ASA (concomitant therapy) was identified as unique predictor of improvement of QoL at 8 weeks. From baseline (start of induction) to week 8 and week 32 a significant IBDQ mean increase (p < 0.05) (32.9 and 25.2; mean value 172 and 170), a significant reduction of median PMS (p < 0.0001) (6vs 2vs 1, respectively) and of median CRP (p < 0.03) (3.6vs 3vs 2.1 mg/l, respectively) were observed. At week 32, 34/38 patients (89.5%) were in sustained clinical response and 32/38 patients (84.2%) were in remission. No safety issues were observed.

Conclusions: This interim analysis of GO-CARE study identified the concomitant therapy oral 5-ASA as predictor of significant improvement of QoL. The analysis confirms the effectiveness of GLM in real life with sustained response and remission, and improvement of QoL.

Reference

Quality of life in Pediatric inflammatory bowel disease Patient: How well do we understand patients?

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Background: Inflammatory bowel disease (IBD) is a chronic relapsing disease which can negatively affect the quality of life (QOL) of the patient. Improving QOL is one of the important therapeutic targets of IBD, and in order to do so, it is essential to assess one. In this study, we compared the actual QOL of the patients with the QOL of the patients evaluated by their medical staffs or caregivers and estimated how well they know the patients.

Methods: Sixty-two children and adolescent IBD patients followed at Severance Children’s Hospital were enrolled in this study. The patients themselves answered the questionnaire (IMPACT-III) at the hospital visit. On the same day, parents, physicians and IBD nurse conducted the same questionnaire for each patient. The actual total IMPACT-III score of the patients themselves and each subdomain scores were compared with the IMPACT-III scores conducted by guardians and medical staffs.

Results: The intraclass correlation coefficient (ICC) of total IMPACT-III score was the most relevant between father and patient (0.824, 95% confidence interval 0.495–0.938) and was higher in order of mother (0.689, 95% confidence interval 0.474–0.816), physician (0.625, 95% confidence interval 0.386–0.772), and nurse (0.499, 95% confidence interval 0.179–0.694). Among the subdomain scores, bowel symptom subdomain was the most relevant one between patient and others whereas “treatment and intervention” was the least relevant subdomain. Both parents and medical staffs assessed the patients’ QOL lower than the QOL assessed by patients themselves. The differences of IMPACT-III scores to patients were −10.09 ± 17.86 for physician, −9.87 ± 15.80 for mothers, −5.72 ± 17.04 for nurse and −3.81 ± 11.82 for fathers.

Conclusions: The QOL of the patients estimated by the caregiver or the medical staffs showed a relatively high correlation with the QOL of the patients documented by patients themselves. However, both medical staffs and caregivers tend to underestimate the QOL of the patients.

Drug level thresholds in patients with Crohn’s disease on dose-intensified anti-TNF therapy predict intestinal wall healing for infliximab but not adalimumab

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Background: Secondary loss of response to infliximab (IFX) or adalimumab (ADA) occurs in up to 30–40% of patients with Crohn’s disease (CD). Recapturing response, with subsequent disease quiescence, may be achieved via dose-escalation of anti-TNF therapy. We sought to determine the target drug level and drug level increment associated with quiescence on intestinal ultrasound (IUS) in patients with CD receiving dose-intensified IFX or ADA for secondary loss of response.

Methods: Retrospective observational study of CD patients with secondary loss of response receiving dose-intensified anti-TNF therapy (IFX 5 mg/kg 6 weekly, ADA 40 mg weekly) for a period between September 2013-March 2017. IUS and trough drug level were measured at baseline and every 6 months after dose escalation. IUS were graded based on a global assessment of bowel wall thickness and stratification, hyperaemia on colour Doppler, mesenteric hyperechogenicity and lymphadenopathy. Patients were dichotomised into one of two groups based on their most recent IUS: quiescent or active. Non-parametric tests were used for intra- and inter-group comparisons and Receiver Operating Characteristic analyses to identify a threshold drug level and drug level increment from baseline associated with quiescence.

Results: Of 35 patients (49% male, mean age 41 years), 54% used IFX and 74% concomitant immunomodulation. 22 patients (63%) had quiescent disease on their most recent IUS. There were no significant differences in demographics, baseline drug levels or baseline IUS activity between quiescent and active groups. Absolute IFX drug levels and the increment from baseline were significantly higher in the quiescent compared with the active group, but no such differences were observed for ADA (Table 1). IFX level ≥4.8 μg/ml or increasing drug level by ≥5.5 μg/ml from baseline best predicted IUS quiescence. ADA drug levels were not predictive of sonographic activity.

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Role of C-reactive protein kinetics after surgery for Crohn’s disease

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Background: C-reactive protein (CRP) is a reliable predictor of major anastomotic leak after colorectal resection for cancer. However, there is lack of data on its role when surgical resection is performed for Crohn’s disease (CD). Moreover, the higher postoperative CRP level of CD patients, as a consequence of an enhanced postoperative inflammatory response, may not reflect an actual underlying septic complication. The aim of this study is to characterise postoperative CRP kinetics with regards to postoperative course and its relevance in predicting anastomotic leakage after CD surgery.

Methods: All CD patients undergoing surgical resection with primary anastomosis between January 2013 and January 2017 were retrospectively analysed. Demographic, surgical, comorbidity was collected. Postoperative CRP levels, measured daily until discharge, were retrieved. Data regarding postoperative course including anastomotic leakage, infectious and non-infectious complications were retrieved. The discrimination ability of CRP levels in predicting the incidence of anastomotic leakage was evaluated according to the area under the curve (AUC), using the receiver-operating characteristic (ROC) methodology.

Results: A series of 251 consecutive patients who underwent elective colorectal surgery in a specialised unit was retrospectively analysed. Anastomotic leak was detected in 10 patients (4%). C-reactive protein level was a good predictor of anastomotic leak on postoperative day 3 to 5 (AUC equal to 0.741, 0.783 and 0.825 for day 3, 4 and 5, respectively). A delta cut-off of 14 measured between the first and the third day after surgery (AUC .800) maximises sensitivity and specificity (NVP: 98.6% PPV 27%).

Conclusions: Postoperative C-reactive protein could be a useful tool to rule out anastomotic complications after surgery for CD. Its high negative predictive value is crucial to allow early discharge and reduce hospital-acquired infection in particularly fragile CD patients after surgery.

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Quantum Blue® fCAL extended POC user performance evaluation

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Background: The objective of the user performance evaluation was to demonstrate the ease-of-use of the Quantum Blue® fCAL extended POC test to allow non-laboratory professionals to independently and correctly determine calprotectin concentration in patients’ stool samples under actual conditions of use.