

P314 TNF gene activation used as criterion to discontinue biologic therapy – A patient series introducing the NovaPrime TNF kit

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Abstract

Background - Severe inflammatory bowel disease can be successfully treated with biologic drugs such as anti-TNF. However, there is no consensus on if and how to stop treatment. Our group has earlier shown that normalization of TNF gene expression may be a beneficial prognostic factor when attempting to discontinue biologic therapy. We here present data from a series of patients in endoscopic remission and with normalized TNF gene expression.

Methods - Severe inflammatory bowel disease can be successfully treated with biologic drugs such as anti-TNF. However, there is no consensus on if and how to stop treatment. Our group has earlier shown that normalization of TNF gene expression may be a beneficial prognostic factor when attempting to discontinue biologic therapy. We here present data from a series of patients in endoscopic remission and with normalized TNF gene expression. A total of 91 patients were recruited at hospitals in Norway and Italy: 55 patients (32 UC, 23 CD) in remission (picked by normalization of TNF using our in-house TNF qPCR), and for comparison: 14 patients with active disease, and 22 normal controls. Mucosal samples taken prior to drug discontinuation from all patients were re-measured for TNF mRNA by the NovaPrime TNF kit.

Results - A clear difference could be seen between normal controls and patients with active disease, showing highly elevated TNF mRNA values in the active disease group. The patients in remission had values resembling the normal controls with values generally below a cut-off of 9060 copies/ μ g total RNA by the NovaPrime TNF kit. The patients in remission were followed for up to 5 years noting two endpoints: relapse triggering any adjustment of medication, and relapse triggering restart of biologics. Median survival time before adjusting medication was 12 months for ulcerative colitis and 17 months for Crohn's disease. Median time to restart of biologics was 21 months (2 – 40) overall, and after 3 years 43% still were not in need of biologic therapy.

Conclusion - We conclude that the NovaPrime TNF kit yields consistent readings comparable to our in-house assay, and that this industrial standard kit enables any PCR lab to perform TNF gene expression in samples from intestinal mucosa. A considerable proportion of patients with normalized TNF gene expression can maintain long term remission without biologic therapy, relieving health care costs and potential side effects of long-term therapy.