Royal College of Physicians | Inflammatory Bowel Disease Programme

Biological therapy

Executive summary of the national clinical audit of biological therapies

UK Inflammatory Bowel Disease (IBD) audit

Paediatric executive summary report
August 2013

Prepared on behalf of the Clinical Effectiveness and Evaluation unit at the Royal College of Physicians on behalf of the IBD programme steering group

Paediatric

The Clinical Effectiveness and Evaluation Unit (CEEU) of the Royal College of Physicians runs projects that aim to improve healthcare in line with the best evidence for clinical practice: national comparative clinical audit, the measurement of clinical and patient outcomes, clinical change management and guideline development. All our work is carried out in collaboration with relevant specialist societies, patient groups and NHS bodies. The unit is self-funding, securing commissions and grants from various organisations, including the Department of Health and charities such as the Health Foundation.

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Executive summary

Background

The purpose of the audit is to measure the efficacy, safety and appropriate use of biological therapies, also known as anti-TNFα therapy (Infliximab and Adalimumab) in patients with IBD in the UK and to capture the views of patients on their quality of life at intervals during their treatment.

This is the first full national report of the biological therapy element of the UK IBD audit and all analyses within this report include only those patients that were newly started on biological therapies between 12 September 2011 (start of data collection) and 28 February 2013. The data contained within this report has been taken from **only** completed submissions within the biological therapy audit web tool (https://www.ibdbiologicsaudit.org).

Participation in the biological therapies audit provides local IBD teams with the means to meet Standard A6 of the IBD Standards; specifically the regular review of patient outcomes and auditing of biological therapy. Participation in the audit also provides the opportunity to review treatment against NICE recommendations (TA187)

Overall summary

The data presented in this report suggest that the biological therapies are effective treatments for IBD that are used to good effect throughout the participating paediatric units in the UK. In this audit we have identified a number of issues, that when addressed should improve the delivery of these medicines and the resultant quality of patient care.

Engagement in the biologics audit has been reasonably good but clinicians should be encouraged to enter data on all appropriate patients to provide the universal patient population needed to strengthen the report's conclusions, especially in relation to safety. Objective assessment of response to therapy is an important part of using biological medicines and the assessment of change in disease activity and quality of life data are integral to this.

Individual services should assess the barriers to local appropriate delivery of these drugs to ensure that patients are not waiting unduly for these therapies when their use is clinically indicated. It is also vital that patients are appropriately screened before receiving treatment in keeping with current guidelines. Continued audit of biological therapy treatment will ensure improvement in these issues and that the quality of care for IBD patients continues to improve.

Key findings

1. Although the level of participation from specialist paediatric sites is encouraging (76%) non-participation of some sites limits the universal coverage aimed for at the audit's inception
2. The majority of paediatric patients received Infliximab as their biologic treatment
3. 39% of Crohn's disease patients waited more than 2 weeks to begin treatment on Infliximab, with 39% of this delay attributed to waiting for the next available clinic appointment.
4. It is disappointing to find that pre-treatment screening chest x-ray (78%), stool culture collection (34%) and testing for Hepatitis B (34%) as part of pre-treatment screening is not being carried out in 100% of cases.
5. Informed consent to receive treatment is taken in the majority of patients (99% Crohn's disease Infliximab) and usually takes the form of written consent (64%).
6. The majority of Crohn's disease patients (91%) are receiving concomitant therapy at initial treatment. Of these 90% are receiving an immunosuppressant at initial Infliximab treatment.
7. Recorded adverse events are uncommon. Acute treatment reactions and infections are the commonest events recorded among 3.4% and 10.1% of all patients, respectively. There were no deaths or cases of malignancy reported at follow up.
8. Routine collection of quality of life scores (IMPACT III) is low in clinical practice with 23% recording this at baseline and 8% at either 3 or 12 months follow up, in all IBD patients.

9 Only 11% of patients were recorded as having been appropriately prescribed anti-TNFα treatment, when compared against NICE TA187 criterion 1.5.
10 Biological therapies are effective treatments for patients with IBD with 73% of paediatric patients entering remission at the first recorded treatment after 12 weeks.
11 The majority of patients being started on anti-TNFα treatment have moderate disease activity as assessed by the Paediatric Crohn's Disease Activity Index (PCDAI).

Key recommendations

1 Sites should continue to participate in national audit and aim to submit data on **all** appropriate patients. Increased participation will be encouraged by greater system utilities that have been introduced to the audit web tool recently.
2 All organisations should ensure that patients are not waiting more than 2 weeks to begin treatment wherever possible.
3 Clinicians should be vigilant in screening for opportunistic infections both before starting and while patient's remain on biological therapy.
4 Sites should routinely assess disease activity at baseline and again at 3 and 12 month follow up. This measure is a vital part of objectively assessing the appropriateness of initial treatment, response and the ongoing need for maintenance therapy.
5 Local teams should encourage patients to complete patient reported outcome measures (IMPACT III) at baseline and again at 3 and 12 month follow up.
6 Sites participating in the audit should export their own local data and use this for local analyses, benchmarking and local quality improvement activities.
7 The findings and recommendations of this report should be shared at relevant multi-disciplinary and clinical governance / audit meetings

This is the executive summary version of this report to view the full national report please visit: www.rcplondon.ac.uk/biologics

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