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Brief Research Report

# No post-infusion reactions after infliximab or vedolizumab

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## ABSTRACT

**INTRODUCTION.** Biologic therapies like infliximab and vedolizumab effectively treat inflammatory bowel disease (IBD), but post-infusion observation consumes considerable clinical resources. This study evaluated whether post-infusion observation periods may be safely reduced or eliminated.

**METHODS.** A retrospective analysis included all IBD patients receiving infliximab or vedolizumab from January 2019 to December 2020 at Sygehus Lillebaelt, Denmark. Data included infusion counts, observation duration, timing and severity of reactions.

**RESULTS.** Among 380 patients receiving 3,847 infusions, 43 reactions (1.1%) occurred exclusively during infusions, mostly within the first 15 minutes. No reactions were reported after infusion had concluded.

**CONCLUSIONS.** Routine post-infusion observation after infliximab and vedolizumab appears unnecessary. Reducing or eliminating this practice may optimise clinical resources without compromising patient safety.

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The incidence of inflammatory bowel disease (IBD) in Denmark has increased threefold over the past 30 years [1]. As a chronic condition characterised by recurring disease activity, IBD requires ongoing monitoring and treatment at specialised hospital units. The burden includes substantial morbidity, sick leave, surgical interventions and elevated healthcare costs, and — in certain patient subgroups — an increased colorectal cancer risk. Biologic agents are among the most effective therapies, contributing substantially to healthcare expenditures with steadily rising usage [2].

At the time of our data collection, national guidelines from the Danish Medicines Council recommended infliximab (IFX) as first-line treatment for both ulcerative colitis and Crohn's disease [3]. Meanwhile, the use of intravenous vedolizumab (VDZ) was also on the rise. In parallel with an overall increase in IBD prevalence, these trends result in a growing need for personnel and physical space for infusions and monitoring, which represent a considerable share of the total cost of these therapies.

IBD patients receiving IFX or VDZ are observed post-infusion following guidelines, requiring one-hour monitoring for the first three infusions. Subsequently, when ustekinumab was introduced, no post-infusion

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observation was required. This discrepancy prompted us to assess whether IFX and VDZ observation periods could be reduced or eliminated.

A retrospective study from 2018 analysed 1,152 IFX and 330 VDZ infusions made in the course of one year (953 observation hours) [4]. Ten infusion reactions occurred (0.9%), none during the defined post-infusion observation period.

A retrospective multicentre study analysed 4,182 IFX and 2,132 VDZ infusions over 12 months [5]. Across three centres, 6,665 observation hours recorded 16 IFX reactions (0.4%), all within 20 minutes, with none occurring after infusion. VDZ had three reactions (0.14%), also within 20 minutes.

Thus, we hypothesised that most infusion reactions occur during the infusion itself. Consequently, the standard observation time could potentially be eliminated, releasing staff and clinical resources for other treatments. We also aimed to examine the handling of infusion reactions to help ensure optimal medical therapy and to avoid unnecessary discontinuation of biologic agents.

## Methods

### Design

This was a retrospective study including all patients who received biologic therapy with IFX or VDZ at the Medical Outpatient Clinic at Lillebaelt Hospital, Denmark.

### Sample size, power calculation and statistics

Assuming an annual total of around 1,480 biologic infusions (1,150 IFX, 330 VDZ) at our outpatient clinic, roughly 15-44 annual infusion reactions were anticipated (based on an estimated 1-3% incidence rate). To ensure adequate statistical precision (alpha = 0.05, power = 80%), the study aimed to capture at least 30 infusion reactions. Data are presented using descriptive statistics.

### Study population

Included in the study were patients diagnosed with IBD, identified by International Classification of Diseases, tenth version (ICD-10) codes DK500-509, DK510-519, DK529A, and DK523, who received biologic treatment with IFX (ML04AB02) or VDZ (ML04AA33) between 1 January 2019 and 31 December 2020. Eligible patients were identified via electronic health records by screening diagnosis and treatment codes. No specific exclusion criteria were applied as the primary aim was to document infusion reactions during biologic therapy. Collected data included total infusions, observation hours, reaction timing, symptoms, clinical findings, severity grading and smoking status.

### Data and ethical approvals

This quality improvement project involved a retrospective evaluation of electronic health records at Lillebaelt Hospital, without patient interventions or biological sampling. It was registered according to Danish legislation and approved by the hospital management and the regional data oversight authorities. Ethical approval was not required as the project was classified as a quality initiative. All data handling complied with current regulations, with sensitive information accessible only to authorised project personnel.

### Definition of infusion reaction

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An infusion reaction was defined as any unintended effect during or immediately after infusion and graded per the Common Terminology Criteria for Adverse Events (CTCAE) v5.0 [6]. Grades 1-2 (mild-moderate) included symptoms like itching and flushing; Grades 3-5 (severe-fatal) involved dyspnoea, hypotension or chest pain and were considered serious.

*Trial registration:* not relevant.

## Results

In total, 380 patients were included, accounting for 3,847 biologic infusions (IFX or VDZ). Patient demographics, including smoking status, disease diagnosis, disease localisation and Montreal Classification details are summarised in **Table 1**.

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**TABLE 1** Patient demographics and clinical characteristics (N = 380).

| Category | Patients, n (%) |
|---|---|
| *Gender* | |
| Female | 195 (51.3) |
| Male | 185 (48.7) |
| *Smoking status* | |
| Current smoker | 80 (21.0) |
| Former smoker | 69 (18.2) |
| Never smoker | 191 (50.3) |
| Not reported | 40 (10.5) |
| *Diagnosis* | |
| Crohn's disease | 202 (53.2) |
| Ulcerative colitis | 171 (45.0) |
| Inflammatory bowel disease, unclassified | 7 (1.8) |
| *Localisation in Crohn's disease* | |
| Ileal | 80 (39.6) |
| Colonic | 65 (32.2) |
| Ileocolonic | 56 (27.7) |
| Isolated upper | 1 (0.5) |
| Subtotal | 202 |
| *Montreal disease behaviour: Crohn's disease* | |
| Non-stricturing, non-penetrating | 102 (50.5) |
| Stricturing | 61 (30.2) |
| Penetrating | 34 (16.8) |
| Not clearly reported | 5 (2.5) |
| Subtotal | 202 |
| *Perianal disease in Crohn's disease?* | |
| Yes | 41 (25.5) |
| No | 120 (74.5) |
| Subtotal | 161 |
| *Localisation in ulcerative colitis* | |
| Proctitis | 39 (22.9) |
| Left-sided colitis | 71 (41.8) |
| Extensive | 58 (34.1) |
| Not reported | 2 (1.2) |
| Subtotal | 170 |

Infusion reactions occurred in 43 cases (1.1%), all during the infusion period itself, with no reactions observed in the post-infusion monitoring phase. Most of these reactions occurred within the first 15 minutes after infusion was initiated, as detailed in **Table 2.** Among the 43 documented infusion reactions, most were mild to moderate. Grade 1 reactions accounted for 17 cases (39.5%), whereas Grade 2 reactions were most common, occurring in 24 cases (55.8%). Only two reactions (4.7%) were classified as Grade 3, requiring clinical intervention, but no Grade 4 or Grade 5 reactions were observed.

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**TABLE 2** Timing of infusion reactions among patients (N = 43).

| | Patients | |
|---|---|---|
| **Time into infusion, min.** | **n (%)** | **cumulative %** |
| 2 | 1 (2.3) | 2.3 |
| 3 | 3 (7.0) | 9.3 |
| 5 | 7 (16.3) | 25.6 |
| 7 | 2 (4.7) | 30.2 |
| 8 | 2 (4.7) | 34.9 |
| 10 | 5 (11.6) | 46.5 |
| 12 | 1 (2.3) | 48.8 |
| 13 | 1 (2.3) | 51.2 |
| 14 | 1 (2.3) | 53.5 |
| 15 | 9 (20.9) | 74.4 |
| 16 | 1 (2.3) | 76.7 |
| 18 | 1 (2.3) | 79.1 |
| 20 | 1 (2.3) | 81.4 |
| 25 | 1 (2.3) | 83.7 |
| 30 | 3 (7.0) | 90.7 |
| 45 | 2 (4.7) | 95.3 |
| Not recorded[a] | 2 (4.7) | 100.0 |
| Total | 43 (100.0) | |

a) Cases in which the exact timing of the infusion reaction during the infusion was not documented.

Among 42 reactions with available timing data, 31% occurred during induction and 69% during maintenance. In the first series, 18% occurred during induction; in the second series, 78%. One patient's data were missing data, which explains why the total is 42 rather than 43.

## Discussion

Our findings confirm that no severe infusion reactions occurred during the post-infusion observation

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period for IFX or VDZ. All observed reactions occurred during infusion, suggesting that the standard post-infusion monitoring may safely be shortened or eliminated. This aligns with previous studies reporting a similar low incidence of delayed severe reactions [4, 5].

Although the risk after infusion appears negligible, clinicians should still consider individual patient factors such as previous infusion reactions or important comorbidities when modifying observation protocols. Vigilance during infusion remains critical to detect and manage reactions promptly and avoid unnecessary discontinuation of treatment.

## Conclusions

Our retrospective review of 3,847 infusions found that all 43 reactions occurred exclusively during administration. Thus, reducing routine post-infusion observation time could optimise resource utilisation and accommodate more patients. A subgroup analysis showed a higher risk of infusion reactions when restarting treatment after a drug holiday (second series), particularly during re-induction. In contrast, reactions during first-time treatment tended to occur in the maintenance phase.

Further prospective studies should explore patient-specific risk factors and validate the safety of reduced observation periods.

### Strengths and limitations

The primary strength of this study was the large, real-world dataset comprising nearly 4,000 biologic infusions, providing robust clinical evidence. Furthermore, the clearly defined, standardised grading of infusion reactions enhanced reliability. However, the retrospective design risked reporting bias, particularly for mild symptoms, and the single-centre approach limited generalisability, highlighting the need for prospective multicentre validation.

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