Post biological infusion monitoring; Is it really necessary?

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ABSTRACT

With expanding formularies, IBD biologics services throughout the UK are seeing increasing numbers of intravenous (IV) biologic infusions, often with little or no increase in service capacity. Ustekinumab has recently been licensed without the need for post infusion monitoring. We retrospectively reviewed 1152 infliximab (IFX) infusion and 330 vedolizumab (VDZ) infusions looking for incidences of complications within the current recommended observation periods. No immediate post infusion reactions occurred in either the IFX or VDZ patients. In view of our findings, we have subsequently amended our post infusion monitoring policy.

BACKGROUND

The biologic infusion service at the Royal London Hospital is seeing ever increasing activity. Facilitating this in a timely and safe manner with current clinic capacity and staffing levels is becoming increasingly difficult Manufacturers of both IFX and VDZ recommend that patients are monitored following their infusion for defined periods, to observe for post infusion reactions. Patients receiving IFX infusions are monitored in our unit for 2 hours following their infusion for the first four infusions, 1 hour following infusions 5-9 and 30 minutes for each infusion thereafter.

Patients receiving VDZ, are observed for 2 hours following the first 2 infusions

The introduction of ustekinumab, licensed without a defined post infusion observation period, led us to consider the need for post infusion observation periods in other patient groups

OBJECTIVES

We wanted to explore whether, like ustekinumab, IFX and VDZ might not require such regulated and prolonged post infusion monitoring. If not required this would greatly increase capacity within the IV biologics clinics, allowing us to give biologics safely to a larger number of patients in order to meet the increasing demand.

METHODS

We reviewed the infusion records of all patients receiving IFX and VDZ infusions in our nurse led IV biologic clinic between September 2016 and September 2017 to identify incidence and type of infusion reactions and at what time during the patients visit these occurred (Table 1).

RESULTS

1152 infusions of IFX and 330 infusions of VDZ were administered over the 12 month period. The total post-infusion observation time for these patients was 953 hours.

10 infusion reactions occurred (0.9%), all in patients receiving IFX. 6/10 (60%) occurred within 10 mins of starting IFX infusion (immediate), 2/10 (20%) later during the infusion (acute), and 1/10 (10%) occurred 2 weeks after receiving the infusion (delayed).

No infusion reactions occurred during the recommended post-infusion observation periods for patients receiving IFX infusions

No infusion reactions were observed in patients receiving VDZ either during, or in the recommended post observation period following their infusions

CONCLUSIONS

- We analysed a total of 953 post-infusion observation hours after 1152 IFX and VDZ infusions in our unit over a one year period
- The total reaction rate was 0.9% (10/1152). None of the reactions occurred during the manufacturers recommended post-infusion period
- The results from this large single centre retrospective study demonstrate that the risk of onset of adverse reactions to either IFX or VDZ during the post infusion observation period is very low
- These findings suggest that patients who have not had a reaction during their infusion do not routinely need to stay in the unit for post infusion observation
- We hope that by formally adapting this strategy we will better able to manage the increasing demands on our capacity, whilst still providing safe and appropriate care to our patients

	Duration of Treatment	Onset of Reaction	Reaction Type	TDM	Management
IFX	2nd Induction Dose	Immediate	Moderate HSR	N/K	HCS 100mg IV O2
IFX	7/12	Immediate	Mild	TL 0.3 ADA >200	HCS 100mg IV CPM 10mg IV O2
IFX	5/12	Acute	Mild	TL 1.2 ADA <10	HCS 100mg IV CPM 10mg IV O2
IFX	7/12	Immediate	Moderate HSR	TL 1.5 ADA <10	HCS 100mg IV CPM 10mg IV O2
IFX	First Dose (previous exposure)	Delayed (2 weeks)	Delayed HSR	N/K	HCS 100mg IV
IFX	2nd Induction Dose	Immediate	Moderate HSR	N/K	HCS 100mg IV CPM 10mg IV O2
IFX	4th Infusion	Immediate	Severe	TL 0.3 ADA <10	HCS 100mg IV CPM 10mg IV O2
IFX	5/12	Immediate	Moderate HSR	TL 0.3 ADA 20ng/mL	HCS 100mg IV CPM 10mg IV O2
IFX	2nd Induction Dose (previous exposure)	After 1 hour	Moderate HSR	N/K	HCS 100mg IV CPM 10mg IV O2
IFX	3rd Induction Dose	Immediate	Severe	N/K	HCS 100mg IV CPM 10mg IV O2 Cyclizine 50mg IV IV fluids

HSR = Hypersensitivity Reaction, TL = Trough Level, ADA = Antidrug Antibodies, HCS = Hydrocortisone, CPM = Chlorphenamine

Table 1. Infusion reactions by onset and type