Intravenous immunoglobulin (IVIg) reactions

Serious Transfusion Incident Report (STIR): Bulletin no. 12

OFFICIAL

While STIR does not accept reports of IVIg reactions, recent changes to immunoglobulin products highlight the importance of recognising and reporting IVIg reactions.

Reactions to IVIg

Adverse reactions associated with immunoglobulin administration are generally mild to moderate in nature and can include:

- chills, headache, dizziness, fever, vomiting, nausea, allergic reactions, arthralgia, low blood pressure, moderate back pain and localised infusion site reactions.

More serious reactions to IVIg are uncommon. Aside from anaphylaxis, which can occur even if a patient has not shown hypersensitivity to previous administration, these reactions may be delayed in onset with signs and symptoms appearing in the days or weeks after discharge and can include:

- aseptic meningitis, haemolytic reactions (especially in those receiving doses for immunomodulatory indications), acute renal failure and thromboembolic events.

The risk of a patient reaction is increased when:

- it is the patients' first dose or there is an increased period between doses, usually > 6-8 weeks
- there is a change in IVIg product
- there is an increased rate of infusion (rate related reactions)
- the patient has hypogammaglobulinaemia or agammaglobulinaemia, with or without IgA deficiency.[1]

Potential complications can often be avoided by ensuring patients:

- are not sensitive to human immunoglobulin by initially infusing the product slowly (as per the product information provided by the manufacturer)
- are well hydrated prior to administration
- avoid concomitant use of loop diuretics
- are educated about signs and symptoms to look for and how to report these, and where and how to get medical attention
- are carefully monitored for any symptoms throughout the infusion period. In particular, patients naive to human immunoglobulin, patients switched from an alternative IVIg product or when there has been a long interval since the previous infusion. These patients should be monitored for the first hour after the first infusion, to detect potential adverse signs and symptoms. All other patients should be monitored for at least 20 minutes after the infusion.
- are considered for the use of subcutaneous immunoglobulin if they meet the criteria and are suitable for self-administration of Ig.[1]

If a reaction occurs it is important that staff can:

- recognise signs and symptoms that may indicate a reaction
- respond appropriately
- report the reaction both locally and to appropriate haemovigilence systems.

Signs and symptoms of adverse events may present differently in paediatric patients. Signs may include irritability, agitation or an inability to be consoled by their parent or carer. These signs may be present in the absence of, or prior to, any changes in vital signs.[2]

In patients who experience severe and/or repeated reactions, consider a change to subcutaneous immunoglobulin, if they meet criteria.

Reporting of reactions

Adverse events should be investigated and reported to:

- the medical officer to ensure appropriate and timely clinical care is provided to the patient
- the transfusion service or pharmacy that dispensed the immunoglobulin
- the incident management system in your health service to allow for appropriate investigation and tracking of trends
- the patient or their carer and involve them in developing a management plan
- the manufacturer of the product and/or the TGA
- Lifeblood, where there is a planned change in product a note needs to be added to BloodSTAR of unsuitability of implicated product. Notification to Lifeblood should include the signs and symptoms of the reaction.

Suspected reactions can be reported by using the manufacturer's forms, who are obligated to report reactions to the Therapeutic Goods Administration. Contact the manufacturer directly to obtain their specific reporting form.

Reports can also be made directly to the TGA via their online form <https://www.tga.gov.au/safety/reporting-problems/report-adverse-event-or-problem-health-professionals> or via email ADRreports@health.gov.au.

Reporters are encouraged to provide as much detail as possible. Any information that may identify the patient or reporter is kept confidential.

Lifeblood do not require direct reporting of reactions to IVIg, except in the instance where the decision is made to change the product administered.

Note: For patients that have an adverse reaction resulting in a product change, a 'Do Not Prescribe' alert should be added to the patient's record in BloodSTAR by the treating clinical team.[3] This helps prevent future adverse reactions and raises an alert if the same product is requested in the future. For assistance with this, contact support at the National Blood Authority on 1300 BLOOD, or go to BloodSTAR user tips and support materials | National Blood Authority <https://www.blood.gov.au/bloodstar-user-tips-and-support-materials>.

For more information, BloodSafe eLearning Australia <https://bloodsafelearning.org.au/> offers 5 courses focused on immunoglobulins.[2]

References

1. CSL Behring. Australian Product Information Privigen® (Human normal immunoglobulin). Revised 2024.
2. Immunoglobulin: Adverse Events - BloodSafe eLearning Australia (bloodsafelearning.org.au) <https://learn.bloodsafelearning.org.au/course/about/immunoglobulin-adverse-events> viewed 11 June 2024.
3. National Blood Authority Criteria for immunoglobulin products | National Blood Authority <https://www.blood.gov.au/supply-system/governance-immunoglobulin-products/criteria-immunoglobulin-products>

To receive this document in another format, phone 03 9694 0102, using the National Relay Service 13 36 77 if required, or email Blood Matters <bloodmatters@redcrossblood.org.au>.

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

ISSN 2652-6212 (online/PDF/Word) or (print)

Available at Blood Matters <https://www.health.vic.gov.au/patient-care/blood-matters-program>