Detection of SARS-CoV-2 Antibodies in Immunoglobulin Products

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Learning Objectives

1. To discuss what is currently known about the SARS-CoV-2 antibody content in immunoglobulin (Ig) therapy available on the market
2. To discuss post analysis findings of Ig replacement for SARS-CoV-2 antibodies
3. To highlight potential clinical relevance of findings regarding the SARS-CoV-2 antibodies found in Ig therapy

How this project gained a life of its own

- Initial project | Primary Immunodeficiency and COVID (CoVPID)
- Key observation noted: multiple patients began to test positive for both SARS-CoV-2 antibodies in a particular pattern
- The hypothesis: Ig therapy available on the market now contains SARS-CoV-2 antibodies
**Background and Objective**

- Pre-pandemic immunoglobulin products were not found to have SARS-CoV-2 antibodies
- To date, there is limited data on SARS-CoV-2 antibodies in immunoglobulin products used in the management of primary immunodeficiency
- Objective: To examine immunoglobulin products for evidence of SARS-CoV-2 antibodies

**Methods**

- Ig products were collected from Mount Sinai infusion center and from patients undergoing home infusion.
- 156 lots of 9 different brands of Ig products were analyzed
- Ig product used in the Mount Sinai infusion center or for home infusions was examined for IgG binding activities against recombinant SARS-CoV-2 receptor binding domain (RBD), spike and nucleocapsid (NP) by ELISA.
- The area under the bind curve (AUC) was calculated and used for statistical analyses.
Fig 1: Products analyzed for IgG binding activities against recombinant SARS-CoV-2 RBD, spike and (NP) using ELISA assay. Graph represents area under curve comparing brands of Ig product. No significant difference between products. Error bars indicate mean and Standard Deviation.
Fig 2: Products analyzed for IgG binding activities against recombinant SARS-CoV-2 receptor binding domain (RBD), spike and nucleocapsid (NP) using ELISA assay. Graph represents Area under curve by location of the infusion, AUC values were significantly higher in products that were used in the infusion center compared to the products that were home infused. Error bars indicate mean and Standard Deviation. P*** <0.01 (Mann-Whitney test)

Fig 3: Products analyzed for IgG binding activities against recombinant SARS-CoV-2 receptor binding domain (RBD), spike and nucleocapsid (NP) using ELISA assay. Graph represents Area under curve by route of administration, AUC values were higher in intravenous products compared to the subcutaneous products. Error bars indicate median, 25th and 75th percentiles, respectively. P <0.0001, P<0.005 and P<0.006 for RBD, spike and NP respectively (t-test)
Fig 4: Products analyzed for IgG binding activities against recombinant SARS-CoV-2 RBD, spike and (NP) using ELISA assay. Graph represents area under curve comparing expiration date of Ig product. Significant increase in AUC in Ig products with expiration dates of 2023 and 2024 compared to pre-pandemic products. Error bars indicate mean and Standard Deviation. P*<0.05, p**<0.01, p***<0.001, p**** (One-way ANOVA with Krushal-Wallis test)

Conclusion

- Significant increase in AUC values were observed in Ig products with expiration dates of 2023 and 2024 compared to pre-pandemic Ig products.

- Approximately 60% and 100% of Ig products with expiration dates of 2023 and 2024 tested positive for anti-SARS-CoV-2 proteins respectively.

- No significant difference between products was noted, however when accounting for expiration year, was noted.

- AUC values were significantly higher in products that were used in the infusion center compared to the products that were home infused.

- When found, SARS-CoV-2 antibodies may provide a therapeutic option for patients who do not make a robust vaccine response.
Questions?

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The End