Case Study: IgG deficient patient receiving immune globulin intravenous, human-slra 10% demonstrates improvement in quality of life

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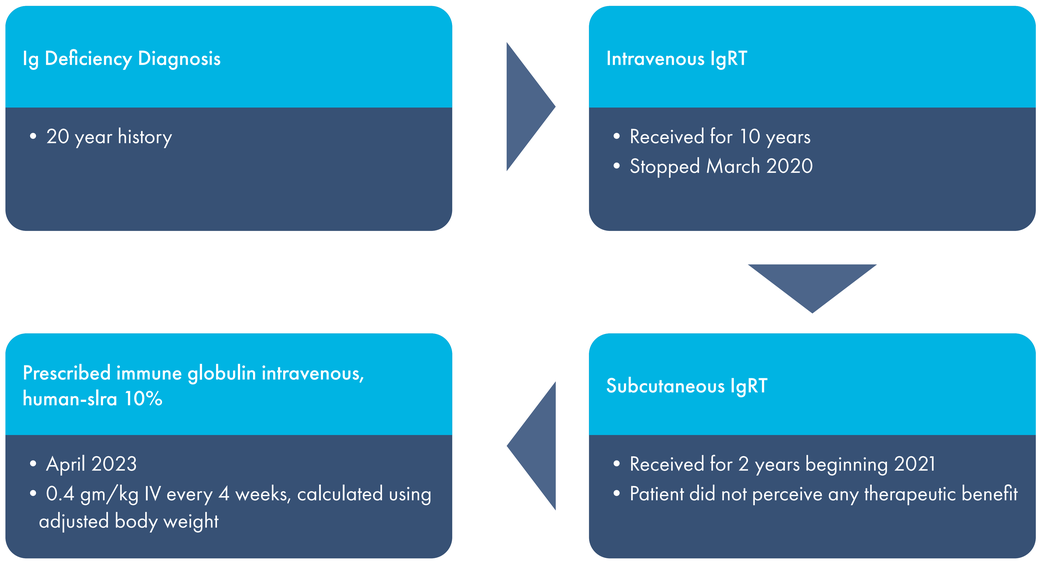
Rationale

Immunoglobulin replacement therapy (IgRT) is proven to be effective in preventing the occurrence of serious bacterial infections in patients with immunodeficiencies, but quality of life is not frequently studied in IgRT clinical trials. This case study highlights the effect of IgRT on quality of life. A 68 year-old female was referred to this complex specialty pharmacy to initiate IgRT infusions in the home for selective IgG deficiency, selective deficiency of immunoglobulin A, pemphigus, and mild asthma. She was prescribed immune globulin intravenous, human-slra 10%, an Ig product that is manufactured using plasma from donors that possess high antibody titers against RSV and other common pathogens including influenza, parainfluenza, metapneumovirus, and seasonal coronaviruses.[1,2]

Figure 1. Patient history and IgRT details



Methods

A retrospective analysis of the patient's medical records was performed. The review consisted of data contained within a customized clinical assessment created by this complex specialty pharmacy, including the Primary Antibody Immune Deficiency Quality of Life (PADQOL-16), a validated quality of life measure specific to primary immunodeficiency.[3] Additional items collected and analyzed from the customized clinical assessment included drug tolerability, side effect management, infection history, and anti-infective us

References

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3. Ballow M, Conaway MR, Sriaroon P, Rachid RA, Seeborg FO, Duff CM. Construction and validation of a novel disease-specific quality-of-life instrument for patients with primary antibody deficiency disease (PADQOL-16). J Allergy Clin Immunol. 2017 Jun;139(6):2007-2010.e8. doi: 10.1016/j.jaci.2016.11.029. Epub 2017 Jan 5.

Results

After 148 days of therapy, the patient experienced an 11-point improvement in the PADQOL-16 (Table 1). The most significant improvement in the PADQOL-16 total score was obtained at day 58 of therapy (score = 2), which was then sustained through the remainder of the available clinical documentation at day 148. The patient did not experience any infections while on therapy, and reported side effects were chills/rigors with one infusion. Differences in the PADQOL-16 scores around the same infusion were observed depending on the interviewer – a pharmacy team member via telephonic outreach versus a registered nurse during IgRT administration. A therapy satisfaction questionnaire was conducted with the patient in January 2024 (Table 2). No issues related to immune globulin intravenous, human-slra 10% or barriers to care were reported.

Table 1. PADQOL-16 questions and results

Scoring: 0 = Rarely/never, 1 = Sometimes, 2 = Often/always

Date	5/2/2023	5/4/2023	5/24/2023	6/1/2023	6/29/2023	7/27/2023	8/24/2023	9/21/2023	10/19/2023
Interviewer	Pharmacist	Nurse	Pharmacist	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse
1. I get infections between infusions	2	0	1	0	0	0	0	0	0
2. I am more than tired than normal	2	2	1	2	0	0	0	0	0
3. My cough has worsened	0	0	0	0	0	0	0	0	0
4. I have flare ups and symptoms of sinusitis	2	0	2	0	0	0	0	0	0
5. I have to seek unscheduled medical visits for my PIDD	2	0	2	0	0	0	0	0	0
6. I have nausea and bloating	0	0	0	0	0	0	0	0	0
7. I have trouble with infections	2	0	1	0	0	0	0	0	0
8. The effects of my treatment wears off between infusions	0	0	0	0	0	0	0	0	0
9. I have trouble with shortness of breath	0	0	0	0	0	0	0	0	0
10. I struggle to keep up with others	1	1	1	1	1	1	1	1	1
11. I have trouble sleeping	0	1	0	1	1	1	1	1	1
12. I feel downhearted and depressed about my PIDD	0	0	0	0	0	0	0	0	0
13. I have missed school or work due to my PIDD	0	1	0	1	0	0	0	0	0
14. I feel that I am a burden to others	0	0	0	0	0	0	0	0	0
15. I require help from others frequently	1	0	1	0	0	0	0	0	0
16. I avoid certain places and situations because of my PIDD	1	2	1	2	0	0	0	0	0
PADQOL-16 Total Score	13	7	10	7	2	2	2	2	2

Table 2. Therapy satisfaction questionnaire

Therapy Satisfaction Question	Response
1. The medication is working for me*	7 – Strongly agree
2. The medication is worth my time and energy*	7 – Strongly agree
3. The therapy is a burden to me and my family*	1 – Strongly disagree
4. The side effects are outweighing the benefits of the therapy*	1 – Strongly disagree
5. Are there any barriers you face related to receiving your medication?†	None
6. Any problems with infusing?	No

*Scoring for Questions 1-4: 1 - Strongly disagree, 2 - Disagree, 3 - Somewhat disagree, 4 - Neither agree nor disagree, 5 - Somewhat agree, 6 - Agree, 7 - Strongly agree
†Response options for Question 5: Financial, Scheduling, Travel to the infusion center/office, Other, None

Conclusion

Immune globulin human-slra 10% is well-tolerated and effective in preventing infections in IgG deficient patients, and this case study demonstrates the added quality of life benefit this IgRT provides. The addition of a validated, disease-specific quality of life measure, such as the PADQOL-16, in routine clinical assessments allows the opportunity for this national complex specialty pharmacy to collect and analyze real-world data for IgRT beyond single case reports in future studies.

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