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Retrospective Review of Real-World Evidence of Immune Globulin Intravenous (IVIG), Human-slra 10% in Patients with Primary Immunodeficiency with Recurrent Infections

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INTRODUCTION

Immune globulin intravenous (IVIG), human-slra 10% is an immune globulin indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years).[1] IVIG, human-slra is a blend of normal source plasma with plasma from donors with high neutralizing antibody titers to respiratory syncytial virus (RSV).[2] The objective was to analyze real-world evidence to characterize patients with PI that may benefit from IVIG, human-slra for immune globulin replacement therapy (IgRT).

METHODS

We performed a retrospective review of real-world evidence from presented case reports of patients with PI who initiated IVIG, human-slra for replacement therapy in the outpatient setting. Patient demographics were collected from clinical presentations along with past medical history and clinical course. Patient characteristics analyzed included respiratory comorbidities and infection history. Key outcomes in the clinical course included infections, antibiotic use, hospitalizations, respiratory medication use, and adverse events.

RESULTS

Characteristics	N=26
Age in years, mean (range)	57 (16 to 86)
Female, n (%)	18 (69)
Documented previous IgRT, n (%)	23 (88)
Past Medical History	
Recurrent respiratory infections, n (%)	25 (96)
Frequent or prophylactic antibiotic use, n (%)	19 (73)
Hospitalizations, n (%)	10 (38)
Asthma, n (%)	15 (58)
Sinusitis, n (%)	15 (58)
Bronchiectasis, n (%)	14 (54)
Chronic bronchitis, n (%)	13 (50)

Table 1. Characteristic of patients treated with IVIG, human-slra 10% as reported (n=26)

Patient Characteristics
Twenty-six patients were included, with an average age of 57 years old (range: 16 to 86). Twenty-three patients (88%) had documented previous IgRT. A majority of patients had a history of asthma (58%), frequent or prophylactic antibiotic use (73%), bronchiectasis (54%), chronic bronchitis (50%), recurrent infections (96%), and sinusitis (58%).

Clinical Course on IVIG, human-slra
After initiating IVIG, human-slra, patients reported improved asthma control (19%) and reduced infections (100%) with 54% reporting zero respiratory infections. Additionally, 58% of patients reported improved quality of life. Three patients had documented hospitalizations after initiating IVIG, human-slra. All patients tolerated IVIG, human-slra well without any serious adverse events reported.

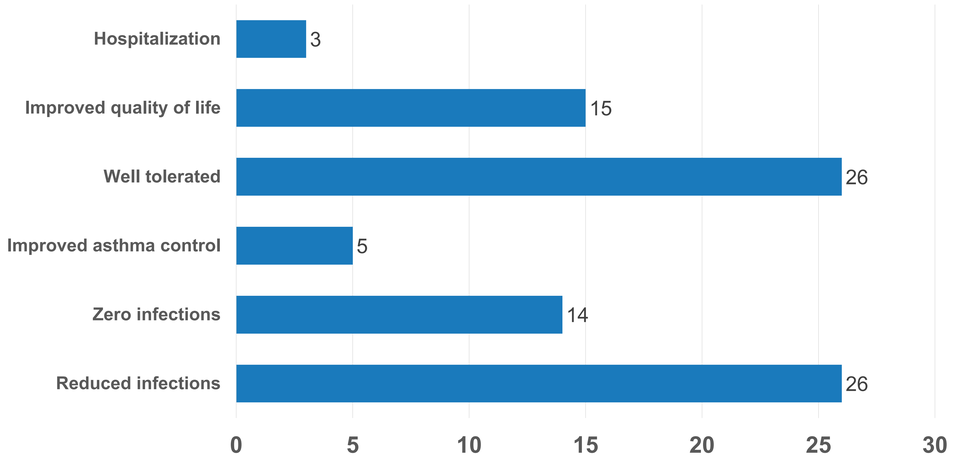

Figure 1. Clinical Outcomes as reported by physician in case presentation(n=26)

DISCUSSION

Most patients who were initiated on IVIG, human-slra had a history of recurrent respiratory infections, frequent antibiotic use, hospitalizations due to infections, asthma, sinusitis, and bronchiectasis. During the clinical course once initiated on IVIG, human-slra, patients experienced reduced infections, improved asthma control, and improved quality of life as reported by the physician. All patients reported favorable tolerability and no serious adverse events.

This study is limited due to its retrospective nature and differences in reporting; however, these preliminary indicators may help guide future studies.

Overall, patients with PI and a history of recurrent infections and respiratory comorbidities despite IgRT may benefit from IVIG, human-slra. Additional studies may be warranted in larger populations to confirm these results.

REFERENCES

1. ASCENIV™ (immune globulin intravenous, human-slra), 10% liquid. [Prescribing Information].Boca Raton, FL: ADMA Biologics, Inc. April 2019.
2. Orange JS, et al. Front Immunol. 2015;6:431

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