P-432

Infection Rate Reduction in Primary Immunodeficiency Patients Following Initiation of High-Titer Immunoglobulin

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KEY FINDINGS

- **IVIG-slra initiation was associated with significant reductions in total, bacterial, and viral respiratory infection rates and a numerical reduction in SBIs.**
- **IVIG-slra was well tolerated, with only two adverse events across 382 infusions and no treatment discontinuations.**
- **These findings support the clinical potential of targeted antibody enrichment against respiratory pathogens.**

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Introduction

- Primary immunodeficiency (PI) is associated with recurrent infections despite immunoglobulin (Ig) replacement, with many patients experiencing persistent respiratory infections (RI) on standard Ig.[1-4]
- Immune globulin intravenous, human-slra (IVIG-slra) [ASCENIV™] is a plasma-derived intravenous immunoglobulin (IVIG) produced using targeted donor selection to enhance antibody titers against respiratory viruses, including respiratory syncytial virus.[1, 5]
- Whether this high-titer enriched profile improves infection outcomes remains unclear.
- This study evaluated infection rates and safety after IVIG-slra initiation in a real-world cohort and represents one of the first real-world analyses beyond case reports.

Methods

- This multicenter cohort study was conducted across immunology physician practices from August 2021 through December 2024.
- Patients ≥ 12 years of age with primary immunodeficiency who switched from standard Ig therapy to IVIG-slra or initiated IVIG-slra were included.
- Data collected from a centralized electronic health record included:
  - Demographics, comorbidities and PI disease history
  - Therapy characteristics, including Ig therapy 12 months prior to IVIG-slra
  - Respiratory and serious bacterial infections (SBIs) were identified during the 12 months pre- and post-IVIG-slra initiation
- Efficacy was assessed using annualized respiratory infection and serious bacterial infection rates.
- Safety was assessed by collecting adverse events occurring during therapy, including those leading to therapy discontinuations.
- Healthcare resource utilization was captured after IVIG-slra initiation, including hospitalizations and emergency department visits.
- Continuous data were reported as medians with interquartile ranges (IQR), and categorical data as counts and percentages.
- Pre- and post-initiation infection rates were compared using rate ratios with 95% confidence intervals.

Study Design

Multicenter retrospective cohort study of patients with primary immunodeficiency receiving IVIG-slra



Annualized pre- and post-initiation infection rates compared using rate ratios with 95% CIs

Study Cohort

30 Patients | **93% Female** | **Median Age 57 years** | **Median Disease Duration 3 years** | **BMI 26.2 kg/m²**

Figure 1. Comorbidities

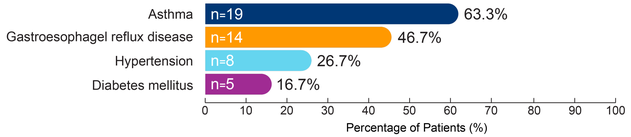


Figure 2. Primary Diagnosis

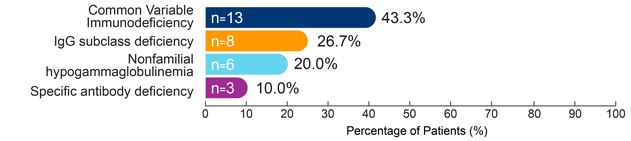
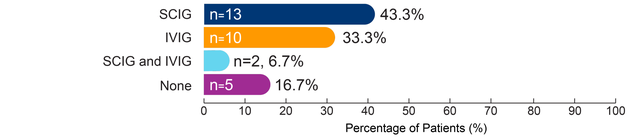


Figure 3. Prior Therapy[1]



IVIG-slra Therapy Characteristics

382 Total Infusions | **466 mg/kg median monthly dose** | **13 median doses per patient** | **80% received premedications** | **1 respiratory-related hospitalization**

Figure 4. Dosing Frequency

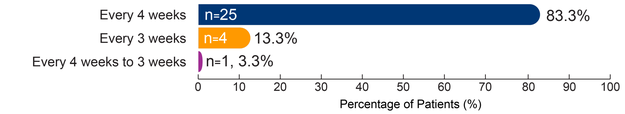
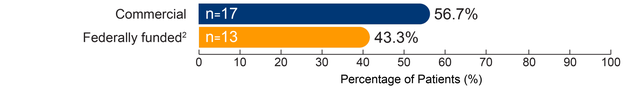


Figure 5. Payor Information



Safety

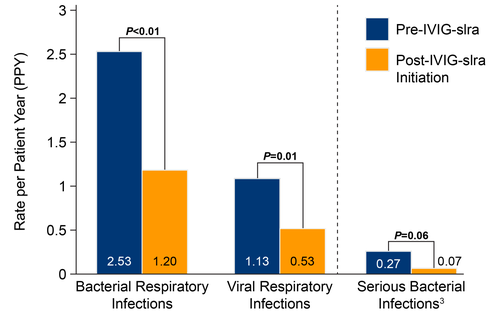
2 patients experienced 2 AEs (6.7%)
- urticaria
- nausea and chills

Rate of AEs per infusion = 0.5%
(2 of 382 infusions)

- No discontinuations during treatment

Efficacy

Figure 6. Respiratory and Serious Bacterial Infections 12 Months Before and After IVIG-slra Initiation



- One fungal infection occurred before initiation, and none after.

Table 1. Rate Ratios for Infections Before and After IVIG-slra Initiation

Outcome	Rate ratio (95% CI)	P Value
Total respiratory infections	0.469 (0.335-0.649)	**<0.01**
Bacterial respiratory infections	0.474 (0.316-0.713)	**<0.01**
Viral respiratory infections	0.471 (0.254-0.845)	**0.01**
Serious bacterial infections	0.250 (0.036-1.081)	0.06

Discussion

This study provides real-world evidence of IVIG-slra [ASCENIV™] use and infection rates in patients with primary immunodeficiency.

- Participants were predominantly female, with a median age of 57 years and a median disease duration of 3 years.
- The cohort had substantial comorbidity and prior treatment exposure; asthma and GERD were the most common comorbidities, and 83.3% of patients had previously received Ig therapy.
- IVIG-slra initiation was associated with significantly lower total, bacterial, and viral respiratory infection rates, while serious bacterial infections decreased numerically.
- IVIG-slra was well tolerated, with adverse events infrequently observed. The incidence and severity were consistent with the established known class effects of IVIG.[5]
- These findings support further evaluation of targeted antibody enrichment against respiratory pathogens in selected patients with PI.
- A limitation of this study is that retrospectively collected infection data may be subject to underreporting and recall bias.

Abbreviations

Abbreviations: AE, adverse event; BMI, body mass index; CVID, common variable immunodeficiency; GERD, gastroesophageal reflux disease; HCRU, healthcare resource utilization; Ig, immunoglobulin; IQR, interquartile range; IVIG, intravenous immunoglobulin; PI, primary immunodeficiency; RI, respiratory infections; SBI, serious bacterial infection; SCIG, subcutaneous immunoglobulin

Footnotes

[1] Median duration of prior therapy (years) = 10, IQR 0-6
[2] Federally funded includes Medicare and Medicare Advantage
[3] SBIs pre-IVIG-slra included pneumonia (n=8); post-IVIG-slra included pneumonia (n=1), sepsis (n=1)

References

1. Orange JS, et al. J Allergy Clin Immunol. 2006; 117: S525-53.
2. Perez EE, et al. J Allergy Clin Immunol. 2017; 139: S1-S46.
3. Cunningham-Rundles C, et al. Clin. Immunol. 1999; 92: 34-48.
4. Busse PJ, et al. J. Allergy Clin. Immunol. 2002; 109: 1001-1004.
5. ASCENIV (immune globulin intravenous, human-slra) [package insert]. Boca Raton, FL: ADMA Biologics, Inc., 2026.

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