Retrospective Crossover of Patients with Primary Immunodeficiency Switching from Standard Immune Globulin Replacement Therapy to ASCENIV

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Background

Inborn errors of immunity are associated with recurrent infections, impaired quality of life, and increased morbidity and mortality.[1] Immunoglobulin replacement therapy (IgRT) improves outcomes; however, some patients continue to experience persistent infections.[2,3] ASCENIV™ is a 10% intravenous immune globulin (IVIg) indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12–17 years) and contains a blend of normal source plasma and plasma with high antibody titers to respiratory syncytial virus (RSV) and other pathogens.[4] In a phase 3 trial, ASCENIV demonstrated zero acute serious bacterial infections over 12 months, and post approval case reports have described reduced infection rates in patients with PI who transitioned to ASCENIV after experiencing recurrent infections on standard IgRT products.[5] The goal of this retrospective crossover was to investigate changes in infection rates among patients with PI who switched from a standard IgRT product to ASCENIV.

Methods

This retrospective analysis used de-identified medical records from Soleo Health captured in SoleMetrics® between January 1, 2020, and December 31, 2024. Patients were included if they received ASCENIV for the treatment of PI after receiving a different IgRT from the same specialty pharmacy prior to transitioning to ASCENIV. The Full Population (n = 29) comprised all eligible patients followed through December 31, 2024, while the Targeted Population (n = 17) included those with ≥120 assessment days on each therapy. Patient reported infections were collected during telephonic pharmacy care team encounters or nursing visits for Ig administration. Infection rates before and after transition were compared using Poisson regression.

Results

In the Targeted Population (n = 17), mean infections/patient were reduced from 2.9 with previous IgRT to 0.9 with ASCENIV (P = 0.0310 adjusted for assessment days) and mean respiratory infections from 2.1 to 0.8 infections/patient. The odds ratio for any infection with ASCENIV in this population was 0.502 (95% confidence interval, 0.096–2.631), representing a 50% reduction in infection risk. A total of 49 infections with previous IgRT were reported over a cumulative 12,403 assessment days across all patients in this population, yielding a ratio of 1 infection per 253 assessment days. There were 16 infections with ASCENIV reported over 6,724 assessment days, yielding a ratio of 1 infection per 420 assessment days.

Figure 1. Number of infections by type

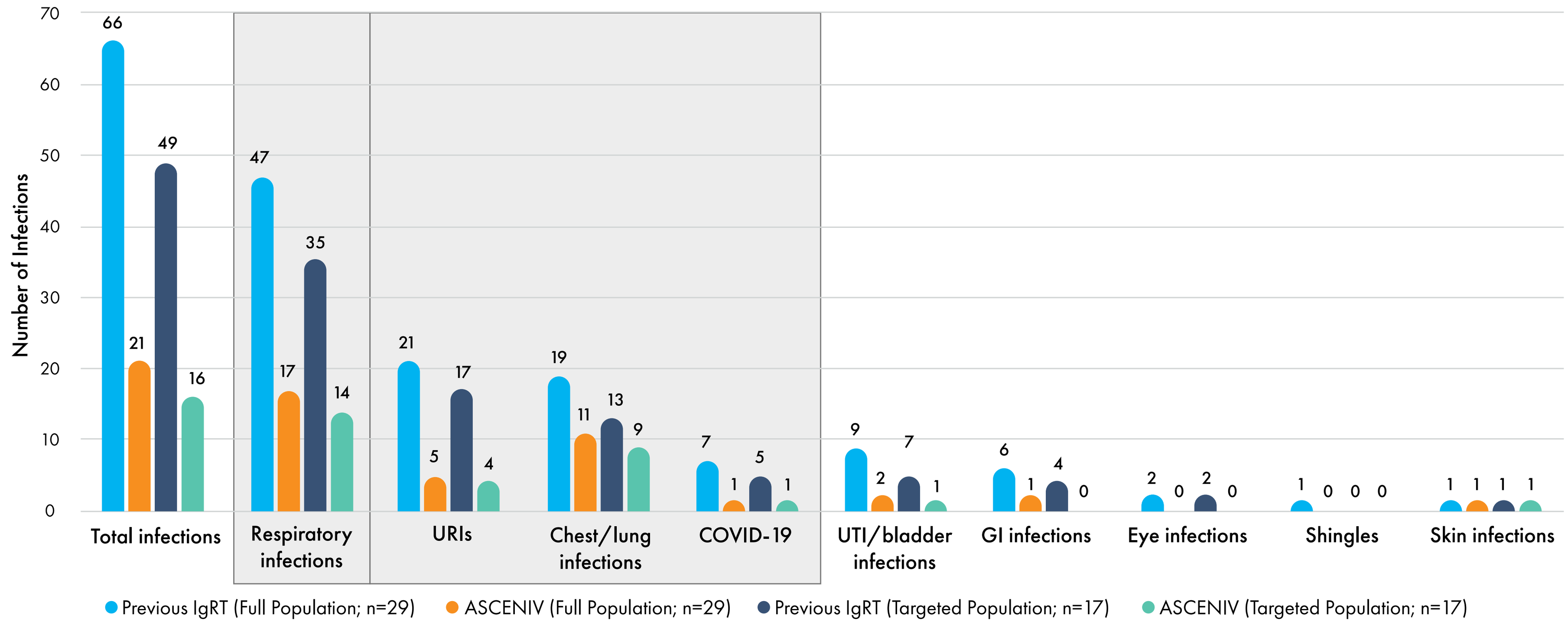

Figure 2. Summary of infection frequency

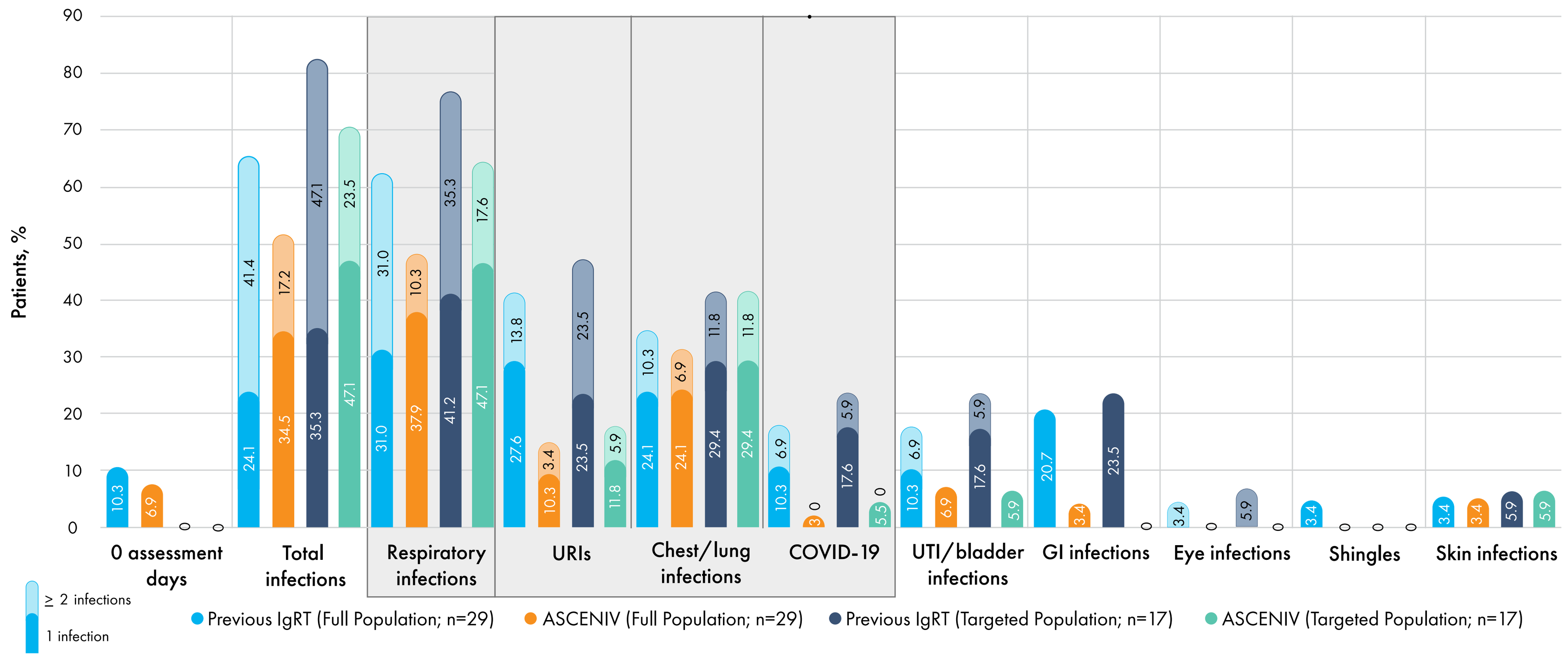

Table1. Summary of infection frequency per assessment year

	Full Population (n = 29)		Targeted Population (n = 17)	
	Previous IgRT	ASCENIV	Previous IgRT	ASCENIV
Patients with 0 assessment days, n (%)	3 (10.3)	2 (6.9)	0	0
Infections per assessment year	n = 26	n = 27	n = 17	n = 17
Total infections	1.32	0.90	1.44	0.87
Respiratory infections	0.94	0.73	1.03	0.76
URIs	0.42	0.21	0.50	0.22
Chest/lung infections	0.38	0.47	0.38	0.49
COVID-19	0.14	0.04	0.15	0.05
UTI/bladder infections	0.18	0.09	0.21	0.05
GI infections	0.12	0.04	0.12	0
Eye infections	0.04	0	0.06	0
Shingles	0.02	0	0	0
Skin infections	0.02	0.04	0.03	0.05

Discussion

In this real world, retrospective crossover analysis, patients with inborn errors of immunity who switched from standard IgRT to ASCENIV experienced fewer infections overall. Consistent directional benefits were observed across multiple infection endpoints, including assessment day-adjusted infection frequency and odds of any infection. Additionally, patients with higher infection burdens on prior IgRT were most likely to experience reductions after switching to ASCENIV, suggesting potential benefit in patients with suboptimal response to standard IgRT products. IgRT product selection should be individualized for each patient's clinical needs and comorbidities. These findings support the role of individualized IgRT selection in patients with persistent infections despite standard Ig therapy.[2] Although variability in follow up duration, dosing, and seasonality may have influenced infection reporting, adjustment for assessment days and focused analysis of patients with sufficient exposure duration strengthen the clinical relevance of the results.

Conclusion

Switching from standard IgRT to ASCENIV was associated with clinically meaningful reductions in infection burden among patients with PI, particularly in those with adequate longitudinal follow up. ASCENIV was associated with approximately 50% lower odds of any infection and reductions in total and respiratory infections compared with prior IgRT. These findings support ASCENIV as a potential therapeutic option for patients with persistent infections despite standard IgRT and warrant further prospective evaluation in larger cohorts.

References

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