Real-world experience of a cohort of previously untreated PI patients on SCIG

Christopher Scalchunes, MPA[1], Rajiv Mallick, PhD[2], Jacob M. Romano, PharmD, RPh, BS[2] and Tiffany S. Henderson, PhD[1]

1. Immune Deficiency Foundation (IDF), Towson, MD; 2. CSL Behring, King of Prussia, PA

Introduction

- Primary immunodeficiency (PI) diseases include over 300 diverse disorders and the use of intravenous (IV) immunoglobulin (IgG) has long been considered the standard of care in the US for many of these [1, 2]
  - To minimize the risk and severity of infections, IgG therapy in PI is often a lifelong treatment
- Over the past two decades subcutaneous immunoglobulin (SCIG) has grown in popularity, which for some offers a more convenient administration option than intravenous immunoglobulin (IVIG) with reduced systemic adverse events and no requirement for venous access [3, 4]
- SCIG is typically used as a maintenance treatment: patients are often initiated and stabilized with IVIG (every 3–4 weeks for 3 months) before transitioning to a weekly SCIG maintenance dose [5, 6]
- Growing evidence suggests that initiation with SCIG in patients previously untreated with IgG, could be viable and well tolerated [4, 5, 7]. A retrospective study showed that SCIG initiation is well tolerated in elderly patients [5]
- The proportion of PI patients aged ≥65 years has been increasing, and older patients with PI have higher rates of comorbidities and secondary infections than those aged ≤64 years [8]
  - Therefore, a means of administering IgG treatment that may improve tolerability versus IVIG could be of particular benefit in this population

Aim

- Here, we report the characteristics and treatment satisfaction of previously untreated (IgG-naïve) PI patients initiated directly on SCIG, and compare the results with SCIG-treated patients who previously received IVIG

Methods

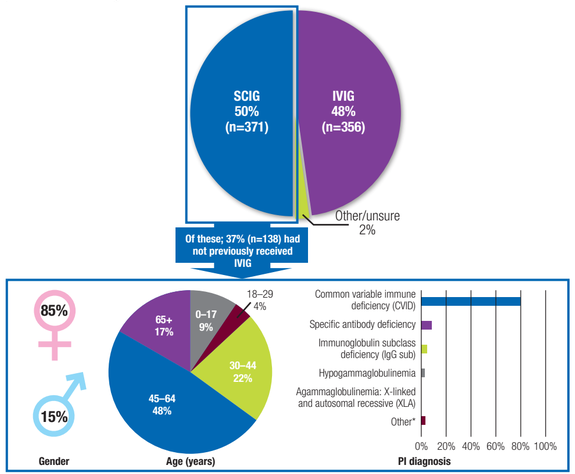
- An online survey was sent to patients with PI or their caregivers from a nationally distributed database of the membership of the Immune Deficiency Foundation (IDF), between March 10–31, 2017. The survey represented a non-probability sample, i.e. may not be completely representative of the entire PI population in the US
- The survey included questions on treatment history, SCIG infusion experience, and reasons for initiating IgG therapy on SCIG
- Treatment satisfaction was captured via the Treatment Satisfaction Questionnaire for Medication (TSQM) [9]
- TSQM is a validated quality-of-life tool that measures patients' satisfaction with their medication and consists of 14 questions reflecting four domains: *effectiveness*, *side effects*, *convenience*, and *global satisfaction*
- Raw scores were transformed to a 0 (lowest satisfaction) to 100 (highest satisfaction) scale, consistent with TSQM scoring [9]

Results

Patient characteristics

- Of patients currently receiving SCIG, 37% (n= 138) reported they had directly started on SCIG; these patients tended to be female, more than 30 years old, and diagnosed with common variable immune deficiency (CVID) (**Figure 1**)
- The previously untreated patients were more likely than those who had previously received IVIG to have a late diagnosis, with 57% of patients diagnosed aged ≥45 years, compared with 37% of those SCIG patients previously receiving IVIG (p<0.001)
- For most patients (>70%), the decision to start SCIG was made by the prescriber
- The most important factors, selected from a predefined list, that influenced the previously untreated cohort of patients to choose SCIG were that no travel was required and they could do it themselves without nurse assistance (**Figure 2**)

Figure 1: IVIG/SCIG distribution and demographics of previously untreated PI patients receiving SCIG†



PI: primary immunodeficiency.
*other diagnoses included: Dysgammaglobulinemia, Hypocomplementemia and Hype-IgE Syndrome.
†Due to the nature of patient-reported survey data, a minority of respondents provided incongruent answers with respect to their IgG product and IgG route of administration; this data is based on those who selected SCIG as their route of administration

Infusion characteristics

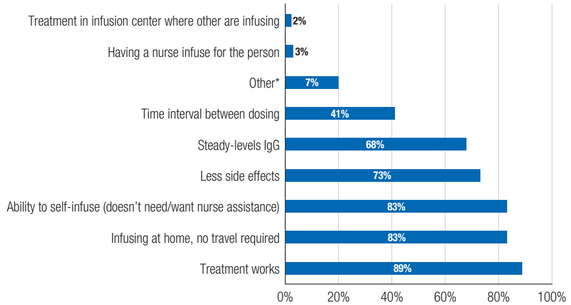
- Although the majority of respondents on SCIG were prescribed to infuse weekly, infusions were less frequent in the previously untreated cohort (p<0.001) (**Table 1**)

Table 1: Comparison of infusion characteristics between previously untreated SCIG patients and those previously on IVIG

		Previously on IVIG (n=231)	Previously untreated (n=138)	P-value
High dose IgPro20	Everyday	2	1	<0.001
	2–3 times per week	8	3	
	Weekly	68	62	
	Every 2 weeks	12	15	
	Every 3 – 4 weeks	9	19	
	Other*	2	1	
Infusion time Mean ± SD (mins)		132 ± 76	116 ± 56	0.05
Number of infusion sites (%)	1	6	9	0.007
	2 – 3	47	58	
	4+	47	33	

A Fisher's exact test was used to compare the categorical variables between the two groups and calculate p-values. The total number of patients providing data on their infusions was 369 (2 responses were missing). *Other responses included: 'every six weeks', 'five times per week', and 'every ten days'.

Figure 2: Factors considered important by the previously untreated cohort of PI patients when selecting SCIG treatment (respondents, n= 138)



Respondents were able to select all answers that applied from a pre-defined list or select 'other' and provide their own reason.
*Other responses included: poor veins, venous access difficult; I can travel and self-infuse when I want; SCIG is quicker and doesn't need refrigeration; my insurance will pay for SCIG. SCIG: subcutaneous immunoglobulin.

- Previously untreated respondents tended to have a shorter infusion duration (p=0.05) and reported using fewer infusion sites (p<0.007) (**Table 1**)
  - Infusion time and duration would have been affected by the use of different SCIG products, patient weight, and specific dosing instructions

Treatment satisfaction

- There was no significant difference in treatment satisfaction between the two SCIG groups; the mean TQSM (standard deviation) was identical for both groups at 74 (16)
- Overall, 85% of previously untreated respondents reported they were either satisfied, very satisfied, or extremely satisfied with SCIG

Conclusions

- **SCIG use in previously untreated (IgG-naïve) PI patients was relatively common in this survey of IDF members**
- **Compared to those who had switched from IVIG, previously untreated SCIG patients seemed to have lower infusion frequency and infusion times**
- **Most previously untreated respondents were satisfied, very satisfied or extremely satisfied with their current SCIG treatment**
- **These findings indicate similar flexibility and convenience of SCIG in patients who were not initiated on IVIG without any apparent difference in treatment outcomes/satisfaction**

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