Optimizing Infusion Time in Patients with Primary Immunodeficiency Disease Using Home-Based Subcutaneous Immunoglobulin Infusion Therapy

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Aim

To understand how to optimize subcutaneous infusion time in primary immunodeficiency treatment

Introduction

The standard of care for primary immunodeficiency patients is home-based IgG treatment delivered subcutaneously. This therapeutic modality improves quality of life over alternative administration modalities.[1] Moreover, subcutaneous therapy is associated with reduced side effects.[2] This therapy is delivered through an infusion system consisting of a pump, tubing and needle set that presents a range of possible infusion times for the prescribed drug and dose. This study was undertaken to determine whether an opportunity exists to save infusion time, and to quantify time savings; savings that would benefit patients and caregivers. Infusion time optimization has not been studied previously.

Study Overview

This is a simulation study using the Koru Freedom Flow Rate Calculator. All simulations were based on existing patients, beginning with their prescribed infusion protocols. Only patients where existing prescribed protocols utilized a complete KORU system were included. Ninety-seven patients with existing prescriptions were included.

Methodology

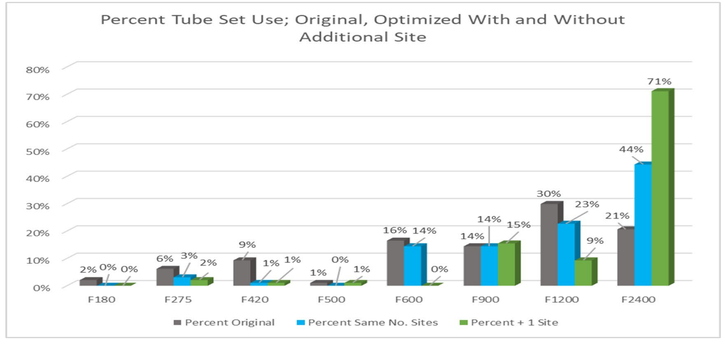
A simulation was conducted using the patient's prescribed protocol, and infusion times were captured. Five different drugs were evaluated. Next, the same drug and dose were maintained in simulations while (1) the number of needle sites in the original protocol was maintained and (2) where the number of needle sites was increased by one site over the original number of sites.

Needle gauge (24g and 26g) and tubing sets were adjusted to maximize flow, without exceeding the drug manufacturer's recommendations, or without exceeding rates found in the original protocol where the drug manufacturer's stipulated rates were exceeded. Simulation infusion times were captured in both instances. Time savings were calculated on a per-infusion and yearly basis. Yearly savings were calculated using the number of infusions indicated in the original prescribed protocol. Results are shown at right. In the +1 site simulation, all time savings were statistically significant.

Results

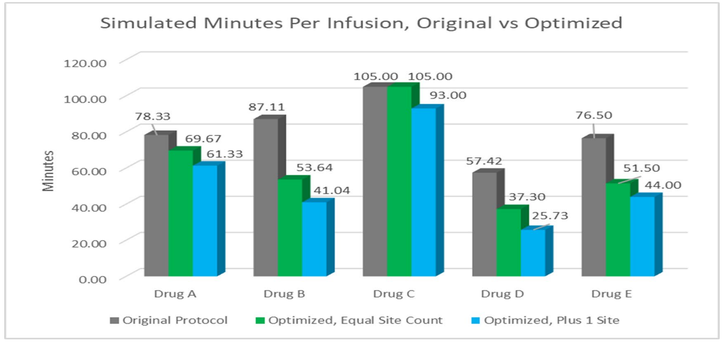
For the cohort of 97 patients, the weighted mean simulated savings was 25.97 minutes per infusion, when number of needle sites remained the same; and 38.94 minutes per infusion when one additional needle site was added to the original protocol. In the case of one additional site added, this corresponded to a mean yearly time savings of 1 day 8 hours and 13 minutes ($p < .00001$).

Demographics		
Variable	Results	
N	97	
Gender	71 F, 26 M	
Statistic	Mean	Std. Dev.
Age, years	59.42	19.79
Height, inches	64.82	5.95
Weight, pounds	165.59	49.96



Range and Mean of Time Savings Over 1 Year with Optimization, by Drug, Keeping Site Count Constant				
Drug	N	Lowest Savings	Highest Savings	Mean Savings per Year
Drug A	3	0 days 0 hr 0 minutes	0 days 22 hr 31 minutes	0 days 7 hr 30 minutes
Drug B	54*	0 days 0 hr 0 minutes	2 days 10 hr 56 minutes	1 day 3 hr 0 minutes
Drug C	4	No Savings for any Patient		
Drug D	33	0 days 0 hr 0 minutes	5 days 9 hr 16 minutes	0 days 15 hr 48 minutes
Drug E	2	0 days 1 hr 44 minutes	1 day 17 hr 36 minutes	0 days 21 hr 40 minutes
*One of 55 patients excluded because dose frequency is unspecified				

Range and Mean of Time Savings Over 1 Year with + 1 Site Optimization, by Drug				
Drug	N	Lowest Savings	Highest Savings	Mean Savings per Year
Drug A	3	2 hrs 36 minutes	1 day 7 hrs 12 minutes	13 hrs 51 minutes
Drug B	54*	6 hrs 3 minutes	8 days 22 hrs 56 minutes	1 day 12 hrs 17 minutes
Drug C	4	1 hr 44 minutes	1 days 2 hrs 52 minutes	10 hrs 24 minutes
Drug D	33	52 minutes	5 days 22 hrs 57 minutes	1 day 1 hr 7 minutes
Drug E	2	9 hrs 32 minutes	1 day 22 hrs 47 minutes	1 day 4 hrs 10 minutes
*One of 55 patients excluded because dose frequency is unspecified				



Discussion

Infusion time can be reduced in most instances by increasing tubing set flow rating, and in a limited number of instances by changing needle gauge, while keeping drug and dose constant. Further time reduction is possible by increasing the number of needle sites. Presently, few prescribed protocols are optimized with respect to infusion time.

Conclusion

The potential to reduce subcutaneous infusion time has not been studied systematically before. Reducing infusion time is likely to improve the infusion experience for patients and caregivers, and may improve compliance. Further patient and caregiver assessment is recommended

References

1. Pasquet M, Pellier I, Aladjidi N, Auvignon A, Cherin P, Clerson P, Cozon G, Jaussaud R, Bienvenu B, Hoarau C. A cohort of French pediatric patients with primary immunodeficiencies: are patient preferences rearding replacement immunotherapy fulfilled in real-life conditions? Patient Preference and Adherence 10 July 2017:11.
2. Geng B, Clark K, Evangelista M, Wolford E. Low rates of headache and migraine associated with intravenous immunoglobulin infusion using a 15-minute rate escalation protocol in 123 patients with primary immunodeficiency. Front. Immunol. 2023 Feb 2;13:1075527. Doi: 10.3389/fimmu.2022.1075527.