Quality Improvement Study to Evaluate Patient-Centered Outcomes and Infusion Parameters Using the HIgH-Flo Super26 Needle Set Vs. Standard HIgH-Flo 26g Needle Set in Patients with Primary Immunodeficiency (PID) Requiring Chronic SCIg Therapy

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Introduction and Objectives

Immunoglobulin replacement therapy is the cornerstone of the management of antibody deficiency syndromes.[1] Subcutaneous immunoglobulin (SCIg) replacement is increasingly becoming the preferred method of administration for many Primary Immunodeficiency Disorder patients. While there are many advantages of SCIg, some patients continue to experience local adverse reactions that affect quality of life. In certain patients, the local adverse reactions become a limiting factor to comfortable continuation of SCIg. Furthermore, due to the more frequent dosing and self-administration, the time it takes to complete each infusion remains an important concern for some patients.[1,2] Efforts to improve the efficiency of delivery via the subcutaneous route while maintaining tolerability are crucial to enhance the patient experience.

One variable that impacts the flow rate of SCIg is needle size. While increasing the needle size (e.g. 26G to 24G) may increase flow rate and decrease infusion time, it may also lead to decrease in local tolerability. However, by improving the flow rate characteristics of a standard, smaller gauge needle rather than increasing the overall diameter of the needle, it may be possible to increase flow rate without leading to a larger, more traumatic puncture.

The objective of this quality improvement project is to evaluate whether a needle set with an improved (higher) flow rate profile compared to the same size (gauge) needle set with a putatively lower flow rate profile will improve the rate of SCIg infusion without leading to negative changes in local tolerability or self-reported patient experience variables.

Background

The HIgH-Flo Super26™ Subcutaneous Safety Needle Set (HIgH-Flo Super26™) is FDA-cleared and CE-marked for patient use and is designed for use with the FREEDOM60® and FreedomEdge® Syringe Infusion Systems manufactured by KORU Medical Systems (formerly RMS Medical Products).

The HIgH-Flo Super26™ Subcutaneous Safety Needle Set is indicated for subcutaneous infusion of medications in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling for the capacity for infusion of high flow rates including human plasma derived immunoglobulins when used according to the FDA approved biologic labeling for: Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring); and Cuvitru™ Immune Globulin Infusion (Human) 20% (manufactured by Shire/Takeda).

The HIgH-Flo Super26™ has a nominal flow rate that is twice (2x) the nominal flow rate of the Standard HIgH-Flo 26G needle set. The HIgH-Flo Super26™ employs a needle diameter (outside dimension) that is 60% that of the HIgH-Flo 24G needle set.

Methods

- Patients (n=16) were selected according to the following criteria:
  - ✔ > 18 years of age
  - ✔ Diagnosis of Antibody Deficiency requiring immunoglobulin replacement
  - ✔ Stable SCIg treatment (all patients were receiving Hizentra® 20%)
  - ✔ Current users of the FREEDOM60® Syringe Infusion Systems manufactured by KORU Medical Systems (formerly RMS Medical Products)
  - ✔ Current users of Standard HIgH-Flo 26G Subcutaneous Safety Needle Sets™ with appropriate Precision Flow Rate Tubing™
  - ✔ Patients agreed to participate in a Quality Improvement Project administered by Santa Barbara Specialty Pharmacy (SBSP)
- Patients self-administered 4 SCIg infusions according to their currently prescribed dose, flow rate, and supplies.
- Patients then self-administered 4 SCIg infusions according to their currently prescribed dose, flow rate and supplies with the only change being the introduction of the HIgH-Flo Super26™ needle set.
- An Infusion Questionnaire was administered by a trained nurse from SBSP at each of the 4 infusions with the Standard HIgH-Flo 26G needle set and at each of the 4 infusions with the HIgH-Flo Super26™ needle set.
- The Infusion Questionnaire included data capture for the following:
  - ✔ Patient Demographics
  - ✔ Infusion site
  - ✔ Number of needles, needle length
  - ✔ Precision Flow Rate Tubing™ type (e.g. F900)
  - ✔ Infusion volume
  - ✔ Infusion time
  - ✔ Patient Experience & Tolerability measures (10cm visual analong scale (VAS) {0 – 10}) :
    - ▸ Ease of Use ▸ Comfort ▸ Infusion Duration
    - ▸ Redness ▸ Swelling ▸ Pain
    - ▸ Itching ▸ Leakage at site ▸ Overall Satisfaction
- Data were analyzed for mean changes in Infusion Time and Patient Experience variables. Paired t-tests were employed to determine differences in continuous variables pre- and post- introduction of the new needle set.

Results

Table 1:

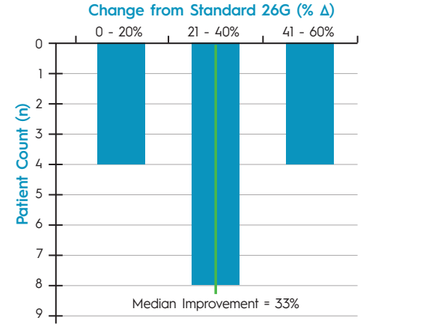
Patient Characteristics (n=16)

Age (year)	65 (28 - 91)
Sex % (F/M)	62/38
Weight (kg)	81.4 (46.7 – 117.9)
BMI (kg/m²)	28.7 (18.8 – 42)
Infusion Volume (ml)	50 (25 – 110)
Infusion Sites (n)	3 (2 – 5)

*Data = median (range) unless otherwise indicated

Figure 1:

Infusion Time Decrease from Standard HIgH-Flo 26G to HIgH-Flo Super26* (n=16)



*Data = the first infusion using the HIgH-Flo Super26™ needle set, 2 patients experienced no change in infusion time

Figure 2:

Patient Experience Questions

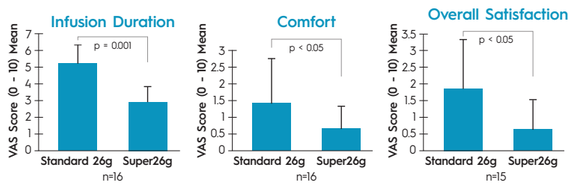


Table 2:

Patient Tolerability (n=16)

Variable	Standard 26g	Super26g
Redness	0.56 (0 – 2)	0.25 (0 – 2)
Swelling	1 (0 – 4)	0.68 (0 – 3)
Pain	0.06 (0 – 1) 1 event reported value = 1	0 (0 – 0)
Itching	0.81 (0 – 4)	0.18 (0 – 2)
Leakage	0.81 (0 – 4)	0.18 (0 – 3) 1 event reported value = 3

Data = mean (range), all comparisons not statistically significant determined via VAS scale for each (0 – 10), 0 = no occurrence, 10 = severe occurrence

Conclusion

- The introduction of the HIgH-Flo Super26™ needle set demonstrated decreased SCIg Infusion Time for 88% of the sampled patients
  - ✔ Median improvement was 33%
  - ✔ 4 patients experienced at least a 41% improvement with one patient experiencing a 53% improvement
- The introduction of the HIgH-Flo Super26™ needle set demonstrated statistically significant improvement vs. the Standard HIgH-Flo 26G needle set with:
  - ✔ Infusion Duration
  - ✔ Patient Comfort
  - ✔ Overall Satisfaction
- The introduction of the HIgH-Flo Super26™ needle set demonstrated no changes in patient self-reported Tolerability (ie. pain, swelling, leakage, etc.)
- These data suggest the HIgH-Flo Super26™ needle set may be a valuable tool to decrease infusion time and improve patient experience with no changes in tolerability in patients requiring SCIg replacement therapy

References:

1. Jolles, S. et. al. Current Treatment Options with Immunoglobulin G for the Individualization of Care in Patients with Primary Immunodeficiency Disease. *Clinical & Experimental Immunology*, 2014; 179: 146-160.
2. Epland, K., Perez, E, IDF Guide to Immunoglobulin Therapy for People Living with Primary Immunodeficiency Diseases. *Immune Deficiency Foundation*, 2018.

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