Poster 116

Successful simulation of infusion pump use for IgPro20 prefilled syringes

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Introduction

- Immunoglobulin (Ig) therapy is a standard treatment for patients with primary immunodeficiencies (PIDs)[1] and immune mediated disorders of the peripheral nervous system, such as chronic inflammatory demyelinating polyneuropathy (CIDP)[2,3]
- Subcutaneous immunoglobulin (SCIG) is typically self-administered and traditionally has been provided in vials for the patient to transfer to a syringe prior to infusion[4]
- SCIG pre-filled syringes (PFS) shown in **Figure 1** offer an alternate drug delivery which, compared with the traditional vial option, may improve the ease of use for some patients, particularly those with visual difficulties or reduced dexterity,[4] while enabling a shorter infusion time[5]
- This summative human factor evaluation study assessed the usability of SCIG IgPro20 (Hizentra®, CSL Behring) by PFS using an infusion pump

Objective

To collect data to demonstrate that the intended users: healthcare professionals (HCPs), patients and caregivers can safely and effectively prepare and perform infusions with the 50 mL Hizentra® PFS using commercially available infusion pumps

Methods

- This study took place at 13 study sites across the United States (US) between January 31st and June 27th, 2022
- A total of 81 participants participated in the study across five cohorts
- All PID and CIDP patients and caregivers (lay users) were trained by an independent nurse at a designated training session
- After all lay users received one training session (**Figure 2**) all participants were asked to administer an infusion into a pad, following three scenarios. Lay users attended a second visit for the assessment, following a training decay period of at least 24 hours
- All HCPs were untrained and therefore attended a single visit to perform the administration
- The ability of users to perform critical tasks required to use the PFS safely and effectively as intended was evaluated
- Unsuccessful infusion or incorrect use was defined as user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user, including need of intervention of moderator or unsuccessful task performance

Scenario A:
- Infusion of 50 mL directly from the 50 mL PFS
- Using the SCIg60 syringe infusion system (EMED Technologies Corporation, El Dorado Hills, California, CA, USA) and a 24G trifurcated catheter, 12 mm (KORU Medical Systems, Mahwah, NJ, USA)

Scenario B:
- Infusion of 40 mL after transfer from a 50 mL PFS into a transfer syringe
- Using a connector (Fluid Dispensing Connectors F1000, B. Braun, Melsungen, Germany), using the "Freedom 60" syringe infusion system (KORU) and a 24G quadrifurcated catheter, 12 mm (KORU)

Scenario C:
- Infusion of 60 mL after pooling a 50 mL and a 10 mL PFS in a transfer syringe
- Using the same ancillaries as for the scenario B

Key findings

This study shows the majority of participants can successfully administer IgPro20 in PFS using an infusion pump

Lay users, including patients with CIDP, were able to administer doses of 40 to 60 mL

Appropriate infusion pump training can address difficulties faced by participants in this study

Figure 1. Hizentra prefilled syringes: 50 mL (10 g), 20 mL (4 g), 10 mL (2 g) and 5 mL (1 g)

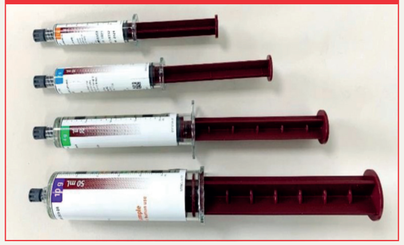

Figure 2. Study set up for training participants

Results

A PARTICIPANT CHARACTERISTICS

- In total, 81 participants were included in this study, including 17 HCPs, 19 caregivers, 15 patients with CIDP and 30 patients with PID
- Across the participant cohorts, 40–66.7% were female, most (76.5–100%) were right hand dominant
- All lay users were either injection experienced (n=39) or injection naïve (n=25)

SCENARIO A (50 mL DIRECT INFUSION)

Most participants (n=80/81, 99%) successfully administered a complete infusion dose with 50 mL PFS

- One CIDP adult participant (n=1/81, 1%) terminated the infusion early (thinking it was complete) and under-delivered the advised dose, root cause not indicating issue with usability of Hizentra 50 mL PFS
- Overall, a ≥ 90% success rate for critical tasks was observed for scenario A
- Many errors concerned use of ancillary materials and therefore were not directly related to the design or usability of the PFS (**Figure 3**)

SCENARIO B & C (TRANSFERRING PROCEDURE)

- The 40 mL (scenario B) and 60 mL (scenario C) transfer and infusions were successfully completed by n=71/78 (**91%**) of participants and n=73/78 (**94%**), respectively (**Table 1**)
- All scenario B errors (n=7/78, 9%) accounted for failure to fully read the prescription (n=5/78, 6.4%), over priming the transfer syringe (n=1/78, 1.3%) and failure to read the volume instructions (n=1/78, 1.3%)
- All scenario C errors (n=5/78, 6%) accounted for failure to read the prescription (n=2/78, 2.4%), study artifacts (n=2/78, 2.4%) and misinterpretation of the Hizentra transfer amount (n=1/78, 1.2%)
  - Study artifacts were defined as a finding caused by conditions not consistent with actual use i.e. confusion due to question formulation and participant did not know if the transfer syringe could hold 60 mL as the label of the transfer syringe stated 50 mL
- Three minor needle stick injuries without sequelae occurred during the training visit. No adverse events occurred during the evaluation sessions

Figure 3. Scenario A: incorrect use

- Check PFS: failure to visually check the content of the PFS (n=5/81, 6%)
- Preparation of infusion tubing: failure to connect Hizentra filled PFS to infusion tubing (resulting in leaking (n=1/81, 1%) and insert Hizentra PFS into syringe pump (n=8/81, 10%)
- Preparation of infusion site: failure to use all needles or select infusion site less than 2 inches apart (n=5/77, 6%)
- Needle insertion: failure to remove needle cap (n=1/81, 1%), fully insert the needle (n=1/81, 1%) and secure the needle with sterile gauze or tape (n=8/81, 6%)

Table 1. Summary of infusion success for transfer scenarios B & C *

	SCENARIO B (N=78)		SCENARIO C (N=78)	
Participant cohort	**Success rate at transferring 40 mL**	**Success rate at infusing 40 mL**	**Success rate at transferring 60 mL**	**Success rate as infusing 60 mL**
HCP	5/5 (100%)	9/10 (90%)	7/7 (100%)	7/7 (100%)
CIDP adult patients	7/7 (100%)	8/8 (100%)	8/8 (100%)	7/7 (100%)
PID adult patients	6/7 (86%)	7/8 (88%)	8/8 (100%)	7/7 (100%)
PID adolescent patients	6/7 (86%)	6/7 (86%)	7/7 (100%)	6/8 (75%)
Caregivers	9/10 (90%)	8/9 (89%)	7/9 (78%)	9/10 (90%)

* Not all participants attempted each scenario in the study

Overall, across all three scenarios, errors associated with unsuccessful infusion did not result in a deviation from the planned dose of more than 10% and appeared unrelated to usability of Hizentra 50 mL PFS

References

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