Importance of Ancillary Supplies for Subcutaneous Immunoglobulin Infusion: Management of the Local Infusion Site

Diane Ochoa,[1] Christine Curtis,[2] Carla Duff,[3] Patty Riley,[4] Elyse Murphy,[4] Annette Zampelli[4]

[1]Dallas Allergy and Immunology, Dallas, TX; [2]Cook Children's Medical Center–Infectious Disease Clinic, Fort Worth, TX; [3]University of South Florida, Tampa, FL; [4]CSL Behring, LLC, King of Prussia, PA

Introduction

- Subcutaneous immunoglobulin (SCIG) is an effective treatment for patients with primary immunodeficiency disease (PIDD).
- Ancillary supplies may contribute to the development of issues at the local infusion site.
- Adjusting the use of specific ancillary supplies used during SCIG treatment (**Table 1**) may be an important step in reducing the incidence and severity of infusion related issues.
  - The choice of ancillary supplies includes disposable and non-disposable items (**Figure 1**).

Figure 1. Ancillary Supplies Used for SCIG Administration

Ancillary supplies used during SCIG administration include disposable items, such as needle sets, and non-disposable items, such as pumps.

Table 1. Common Disposable Ancillary Supply Options for SCIG Administration

Item	Option(s)
SCIG administration sets (tubing + needle)	Needle length (mm): 4, 6, 9, 12, 14
	Needle gauge: 24, 26, 27
	Needle tip: lancet, tricuspid
Flow rate tubing	Size: F120–F2400 for Freedom 60 pump
Skin preparation	Alcohol or antiseptic wipe
Tape	Paper tape or transparent dressing

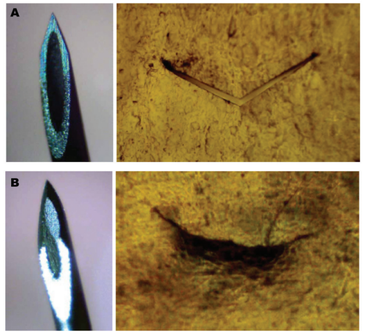
SCIG=subcutaneous immunoglobulin.

Contribution of Ancillary Supplies to Patient Tolerability

Needles

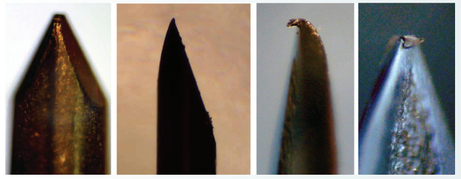
- Improper needle length is a frequent cause of poor tolerability to SCIG treatment.
- Needle length must be chosen to adequately reach into the subcutaneous tissue.
- Improper needle length or diameter may increase leaking at the infusion site[1] or may result in intradermal or intramuscular infusion instead of subcutaneous injection, potentially causing discomfort or pain.[2,3]
  - Smaller diameter needles are associated with less pain during subcutaneous injection.[4]
- Skin punctures associated with different needle types may affect the development of infusion related issues (**Figure 2**).
  - Compared with tricuspid needles (**Figure 2A**), lancet needles potentially result in more coring, with increased bleeding and tissue necrosis (**Figure 2B**).

Figure 2. Needle Types (A, Tricuspid; B, Lancet) Associated With SCIG Administration Sets and Associated Punctures in Simulated Skin[6]



- Needles may be made inconsistently, resulting in flaws.[5]
- Damage to the needle tip may occur during the manufacturing or handling process (**Figure 3**).

Figure 3. Unused Needles Damaged During the Manufacturing Process Discovered Randomly "Out of the Box"[6]



  - The use of flawed or damaged needles for the administration of SCIG may cause undue pain and inefficient or improper delivery of product, potentially leading to infusion related issues.
  - Needle tip damage in the range of 10 microns has been reported to be associated with patients' perception of pain.
- Patients or caregivers should thoroughly inspect needles before use and use only if undamaged.

Other Ancillary Supplies

- Tubing size is a determinant of the maximum infusion rate, which may influence tolerability.
- Skin sensitivity may be affected by antiseptic site preparation and post-infusion dressing.
- The tape used during SCIG administration may lead to local irritation at the site of application.

Case Studies Demonstrating the Effects of Ancillary Supplies on Local Tolerability

Case Study 1

Patient Description	Diagnosis	Initial SCIG and Ancillary Supplies	Technical/ Clinical Complaints	Treatment Adjustment(s)	Outcome
5-year-old, 18-kg male	Hypogamma-globulinemia	20% SCIG: 15 mL, 2 sites (thigh), 26-gauge, 12-mm needle, weekly	• Tegaderm tape not sticking to skin • SCIG needle displaced during infusion • Use of thigh sites limited mobility of child	• Changed from Tegaderm tape to silk tape attached in "x" pattern over needle • Used tincture of benzoin on edges of silk tape to secure • Switched to abdomen sites	Improvement and resolution of all issues reported

Case Study 2

Patient Description	Diagnosis	Initial SCIG and Ancillary Supplies	Technical/ Clinical Complaints	Treatment Adjustment(s)	Outcome
10-year-old, 18-kg female	CVID	Lyophilized IVIG reconstituted to 16% given SC: 3 g, 20 mL, 2 sites, 6-mm needle, weekly	• Redness and swelling at infusion sites • Resolved by the evening of infusions	Changed from a 6-mm to a 9-mm needle	• Decreased swelling and leaking from sites • Patient has tolerated SCIG infusions well • Switched to 20% SCIG after product available

CVID=common variable immunodeficiency disease; IVIG=intravenous immunoglobulin.

Case Study 3

Patient Description	Diagnosis	Initial SCIG and Ancillary Supplies	Technical/ Clinical Complaints	Treatment Adjustment(s)	Outcome
24-year-old, 90-kg male	CVID	20% SCIG: 8 g, 40 mL, 3 sites (abdomen), 9-mm needle, weekly	Swelling, redness, discomfort at sites	• Changed from a 9-mm to 12-mm needle • Changed number of sites from 3 to 2 • Continued to use abdomen sites with site rotation each week	• Improvement in site reactions • Increased compliance

Case Study 4

Patient Description	Diagnosis	Initial SCIG and Ancillary Supplies	Technical/ Clinical Complaints	Treatment Adjustment(s)	Outcome
4-year-old, 16-kg female	• Hypogammaglobulinemia secondary to immunosuppressants • Status post-multivisceral transplant of small intestine, liver, stomach, and pancreas	20% SCIG: 3 g, 15 mL, 2 sites (inner thigh), 6-mm needle, weekly	Palpable nodules at infusion site in right leg only	• Changed infusion sites to left leg only • Patient with left-side hemiparesis. Subcutaneous tissue more easily accessible.	No nodules developed

Case Study 5

Patient Description	Diagnosis	Initial SCIG and Ancillary Supplies	Technical/ Clinical Complaints	Treatment Adjustment(s)	Outcome
• 37-year-old, 46-kg female • Slender patient; long distance runner	CVID	20% SCIG: 8 g, 40 mL, 3 sites (flank), 27-gauge, 6-mm needle, weekly	• Leaking at sites, redness, swelling	• Changed from a 6-mm to a 9-mm needle • Changed from 27-gauge to 26-gauge needle • Changed from 3 sites to 1 site • Changed infusion time to 6 hours (overnight) • Changed infusion site to outer thigh	• Local site swelling and leaking resolved

CVID=common variable immunodeficiency disease.

Case Study 6

Patient Description	Diagnosis	Initial SCIG and Ancillary Supplies	Technical/ Clinical Complaints	Treatment Adjustment(s)	Outcome
• 9-year-old, 27-kg male • Naive to SCIG treatment	X-linked agammaglobulinemia	20% SCIG: 5 g, 24 mL, 3 sites (abdomen), 6-mm needle, F180-rate tubing (4 mL/hr/site), weekly	Swelling, redness, severe discomfort, leakage at site	• Reduced infusion rate by changing to F120-rate tubing (2.32 mL/hr/site) and reduced site volume by adding a fourth site; leaking at site still occurred • Secondary adjustment of a 6-mm to a 9-mm needle	Improvement and resolution of issues reported

Case Study 7

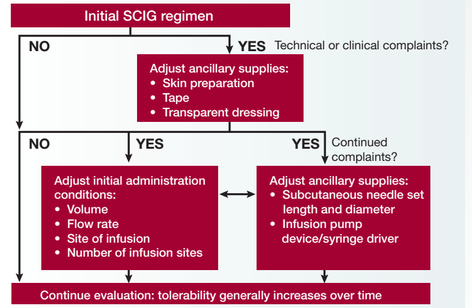
Patient Description	Diagnosis	Initial SCIG and Ancillary Supplies	Technical/ Clinical Complaints	Treatment Adjustment(s)	Outcome
• 25-year-old, 67-kg female • Avid runner	CVID	10% SCIG: 10 g, 100 mL, 4 sites, 27-gauge, 6-mm needle, biweekly	Severe burning, edema, and pain lasting 2-3 days, interfered with running	• Changed from a 6-mm to a 9-mm needle; no improvement • Changed to 16% SCIG product once available	• Improvement and resolution of issues reported, able to run same day as infusion • Switched to 20% SCIG after product available; well tolerated

CVID=common variable immunodeficiency disease.

Treatment Algorithm for Patients With Technical or Clinical Complaints During or Following SCIG Administration

- A logical treatment progression should be followed for patients who experience tolerability problems beyond the mild, transient effects that may occur after SCIG administration (**Figure 4**).

Figure 4. Treatment Algorithm for Patients With Technical or Clinical Complaints During or Following Initial SCIG Regimen



Conclusions

- **Careful management of technical or clinical complaints at the local infusion site is essential in patients receiving SCIG.**
- **Case studies demonstrate that adjustment of, or changes to, ancillary supplies may decrease the occurrence and/or severity of infusion related issues.**
- **Ancillary supplies should be adjusted before changing the SCIG product.**
- **Alterations in the choice of ancillary supplies can improve the patient experience with SCIG administration, which may positively impact patient quality of life and medication adherence.**

References

1. Juul KAP, et al. *Skin Res Technol.* 2012. [Epub ahead of print]
2. Murphy E, et al. *Infusion*. 2007;13(4 suppl):1-8.
3. Schwartz S, et al. *Clin Ther*. 2004;26(10):1663-1678.
4. McKay M, et al. *Diabetes Technol Ther*. 2009;11(3):195-201.
5. Parker RK and White PF. *Anesth Analg*. 1997;85(5):1101-1104.
6. Selafon A and Baker PM. Presented at National Home Infusion Association Annual Conference, Phoenix, AZ, April 23-26, 2012.

Acknowledgments

This presentation was supported by CSL Behring, LLC. Medical writing and editorial support was provided by Daniel McCallus, PhD, of Complete Publication Solutions, LLC, and was funded by CSL Behring, LLC.

Infusion Nurses Society Annual Convention and Industrial Exhibition
April 28–May 3, 2012, Las Vegas, NV