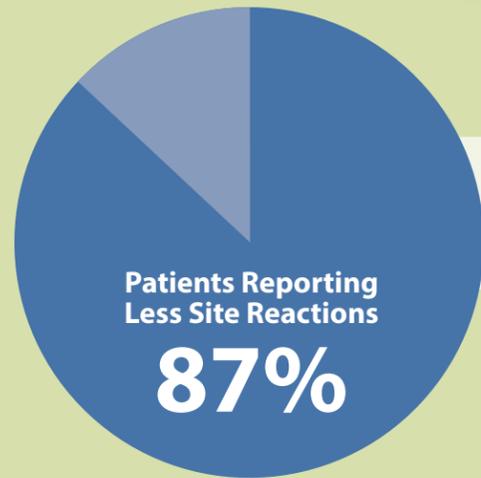


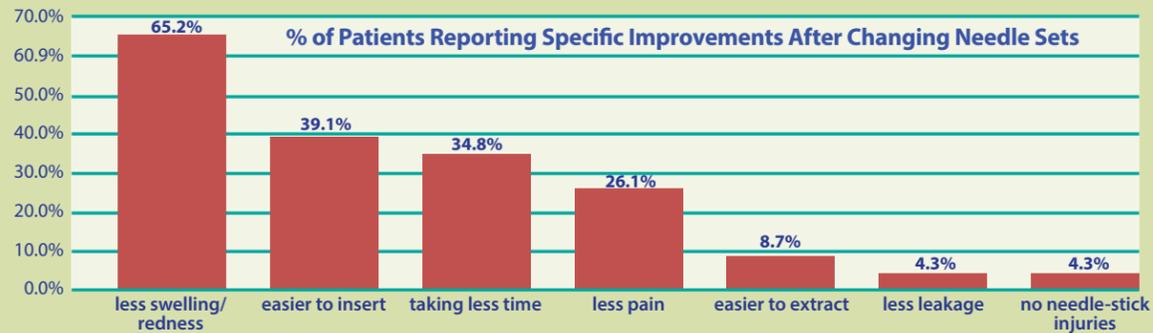
Impact of a Subcutaneous Infusion Set on the Incidence of Local Infusion Site Reactions Reported by Patients Receiving SCIg

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Changing Needle Sets to Address Site Reactions

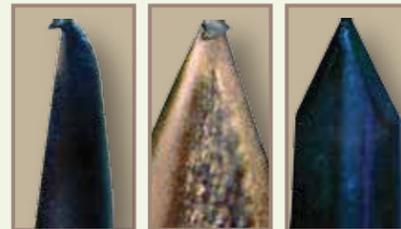
In a recent study of patients who experienced site reactions following SCIg administration, 87% reported decreased site reactions after changing needles. The graph below illustrates the specific improvements described by patients.



Reducing Site Reactions is Possible by Changing the Needle Set Used for Infusions

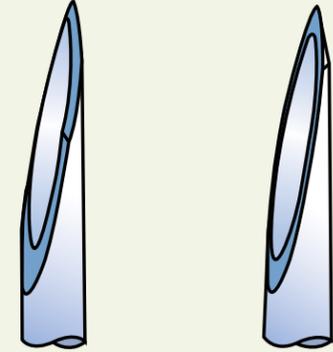


Site reactions cause pain, swelling, redness and impact patient satisfaction with SCIg administration.



Needle quality and tip damage can contribute to pain upon insertion and promote adverse site reactions during and after an infusion.

Effects of Needle Tip Design on Skin Damage



Lancet Tip
 increases tissue damage, which can lead to increased site reactions.



Tricuspid Tip
 provides cleaner insertion with less skin damage.



Needle tip design and sharpness can have a positive effect on insertion and patient comfort.

BACKGROUND: Subcutaneous therapy (SCIg) has been shown to have numerous patient benefits over IVIg, often including substantial provider cost savings and improved patient quality of life. It has been associated with fewer reports of systemic adverse reactions, and allows the patient/caregiver independence in self-administration with appropriate training and ongoing clinical monitoring by the home infusion pharmacy. However, some patients receiving SCIg have reported local adverse reactions that last up to 24 hours or longer, and include pain, redness, excessive swelling and itching around the injection sites. After converting patients from IV to subcutaneous therapy, some patients have elected to stop SCIg and return to monthly IVIg treatments as a result of these local reactions. Resolving local infusion reactions may contribute to patient compliance with this IgG delivery method.

PURPOSE: This study assesses the effects of the needle set on patient discomfort and therapy compliance with SCIg administration. The authors propose that reducing site reactions can increase patient satisfaction and compliance with SCIg therapy.

METHODS: Two studies were used to assess the impact of needle sets on the delivery of SCIg. In the first study, 35 patients who switched from their current needle sets to the new set were solicited for their experience regarding ease of needle insertion and comfort before and after the change. A second study was conducted in which 23 patients were self-selected as having reported site reactions following SCIg administration, which included swelling and/or redness, pain, itching and leakage, some lasting up to 24 hours and beyond. The majority of the patients (70%) were using 20% solutions. SCIg was administered using a FREEDOM60 Syringe Pump and a variety of subcutaneous needle sets were used by the patients. Patients were switched to a different needle set for their next infusions and their response was recorded by follow up contact. 9% of the patients received an adjustment in flow rate, and 13% of received a change in the length of the needle.

RESULTS/DISCUSSION: In the first study, 29 of 30 patients responding reported that the new set reduced insertion pain, observing an apparent difference in sharpness. 97% of patients reported less pain on insertion with the new needle set. In the second study, 87% of patients reported a decrease in local infusion site reactions after switching to the new needle sets. 65% experienced less swelling and redness; 39% reported easier insertion; and 26% reported less pain. 35% reported the overall infusion taking less time.

CONCLUSIONS: Patients who switched needle sets experienced less insertion pain, and fewer site reactions. Thus the needle set appears to impact overall satisfaction with SCIg administration. Because several variables were modified at the same time to achieve a rapid improvement for the patient, it is difficult to attribute which specific changes are responsible for these improvements. Further study is required to determine the specific impact and relative effects of these factors which include needle design and sharpness; needle length; flow rate; even flow to needles; total volume administered per site; skin preparation techniques (EMLA, dry-priming of the needles, antiseptic selection); and pump type. ■

SUPPORT STUDIES:

Hetty Lima, R.Ph., FASHP, and Amy Clarke, R.N. "IG Therapy for the Home Based Patient: Administration and Delivery Method Considerations" *Infusion*, November/December 2012. Vol. 18, No. 6) CSL/Skoda-Smith/Ochs

Mainzer B, Stuhmeier, KD, "Aspects of Pressure Build-up in the Use of Electronic Infusion Devices", *Anasth Intensivther*, August 1987

Mark Paul Baker, MD, Andrew Sealfon "Infusion Pump Design for SCIg: Theoretical Considerations" (poster) http://www.rmsmedicalproducts.com/downloads/resources/highflo/literature/HFL_PO_ScientificSCIgAdminVert_03-2023vB_LR.pdf

Diane Ochoa, Christine Curtis, Carla Duff, Patty Riley, Elyse Murphy, Annette Zampelli, "Importance of Ancillary Supplies for Subcutaneous Immunoglobulin Infusion: Management of the Local Infusion Site" (poster)

DISCLOSURE:

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

Andrew Sealfon: President and CEO of RMS Medical Products
 Paul Mark Baker, M.D.: Member, Board of Directors, Repro-Med Systems, Inc.

This poster was funded by RMS Medical Products, a dba of Repro-Med Systems, Inc.