

Analysis and Perspective: Comparison of Insulin Diluent Leakage Post-Injection Using Two Different Needle Lengths and Injection Volumes in Obese Patients with Type 1 or Type 2 Diabetes Mellitus

Timothy S. Bailey, M.D., FACE, CPI

Abstract

The effects of needle gauge and length on the efficacy and tolerability of insulin injection therapy are becoming better understood. This analysis discusses some of these effects and comments on a new study by Ignaut and Fu in this issue of *Journal of Diabetes Science and Technology* on the effects of needle length on insulin diluent leakage from injection sites.

J Diabetes Sci Technol 2012;6(2):394-395

Initiation of insulin injection therapy remains challenging for both patients and those who care for them. The psychological aspects of why this process is difficult have been well described.¹ In addition to delays in starting insulin therapy, there are patients who miss prescribed insulin injections, which negatively impacts glycemic control.²

Injecting insulin is increasingly recognized as a likely part of therapy during the lifetimes of most patients with diabetes. Efforts have been made to increase health care professionals' awareness of optimal insulin injection technique and site management.³ To overcome the difficulties of using syringes, insulin pen technology was developed. This has been shown to improve dosing accuracy⁴ and to be preferred by many patients.⁵ Given the effort to develop improvements in insulin injection technology, it may seem surprising that a better understanding of the role of insulin needle length is a relatively recent development.

Thinner, shorter needles might seem to be an obvious choice to make the transition to insulin easier. However, the conventional wisdom for many years regarding needle length was that patients require longer needles in order to reduce leakage and improve insulin delivery, particularly with obese patients. Studies have challenged this assumption.

Skin thickness can be measured noninvasively and accurately with ultrasound technology. There is now a body of knowledge regarding skin thickness, showing that the dermis is fairly consistently thin and that needles of 4–5 mm reliably provide access to the subcutaneous space,⁶ avoiding muscle tissue. The data showed remarkable consistency with small differences across gender, age, race, and body mass index. Shorter needles may also be less likely to deliver medication doses intramuscularly inadvertently.⁷ This provides an important foundation for the informed choice of needle length for insulin therapy.

Author Affiliation: Advanced Metabolic Care + Research Institute Inc., Escondido, California

Keywords: backflow, insulin injection, leakage, needle length

Corresponding Author: Timothy S. Bailey, M.D., FACE, CPI, AMCR Institute Inc., 700 West El Norte Parkway, Suite 201, Escondido, CA 92026; email address tbailey@amcrinstitute.com

Two animal studies provide helpful data regarding backflow (i.e., leakage) from the injection site. Wittmann and colleagues⁸ demonstrated in an *ex vivo* pork rind model that leakage of insulin marked with a radiolabel was not substantially different between 12- and 4.5 mm needles. Juul and associates⁹ injected pigskin with 0.4 ml of a radiopaque dye with 8 mm (30 g), 5 mm (32 g), and 3 mm (34 g) needles. Analysis by histology and three-dimensional computed tomography resulted in predictable deposition into the subcutaneous layer by all three needles. Leakage was assessed and found to be least with the shortest needles; however, supplementary experiments were done and showing this to have resulted from the fine gauge (rather than the short length) of the needles.

There have been clinical trials showing the noninferiority of short needles in both type 1 and type 2 patients in terms of hemoglobin A1c.¹⁰ Trials in obese patients are fewer in number but appear to show results consistent with leaner patients.¹¹

In this issue of *Journal of Diabetes Science and Technology*, Ignaut and Fu¹² detail another aspect of injection with needles—that of fluid leakage. Leakage fluid was collected with filter paper and weighed with an analytical balance to calculate the leaked units. This method is more accurate than the semiquantitative methods of leakage analysis using either measurement of residual droplet size or by comparing the droplet to a diagram or photo by the subject or investigator.

Two volumes (0.2 and 0.6 ml) of injected insulin diluent were studied in obese (body mass index 35.6 ± 5.5 kg/m²) patients with type 2 diabetes. These doses are well within those expected to be used within this population of patients with type 2 diabetes.

Data for bruising, bleeding, and pain were similar between the two needle lengths, supporting the notion that shorter insulin needles are appropriate for treatment of obese patients with type 2 diabetes. Placed in context of other available literature, there is now substantial evidence for the noninferiority of shorter needles for insulin delivery. This should simplify insulin starts for both practitioners and patients.

Disclosures:

The author has received consulting honoraria from sanofi-aventis and Novo Nordisk; speaking honoraria from Amylin, Novo Nordisk, BD, and sanofi-aventis; and research support from BD, Halozyme, Lilly, Novo Nordisk, and sanofi-aventis.

References:

1. Polonsky WH, Hajos TR, Dain MP, Snoek FJ. Are patients with type 2 diabetes reluctant to start insulin therapy? An examination of the scope and underpinnings of psychological insulin resistance in a large, international population. *Curr Med Res Opin.* 2011;27(6):1169–74.
2. Peyrot M, Rubin RR, Kruger DF, Travis LB. Correlates of insulin injection omission. *Diabetes Care.* 2010;33(2):240–5.
3. Frid A, Hirsch L, Gaspar R, Hicks D, Kreugel G, Liersch J, Letondeur C, Sauvanet JP, Tubiana-Rufi N, Strauss K; Scientific Advisory Board for the Third Injection Technique Workshop. New injection recommendations for patients with diabetes. *Diabetes Metab.* 2010;36 Suppl 2:S3–18.
4. Luijck YM, DeVries JH. Dosing accuracy of insulin pens versus conventional syringes and vials. *Diabetes Technol Ther.* 2010;12 Suppl 1:S73–7.
5. Bailey T, Thurman J, Niemeyer M, Schmeisl G. Usability and preference evaluation of a prefilled insulin pen with a novel injection mechanism by people with diabetes and healthcare professionals. *Curr Med Res Opin.* 2011;27(10):2043–52.
6. Gibney MA, Arce CH, Byron KJ, Hirsch LJ. Skin and subcutaneous adipose layer thickness in adults with diabetes at sites used for insulin injections: implications for needle length recommendations. *Curr Med Res Opin.* 2010;26(6):1519–30.
7. Tubiana-Rufi N, Belarbi N, Du Pasquier-Fediaevsky L, Polak M, Kakou B, Leridon L, Hassan M, Czernichow P. Short needles (8 mm) reduce the risk of intramuscular injections in children with type 1 diabetes. *Diabetes Care.* 1999;22(10):1621–5.
8. Wittmann A, Köver J, Kralj N, Gasthaus K, Lerch H, Rommel M, Moses S, Hofmann F. Insulin leakage value in relation to pen needle length and administered dose after subcutaneous injection. *Diabetes Technol Ther.* 2010;12(8):587–90.
9. Ann Praestmark Juul K, Bengtsson H, Eyving B, Kildegaard J, Lav S, Poulsen M, Serup J, Stallknecht B. Influence of hypodermic needle dimensions on subcutaneous injection delivery - a pig study of injection deposition evaluated by CT scanning, histology, and backflow. *Skin Res Technol.* 2012. Epub ahead of print.
10. Hirsch LJ, Gibney MA, Albanese J, Qu S, Kassler-Taub K, Klaff LJ, Bailey TS. Comparative glycemic control, safety and patient ratings for a new 4 mm x 32G insulin pen needle in adults with diabetes. *Curr Med Res Opin.* 2010;26(6):1531–41.
11. Schwartz S, Hassman D, Shelmet J, Sievers R, Weinstein R, Liang J, Lyness W. A multicenter, open-label, randomized, two-period crossover trial comparing glycemic control, satisfaction, and preference achieved with a 31 gauge x 6 mm needle versus a 29 gauge x 12.7 mm needle in obese patients with diabetes mellitus. *Clin Ther.* 2004;26(10):1663–78.
12. Ignaut DA, Fu H. Comparison of insulin diluent leakage postinjection using two different needle lengths and injection volumes in obese patients with type 1 or type 2 diabetes mellitus. *J Diabetes Sci Technol.* 2012;6(2):389–93.