

Analysis and Perspective: A Randomized, Open-Label, Comparative Crossover Handling Trial between Two Durable Pens in Patients with Type 1 or 2 Diabetes Mellitus

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Abstract

Insulin pen therapy is superior to vial and syringe with regard to more accurate insulin delivery, patient preference, adherence, and favorable health economics. In this issue of *Journal of Diabetes Science and Technology*, Somavilla and Pietranera compare two generations of NovoPen, showing significant improvements in selecting and injecting the insulin dose as well as superior overall satisfaction with the newer versus older generation insulin pen among both experienced pen users and insulin-naïve patients.

There are other potentially useful features that might be implemented and better-studied in future pen devices. These include insulin dose tracking, insulin error mitigation, and insulin dosing advice. Caring more effectively for the multitude of people impacted by the diabetes epidemic requires a new approach that will require “smarter,” more “connected” devices.

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Insulin pen therapy is the preferred manner of insulin delivery in many locales. There are data supporting insulin pens' superiority with regard to more accurate insulin delivery, patient preference, adherence, and favorable health economics.¹ However, a major insulin market—the United States—has low utilization of pens as compared with many other developed countries.² In the United States, patients still elect to use vial and syringe because of the additional cost of the pen. Higher copayments and significant costs for additional staff time to handle prior authorizations and other paperwork are sufficient to dissuade patients and physicians

from engaging in greater pen utilization (personal communication, staff of Dr. T. Bailey, July 2011.)

In their article entitled *A Randomized, Open-Label, Comparative Crossover Handling Trial between Two Durable Pens in Patients with Type 1 or 2 Diabetes Mellitus* in this issue of *Journal of Diabetes Science and Technology*, Somavilla and Pietranera,³ compare two generations of NovoPen using a survey methodology. They address training time, difficulty and confidence, and pen preference among 82 insulin pen users and 34 insulin-naïve patients with both type 1 and type 2 diabetes. The authors showed

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significant improvements in selecting and injecting the insulin dose as well as superior overall satisfaction with the newer versus older generation insulin pen among both experienced pen users and insulin-naïve patients.

To a United States audience, this article does not address the key issue that is faced there regarding pen versus vial and syringe. However, it is highly relevant globally and reflects the progress being made by device manufacturers in providing superior products to enhance the health of diabetes patients.

Usability is an important focus of device research. The authors provide interesting data that all 82 experienced pen users were able to demonstrate successful use of the new pen without instruction within 5 minutes of exposure. Additionally, the average training time for pen-naïve patients to successfully complete similar pen tasks was just under 10 minutes. These data illustrate how devices have the potential to free up precious time in the diabetes clinic.

The authors chose to exclude important groups who might benefit from pen use: those with diminished visual acuity, impaired dexterity, arthritis, and neurologic dysfunction. These patients may have the most difficulty using insulin syringes, and such disabilities may be more prevalent in patients with diabetes.⁴ The newer pen device studied has features such as easier visibility and decreased injection force. Investigators should consider including such patients in device trials to document the impact of the technology on these special populations.

The characteristics evaluated in this paper have been included in many publications with other pen devices. However, there are other potentially useful features that might be implemented and better studied in future pen devices. These include insulin dose tracking, insulin error mitigation, and insulin dosing advice.

Insulin pens could be capable of storing doses. Several insulin pen devices (MEMOIR™, Echo®, and Innovo®) have accomplished this. However, capability has been limited (e.g., number of doses stored), and download of pens (as compared with glucose meters, glucose sensors, and insulin pumps) is not yet feasible. The ability to accurately record insulin and glucose data has the potential to provide clinicians with a better picture of the actual doses and dosing decisions made by their patients. This knowledge could enable them to give patients better insulin dosing recommendations.

Mitigating errors is another opportunity for insulin pens to assist patients. The “air shot” that is recommended after installation of a new pen needle and prior to dosing is frequently omitted by patients. Pens could remind users to (or actually) deliver this prior to an actual dose. An inadequate dwell time (i.e., time needed for needle to remain in the subcutaneous space prior to removal) may lead to inadvertent underdosing of insulin by patients; pens can notify patients when dosing is complete. Pens are increasingly color coded, which may have an important role in reducing errors where the wrong insulin is administered. The error of failing to remove pen needles after injections (leading to air in the pen reservoir and future underdosing) is another target for future devices.

Insulin dosing advice could benefit patients. Most current insulin pumps now have “wizards” that make insulin dosing recommendations based on ambient glucose level and anticipated carbohydrate consumption according to preset carbohydrate and correction factors. Pens have the potential to provide similar feedback. An “insulin-on-board” feature could mitigate insulin “stacking.”⁵

In conclusion, insulin pens are becoming more useful and usable. There remains great opportunity for wider adoption of insulin pens by patients and clinicians and for greater safety and clinical effectiveness. Regulatory, technological, and cost barriers will need to be overcome to implement the additional advanced features listed here. However, caring more effectively for the multitude of people impacted by the diabetes epidemic requires a new approach that will require “smarter,” more “connected” devices.

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