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An Analysis of the HumaPen® Luxura™ HD Pen: What Is the Role of 0.5-Unit Insulin Dosing?

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Abstract

The HumaPen® Luxura™ HD is an insulin pen device that has the ability to deliver insulin in half-unit increments. This study demonstrates the precision of this pen device using a computer-controlled dose accuracy glide force system. Although one other half-unit pen device is currently on the market, we are not aware of any studies using a similar methodology to verify its precision and accuracy. Clinical experience in treating a select group of adults with diabetes demonstrates the need for such a device. Although there are no outcome studies, this device should help to improve glycemic control and reduce hypoglycemia in such patients. We believe a half-unit insulin pen device is beneficial to more than just the pediatric population, and therefore, this device represents an improvement in present technology.

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Introduction

In this issue of *Journal of Diabetes Science and Technology*, Clark and colleagues[1] present data concerning the accuracy of the initial half-unit dose setting of the HumaPen® Luxura™ HD insulin pen within a 95/95% tolerance interval. The authors state that the main benefit of a pen that can deliver an accurate half-unit dose is for children with type 1 diabetes and their caregivers who must help them to deliver the insulin therapy. While this is certainly a valid group who would routinely benefit from half-unit dosing, there are several other groups who would also benefit from such a pen. Although most adult patients with diabetes who are treated with insulin will find the traditional whole-unit-increment insulin pen devices adequate to meet their needs, there is a select group of patients who often do not. We are frequently confronted in practice with "brittle" diabetes patients and patients with increased insulin sensitivity due to concomitant Addison's disease, hypopituitarism, chronic kidney disease, or chronic pancreatitis. When using traditional insulin pen devices, these patients may find that, due to their sensitivity to insulin, 1 U dose increments are not adequate to meet their needs. Clinical experience with such patients reveals that dosing an additional 0.5 U of a short-acting insulin due to rounding up to the nearest full-unit dose may cause hypoglycemia. Delivering 0.5 U less insulin by rounding down may cause hyperglycemia. Therefore, these patients would benefit from a device that can deliver their short-acting insulin dose in half-unit increments.

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Abbreviations: (DAGF) dose accuracy glide force

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In addition, there are patients who, by virtue of carbohydrate counting or past experience, find that rounding to the nearest full-unit doses is not adequate. These patients often use an insulin pen or syringe that is not designed for half-unit dosing to approximate the half-unit dose they require. With these traditional insulin delivery devices, is the patient really receiving a 0.5 U incremental dose? Probably not. Such inaccuracy can lead to underdosing or overdosing errors, impacting patient care.

With the inclusion of these groups, there is clearly a wider need for a device that can deliver half-unit dosing beyond the pediatric population.

Although the HumaPen Luxura HD insulin pen does have printed markings at half-unit doses above 1 U, it does not have a printed mark at the initial half-unit dose (0.5 U). Therefore, this dose was achieved by the audible/tactile click-stop at the 0.5 U position. Dose accuracy was assessed by a computer-controlled dose accuracy glide force (DAGF) system. The DAGF is based on the weight recorded by the initial dose as measured by a laboratory balance after adequately priming the pen according to the manufacturer's instructions. Variability in this study included five different Luxura HD insulin pen lots, three different temperatures, seven different operators, and three different types of Lilly insulin and three lots of saline cartridges.

In Figure 2 of the article by Clark and colleagues,[1] data from 577 doses showed a mean of 0.53 U with a standard deviation of 0.116 and a k value of 4.474. There were no statistical differences between the mean doses per device lot. These results are convincing and support the authors' claim that the HumaPen Luxura HD pen can deliver accurate 0.5 U doses of insulin lispro or human insulin. Clearly, this accuracy cannot be achieved with an insulin vial and syringe or with most other pen devices, representing an improvement in current technology.

Notably, there is another insulin pen device presently on the market that can deliver half-unit doses. It is called the Novopen Junior and is marketed to the pediatric population. However, we are not aware of any studies that have examined its precision using the DAGF or a comparable system. Therefore, we cannot comment on its accuracy or precision.

Another device that can accurately deliver doses of less than 1 U is an insulin pump. For example, the popular Medtronic MiniMed Paradigm line of insulin pumps has a bolus increment of 0.10 U and a basal increment of 0.05 U (user guide, page 180). The other insulin pumps on the market can also deliver insulin in increments less than 1 U. While some of the patients who would benefit from a half-unit pen delivery device could achieve even smaller increments of short-acting insulin with an insulin pump, not all patients desire or would benefit from an insulin pump. The effective use of an insulin pump requires a significant amount of motivation and skill on the part of the patient. Such devices do not have the ease of administration of a pen device as a stand-alone unit.

Clark and colleagues are to be commended for the care with which they conducted their studies and the number of variables they studied.[1] Hopefully, we can anticipate an increase in precision from all future pen devices being developed throughout the world. Of course, outcome studies showing less hypoglycemia and improved glycemic control would be needed to justify the increased cost involved in developing more accurate devices. We believe that the value of a half-unit insulin pen device is applicable to a much larger population of diabetes patients than a pediatric cohort.

Disclosures:

Dr. Magnotti is on the speaker's bureau of Novo Nordisk and Eli Lilly. Dr. Rayfield is on the speaker's bureau of Amylin, Eli Lilly, Glaxo Smith Kline, Merck, Novartis, Novo Nordisk, and sanofi aventis.

References:

1. Clark P, Okenfuss CR, Campbell M. Half-unit dose accuracy with HumaPen® Luxura™ HD: an insulin pen for patients who need precise dosing. J Diabetes Sci Technol 2010;4(2):353-6.