

Differences in the Dose Accuracy of Insulin Pens

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Abstract

Background:

Modern insulin injection pens provide a convenient and accurate way for diabetes patients to inject insulin. They have widespread use among children and adults with type 1 and type 2 diabetes in the U.S. and Europe. This study compared the dosing accuracy of four commonly available insulin pens (OptiClik® and SoloSTAR® from sanofi-aventis, FlexPen® from Novo Nordisk, and HumaPen® LUXURA™ from Eli Lilly).

Methods:

The dosing accuracy was tested for all pens with 24 x 10 IU and 9 x 30 IU injection volumes to investigate whether the pens complied with the acceptable International Organization for Standardization (ISO) limits of 10% (± 1 IU) for 10 IU and 5% (± 1.5 IU) for 30 IU. The doses were each applied with a new needle strictly according to the instructions for use by the pen manufacturers. A pharmaceutical balance was used for the assessment of the applied volumes, and the results were corrected for the specific density of the insulin formulations. Four insulin pens (two each from different production lots) were used for each of the two volumes, resulting in a total of 192 doses per pen with 10 IU, and 72 doses per pen with 30 IU.

Results:

FlexPen (mean absolute percent deviation for 10 IU and 30 IU: $1.64 \pm 0.84\%$ and $0.83 \pm 0.26\%$, respectively) and HumaPen LUXURA ($1.10 \pm 0.20\%$ and $0.62 \pm 0.19\%$; not significant versus FlexPen for both doses) were more accurate than the OptiClik ($4.78 \pm 3.31\%$ and $2.97 \pm 2.48\%$, $p < .01$) and the SoloSTAR ($2.61 \pm 0.92\%$ and $1.70 \pm 0.84\%$, $p < .05$). While 6.8% of doses were outside the ISO limit at 10 IU with OptiClik (13.9% at 30 IU), the corresponding figures were 0.5% and 4.1%, respectively, for SoloSTAR. No doses outside the ISO limits were seen with FlexPen or HumaPen LUXURA at 10 IU and only one 30 IU dose (1.4%) was outside the limit for FlexPen.

Conclusions:

A direct head-to-head comparison of four insulin pens with a standardized protocol resulted in a more stable dosing accuracy of the FlexPen and the HumaPen LUXURA in comparison to the OptiClik and SoloSTAR. Even though all insulin delivery systems undergo rigorous testing before being approved for sale, there may be reasons to be attentive to the performance of the devices in practical use.

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Abbreviations: (IDDM) insulin dependent diabetes mellitus, (NPH) neutral protamine Hagedorn, (n.s.) not significant

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