

Comparison of the Dose Accuracy of Prefilled Insulin Pens

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Abstract

Background:

Prefilled insulin pens have become a convenient and accurate way for diabetes patients to inject insulin. Their ease of use has helped to reduce the resistance of patients with type 1 diabetes and type 2 diabetes in the United States and Europe toward initiation of insulin therapy. This study compared the dosing accuracy of two prefilled insulin pens (the SoloStar[®] from Sanofi Aventis, Berlin, Germany, and the Next Generation [NG] FlexPen[®] from Novo Nordisk, Mainz, Germany).

Methods:

The dosing accuracy was tested for both pens with 24 × 10 international units of insulin (IU) and 9 × 30 IU injection volumes to investigate whether the pens comply within 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 applied each with a new needle strictly according to the instructions for use of the pen manufacturers. A sensitive pharmaceutical balance was used for the assessment of the applied volumes, and the results were corrected for the specific density of the insulin formulations. We used 18 insulin pens (from two different production lots each) for the two volumes, respectively, resulting in a total of 432 doses per pen with 10 IU and 162 doses per pen with 30 IU.

Results:

Both pens showed a very good performance, which was better for the 10 IU dose than in comparative previous studies. The NG FlexPen (mean absolute percent deviation 10 IU/30 IU: $1.63 \pm 0.84\%/1.23 \pm 0.76\%$) was even more accurate than the SoloStar ($2.11 \pm 0.92\%/1.54 \pm 0.84\%$, $p < .001/p < .05$ versus the NG FlexPen). Only 0.2% of the doses were outside the ISO limit at 10 IU, with the NG FlexPen (0.6% at 30 IU). The corresponding figures for the SoloStar were 0.4% and 1.8%, respectively.

Conclusions:

A direct head-to-head comparison of the two prefilled insulin pens with a standardized protocol resulted in a more stable dosing accuracy of both pens as compared to previous investigations. In this investigation, the NG FlexPen was more accurate than the SoloStar at both tested doses.

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Abbreviations: (ISO) International Organization for Standardization, (IU) international unit [of insulin], (NG) Next Generation

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