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Correct Use of a New Reusable Insulin Injection Pen by Patients with Diabetes: A Design Validation Study

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Abstract

Background:

Insulin pen devices are currently being used by approximately half of insulin users worldwide. ClikSTAR® (sanofi-aventis) is a novel reusable insulin pen for injecting either long-acting insulin glargine or short-acting insulin glulisine. The objective of this study was to demonstrate that individuals with diabetes could use the ClikSTAR pen correctly.

Methods:

In this open-label, single-center study, people with diabetes delivered three 40 U insulin doses after receiving training from a diabetes specialist (group A, $n = 256$) or after self-training (group B, $n = 47$). Administration of a dose of 75–115% of the intended dose was considered successful. Adverse events (AEs) and product technical complaints (PTCs) were recorded.

Results:

In group A (68% females, 93% Hispanic ethnicity, 97% type 2 diabetes mellitus, mean ± standard deviation age 52 ± 11 years, diabetes duration 11 ± 7 years), half of the participants had prior experience in using insulin pen devices. All except one participant (99.6%) in group A successfully delivered three insulin doses. The lower one-tailed 95% confidence limit for the success rate (98.2%) was higher than the predefined target of 90%. Demographic/baseline characteristics were similar in group B, but 70% had not previously used an injection pen. Group B also showed success; 93.6% of participants successfully completed three dose deliveries. No AEs were reported, although one participant (0.4%) in group A reported one PTC during the training period that was due to a blocked needle.

Conclusions:

This study successfully validated the ClikSTAR pen for use by individuals with diabetes.

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Abbreviations: (AE) adverse event, (PTC) product technical complaint, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus

Keywords: design validation, reusable insulin pen device, type 2 diabetes mellitus

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