Novel Methodology to Determine the Accuracy of the OmniPod Insulin Pump: A Key Component of the Artificial Pancreas System

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Abstract

Background:

This article describes two novel and easy approaches for assessing the accuracy of insulin pumps as implemented within the artificial pancreas system. The approaches are illustrated by data testing the OmniPod Insulin Management System at its lowest delivery volume (0.05 U) and at doses of 0.1, 0.2, 1, and 6U.

Method:

In method 1, a pipette, digital microscope, and imaging software were used to measure average bolus delivery on a linear scale for multiple volumes. In method 2, a digital microscope and imaging software were used to measure the volume of a spherical bolus of 0.05 U of insulin.

Results:

Bench testing results using the two novel methods demonstrated that the OmniPod is extremely accurate, with a relative error ranging from -0.90% to +0.96% for all measured doses (0.05, 0.1, 0.2, 1, and 6 U). In method 1, at target bolus dose of 0.05 U, the mean delivered dose (\pm standard deviation) was 0.0497 \pm 0.003 U, 0.099 \pm 0.005 U at 0.1 U, 0.2 \pm <1e-5 U at 0.2 U, 1.001 \pm 0.018 U at 1 U, and 6.03 \pm 0.04 U at 6 U. In method 2, at target bolus dose of 0.5 μ l, the mean delivered dose for both OmniPods was 0.505 \pm 0.014.

Conclusions:

Both methods confirmed a high degree of accuracy for the OmniPod insulin pump. These techniques can be used to estimate delivery volume in other infusion pumps as well.

J Diabetes Sci Technol 2011;5(6):1509-1518

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Abbreviations: (AE) adverse event, (APS) artificial pancreas system, (DKA) diabetic ketoacidosis, (FDA) Food and Drug Administration, (SD) standard deviation

Keywords: accuracy, artificial pancreas, bolus, dose, insulin pump, method, OmniPod, pipette

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