

Accuracy of Dosage Volume for Halfway Doses in the Victoza Pen

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Liraglutide is an analog of a glucagon-like peptide-1, GLP-1. Glucagon like peptide-1 causes an increased insulin release in a glucose-dependent manner, inhibits hepatic glucose output, decreases gastric emptying and decreases appetite, and, thereby, decreases glucose with minimal hypoglycemia and decreases body weight.¹ As with GLP-1, liraglutide treatment is limited by side effects of nausea, vomiting, diarrhea, etc. Liraglutide is dispensed in the Victoza[®] Pen with marked doses of 0.6, 1.2 and 1.8 mg/dose. On occasion the higher-marked dose is associated with intolerable side effects; however, the lower-marked dose is insufficient in its glucose benefit.

There are 10 clicks in the dispensing pen between the marked dosages. It would be reasonable to consider that halfway, five clicks, would deliver a dose with tolerable side effects compared to a larger dose but with more potency than the lower dose. The purpose of this study was to determine the accuracy of halfway doses.

Six Victoza Pens were allowed to warm to room temperature of 20° C. The pens were then fitted with a 32-gauge needle and a dose was delivered into the tip of a 1 ml Mohr's pipette (± 0.01 mg) at the dose of 0.6, 1.2, 1.8 and, at the halfway dose, five clicks between doses, of an assumed dose of 0.3, 0.9 and 1.5 mg. The doses were delivered in a 6 \times 6 randomization schedule. The pipettes were then visually read and the results recorded.

The volume measurements were converted to milligrams using the stated liraglutide concentration of 6 mg/ml. The mean and the 95% confidence interval were calculated.

The results are presented in **Figure 1**. All doses, including those halfway, appear to be linear and equivalent to the stated, or assumed, dose. This study demonstrates that halfway, or five clicks between marked doses, delivers an accurate halfway dose.

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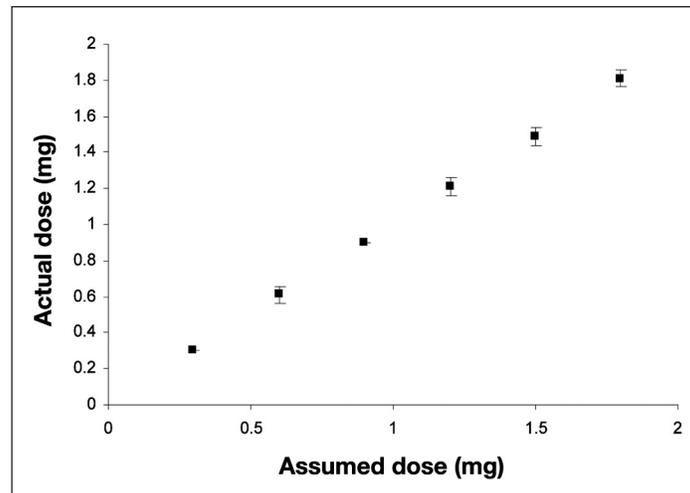


Figure 1. The marked doses and the halfway unmarked doses (five clicks between dose settings) were assessed by volume measurements using pipettes. Values are the mean of six determinations and the 95% confidence interval. The actual dose is a volume measurement converted to milligrams using the stated liraglutide concentration of 6 mg/ml.

References:

1. Drucker DJ. Glucagon-like peptides. *Diabetes*. 1998;47(2):159-69.