Comparison of Lispro Insulin Delivered by Needle-Free Injector and Conventional Needle Injection

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Studies comparing delivery of insulin by needle-free injection versus syringe have shown that bioavailability, represented by area under the curve (AUC) and maximum serum concentrations (Cmax), is comparable, but that time to maximum serum concentration (Tmax) can occur earlier with needle-free injection. However, no studies have been reported that compare the pharmacokinetics (PK) and pharmacodynamics (PD) of fast-acting insulin, such as lispro, between these delivery methods.

This study was an open label, 2-period crossover study in Type I/II diabetic subjects. The 8 subjects received a controlled meal and a 10U lispro insulin dose which was alternately delivered by needle-free injection or syringe. Resulting changes in blood glucose and insulin levels were recorded over a 4-hour period. Insulin concentrations were analyzed to determine Cmax, Tmax, and AUC for each patient. Glucose concentrations were assessed to determine maximum glucose levels (Gmax), time to maximum glucose levels (TGmax), and area under the curve (AUCG).

Figures 1 & 2 show mean values of insulin (PK) and glucose (PD) versus time. The small sample size limits statistical conclusions, but Tmax for lispro delivery using a needle-free device was significantly earlier than for a needle ($p = 0.035$), using a paired, within subject analysis. There were no significant differences in AUC and AUCG between delivery methods ($p = 0.603$ and 0.093, respectively), or in Cmax, Gmax, or TGmax (all p-values > 0.172).

Further studies planned.

Figure 1: PK

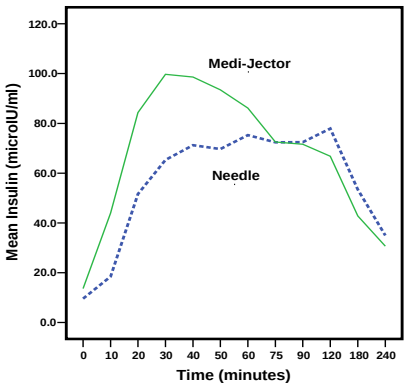

Figure 2: PD