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ORIGINAL ARTICLES

Intra-Individual Variability of the Metabolic Effect of a Novel Rapid-Acting Insulin (VIAject™) in Comparison to Regular Human Insulin

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Abstract

Background:

The variability of the metabolic action of insulin after subcutaneous (sc) injection hampers optimal insulin therapy. Insulin formulations with a reduced tendency to form hexamers might exhibit a reduced variability of absorption from the sc insulin depot into the blood stream.

Methods:

We investigated the within-subject variability of pharmacodynamic and pharmacokinetic properties of an ultra-fast insulin (UFI) formulation and regular human insulin (RHI) in patients with type 1 diabetes. Fourteen patients participated in six 10-hour euglycemic glucose clamp experiments. In this double-blind, crossover study, subjects were randomly assigned to a sequence of two experimental blocks: each block consisted of three doses of 0.1 IU/kg UFI or RHI, respectively, administered on separate days by abdominal sc injection.

Results:

Ultra-fast insulin has an earlier onset of action and shorter time to maximal plasma insulin concentration when compared to RHI ($tGIR_{max}$ 99 ± 36 min vs. 154 ± 74 min, $p = 0.002$; tC_{max} 33 ± 16 min vs. 97 ± 39 min, $p = 0.00001$). The within-subject variability of plasma insulin tC_{max} ($p = 0.027$) and of $tGIR_{max}$ ($p = 0.022$) was less for UFI than for RHI.

Conclusions:

In patients with type 1 diabetes, this UFI showed reduced within-subject variability when compared with RHI.

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Abbreviations: (PD) pharmacodynamic, (PK) pharmacokinetic, (RHI) regular human insulin, (sc) subcutaneous, (UFI) ultra fast insulin

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