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ORIGINAL ARTICLE

A Pilot Study to Examine the Tolerability and Device Preference in Type 1 Diabetes of Insulin Aspart Administered by InsuJet Compared with Subcutaneous Injection

Anne T. Reutens, MBBS, PhD, FRACP,[1] Beverley Balkau, BSc (Hons), PhD,[1–3] and Neale Cohen, MBBS, FRACP[1]

Abstract

Background: Jet injectors allow needle-free insulin delivery. The study objective was to compare the tolerability and device preference of subcutaneous insulin aspart delivery by jet injector (InsuJet™; European Pharma Group, Schiphol-Rijk, The Netherlands) with pen injection in an open-label, randomized, crossover pilot study.

Subjects and Methods: Ten participants with type 1 diabetes underwent two meal tolerance tests 1 week apart. Plasma glucose and serum insulin levels were sampled from 10 min preceding to 240 min after insulin aspart administration by InsuJet or FlexPen® (Novo Nordisk Pharmaceuticals Pty. Ltd., Baulkham Hills, NSW, Australia). Insulin dose was calculated using participants' insulin-to-carbohydrate ratios. Immediately after insulin administration, participants drank 500 mL of Ensure® (Abbott Australasia Pty. Ltd., Botany, NSW, Australia) (providing 2,240 kJ of energy, 18.6 g of protein, 96 g of carbohydrate, and 3 g of fat).

Results: In this small pilot study, the devices were similar in glucose excursion (median [quartile 1, quartile 3], InsuJet vs. FlexPen, 9.4 [4.8, 12.8] vs. 8.1 [5.4, 10.6] mmol/L; $P = 0.43$), in the area under the glucose concentration–time curve for 0–240 min corrected for baseline glucose level (InsuJet vs. FlexPen, 1,230 [623, 2,012] vs. 1,175 [91, 1,774] mmol·min/L; $P = 0.4$), and in insulin absorption over the 240-min period. Devices were similar for participant preference and relative injection pain.

Conclusions: Subcutaneous jet injection of aspart insulin was well tolerated.

Introduction

The use of insulin pens with hypodermic needles to deliver subcutaneous injections of insulin is now widespread. However, needles may cause discomfort or provoke anxiety if the patient has needle phobia, factors that contribute to poor compliance with insulin. Use of needle-free technology has been proposed as a strategy to alleviate these problems.[1] Experimental work conducted with excised cadaveric skin[2] or polyacrylamide gel[3] has studied the mechanics of jet injection. Jet injection produces a microscopic puncture hole in the skin and a spherical area of liquid dispersion in the skin under the hole.[4] Successful jet injection of insulin for treatment of diabetes was documented in 1950 by Perkin et al.[5] using a Hypospray device. Apart from the avoidance of needle use, jet injection produces a more rapid onset of insulin action and other favorable pharmacodynamic and pharmacokinetic effects.[6,7] A recent euglycemic clamp study conducted in healthy volunteers found that insulin aspart delivered by InsuJet™ jet injector (European Pharma Group, Schiphol-Rijk, The Netherlands) had immediate onset of action, more rapid achievement of maximal glucose infusion rate and peak insulin concentration, and a shorter duration of hyperinsulinemia compared with delivery by conventional insulin pen injection.[8] Post hoc analysis of the results showed that adiposity did not affect the time–action insulin profile when the jet injector was used, but there was significant delay in action in those with a body mass index of $>23.6\ kg/m^2$

[1]Baker IDI Heart and Diabetes Institute, Melbourne, Victoria, Australia.
[2]Epidemiology of Diabetes, Obesity and Chronic Kidney Disease over the Life Course, Unit 1018, CESP Centre for Research in Epidemiology and Population Health, INSERM, Villejuif, France.
[3]URMS 1018, University Paris Sud 11, Villejuif, France.
This study is registered with the Australian New Zealand Clinical Trials Registry with clinical trial registration number ACTRN12612000711819.