

Comparison of Blood Sugar and Insulin Kinetics following Needle-free and Pen Injection of Insulin

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Introduction

Insulin therapy is the treatment of choice for all patients suffering from diabetes mellitus type I and for most diabetes mellitus type II patients. Despite the efforts of making insulin treatment easier and more comfortable - for example by developing pen injection systems and inhalative insulin - the current method of injecting insulin subcutaneously is still a substantial barrier for many patients. Failure of overcoming this threshold prevents a lot of diabetics from reaching the intended normoglycemia. Fear of the needle - particularly in those patients with diabetes mellitus II - will often postpone or prevent a timely switch to insulin therapy.

The intra- or subcutaneous application of medication using needle-free systems, so-called jet injectors, was first described by Hingson in 1949. Following a number of technical improvements, subcutaneous insulin injections using jet injection systems were finally established in the U.S. in the 1980's. Although the systems were not widely accepted due to technical difficulties and their rather difficult mode of operation, they are still used by a small number of patients. The following study is an assessment of the INJEXTM system for jet injection of insulin.

Material and Methods

Study population

Ten patients with diabetes mellitus, 8 of which suffered from diabetes mellitus type II and two from diabetes mellitus type I (ADA classification), participated in the study. All of the patients were thoroughly informed of the objectives and the course of the study and consented in writing. During the study period, all of the patients were hospitalised, their diabetes was stable. The patients continued to follow their usual diet and kept their usual insulin dose. None of the patients showed any signs of lipodystrophy or -atrophy. Additional patient characteristics are displayed in Table 1.

Table 1: Basic characteristics of the study patients

| | | | |
|------------------------------|-------------|-------------|-----------|
| Gender (M/F) | 9/1 | HbA1c (%) | 8.5 ± 2.2 |
| Age (Years) | 64.4 ± 15.4 | Neuropathy | 7/10 |
| Diabetes type I/II | 2/8 | Retinopathy | 3/10 |
| Duration of Diabetes (Years) | 10.4 ± 14.8 | Nephropathy | 6/10 |
| BMI (kg/m ²) | 27.1 ± 3.0 | Hypertonia | 7/10 |

Study protocol and procedures

The trial was designed as a randomised, crossover study. On two separate study days that were at least three days apart from each other, the patients received their normal morning dose of insulin (NPH and regular insulin, mean dose: NPH insulin 17.6 + 10.0 IE, regular insulin 9.0 + 3.7 IE) in the abdominal wall using either a commercial insulin pen (Novopen III, NovoNordisk, Copenhagen, Denmark) or the INJEXTM (Rösch AG, Berlin, Germany). All of the insulin injections were performed by a physician who was familiar with insulin injection devices. Thirty minutes after the insulin injections the patients received their usual, and on study days standardised breakfast that contained 30 to 60 g of carbohydrates. On an additional study day, the patients underwent thorough training in the preparation and use of the jet injector INJEXTM and practiced self- injection of saline solution. The patients then evaluated and rated different aspects of the INJEXTM device using the German school grading system, which starts at 1 (excellent) and ends at 6 (unsatisfactory).

Results:

Fig. 1: Histology

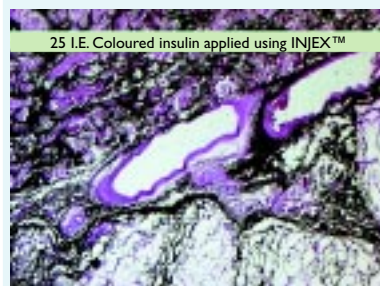
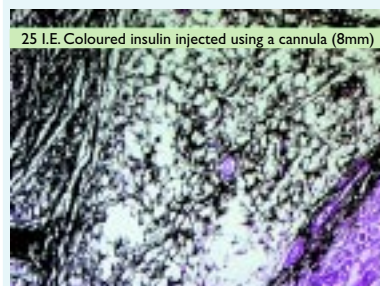
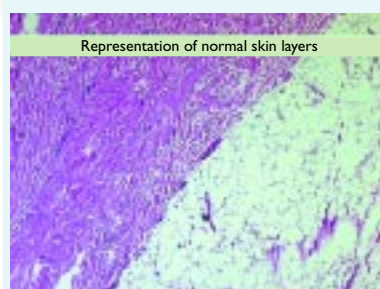


Fig. 2 A: Blood sugar kinetics following the application of insulin with the jet injector compared to pen injection

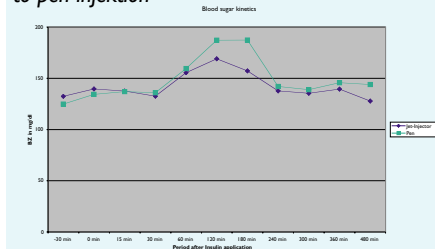


Fig. 2 B: Insulin kinetics following the application of insulin with the jet injector compared to pen injection

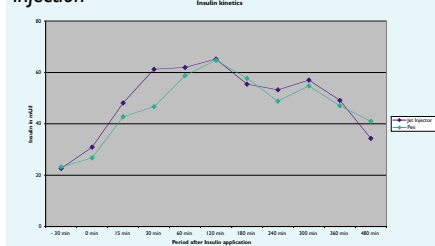
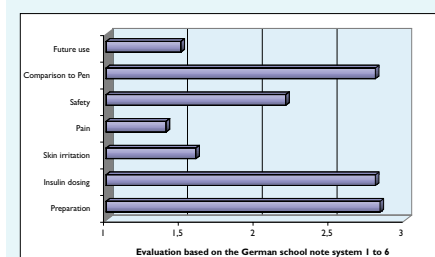


Fig. 3: Patients' evaluation of INJEXTM



Discussion

With the INJEXTM system, control of blood sugar following needle-free insulin injection is very similar to that of the pen. The level of pain is predominantly perceived lower. In comparison with the conventional pen the needle-free injection system causes less skin irritation. However, its somewhat more complex operation is considered a disadvantage. Overall, the INJEXTM system compares well to the insulin pen and provides an attractive alternative to the conventional pen injection for most patients.