ONE-YEAR PILOT STUDY WITH A NEEDLE-FREE INSULIN JET-INJECTOR SUPPORTS SUSTAINED IMPROVEMENT IN HbA1c AND BLOOD SUGAR PROFILES IN TYPE 1 DIABETIC SUBJECTS

M. Velussi, Diabetic Clinic " Pineta del Carso" Monfalcone, Italy

ABSTRACT

Introduction: In a short-term study of a needle-free insulin jet-injector, the Medi-Jector Vision®, blood glucose profiles improved compared to that for pen devices in type 1 diabetic subjects. If sustained over time, this finding should result in improved HbA1c levels. **Aim of the study**: To document HbA1c levels in subjects using the jet-injector and to measure their blood glucose profile after one year. **Materials and Methods**: Five type 1 diabetic patients (3 females, 2 males) had the following profile: age 34 ± 4 years, diabetes duration 9.5 ± 4.5 years, BMI 23 ± 1,2 Kg/m2, systolic BP 126 ± 6 and diastolic BP 76 ± 3 mmHg, daily insulin dose 36 ± 4 IU/day (70% Regular, 30% NPH). All subjects consented to periodic HbA1c evaluations and 72-hours continuous subcutaneous glucose monitoring. A baseline glucose profile was obtained while subjects used a pen-like needle device. Subjects were switched to a jet-injector for one year, and a blood glucose profile was then obtained at one year. The monitoring periods were performed during working days, with the consumption of a stable diet (breakfast 430 ± 30, lunch 860 ± 55, dinner 660 ± 45 Kcal) with 56% carbohydrates, 19% proteins, 25% fats) and minimal physical activity. Regular insulin was injected 30 minutes before food consumption, and NPH was injected at bedtime. **Results**: HbA1c levels decreased from 7.3 ± 0.4% at baseline to 6.7 ± 0.4% after six months and 6.3 ± 0.2% after one year. Daily glucose profiles observed at the end of one year of jet-injection consistently showed lower postprandial blood glucose compared to the baseline (see graph). **Conclusion**: Subjects experienced a continuous decline in HbA1c over one year of jet-injection insulin therapy. Improvements in the blood glucose profile using a jet-injector could be demonstrated with continuous monitoring.

AIM OF STUDY

The aim of the study was to determine whether the improvement in glycemic profile observed in short-term studies of needle-free insulin administration could be sustained long term, resulting in improvement of HbA1c levels.

STUDY DESIGN AND METHODS

Patient Characteristics:

• Type I diabetic patients	5	(2 males, 3 females)
• Diabetes duration	9.5	± 4.5 years
• BMI	23.0	± 1.2 kg/m2
• Systolic BP	126	± 6 mm/Hg
• Diastolic BP	76	± 3 mm/Hg

- Mean Insulin Need 36.0 ± 4.0 IU/day (70% regular, 30% NPH)
- Mean HbA1c 7.3 ± 0.4% (baseline)

Insulin Devices

- Novopen Demipen used by patients at baseline
- Medi-Jector VISION Jet Injector used thereafter for one year

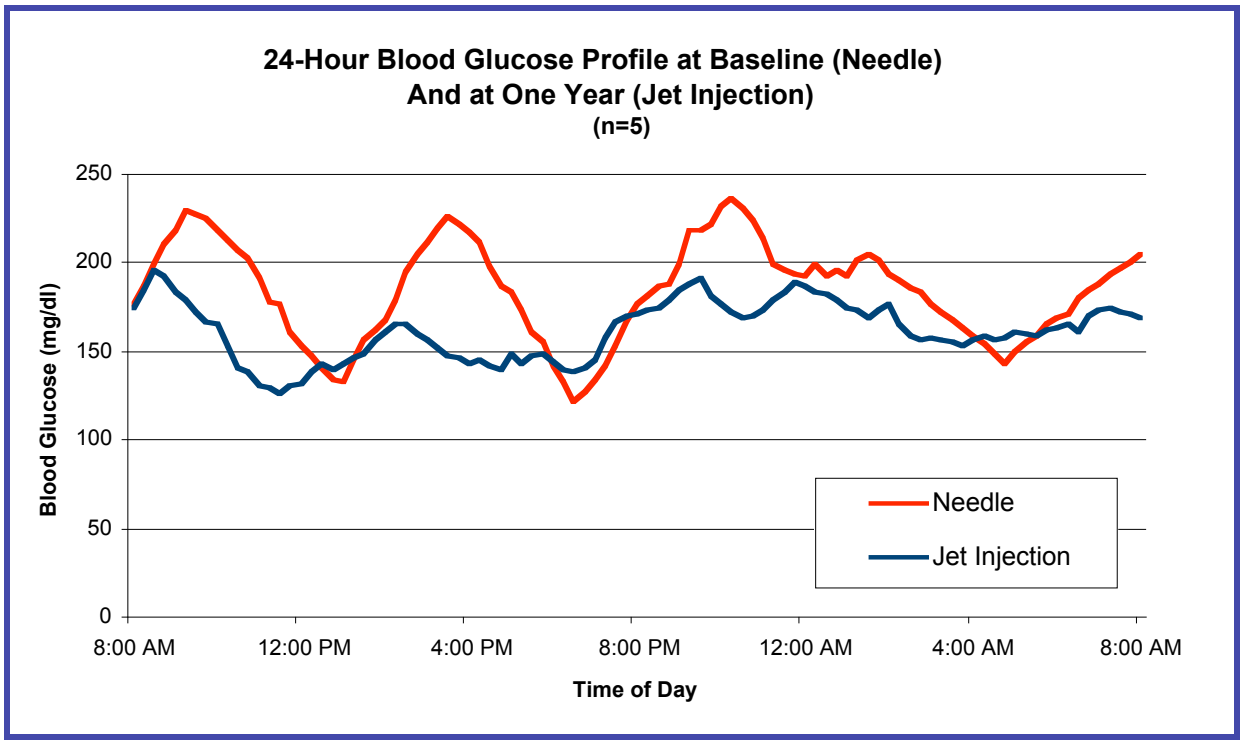
Food Consumption During Monitoring Periods

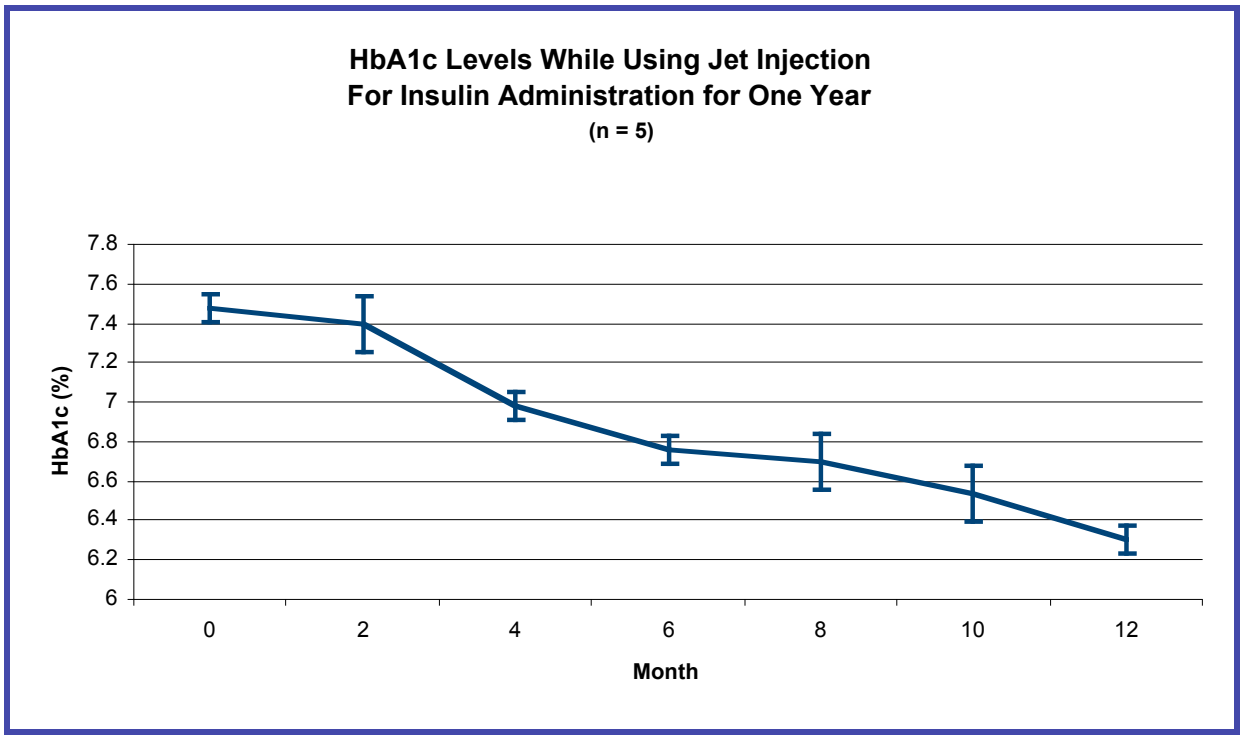
- Breakfast 430 ± 30 Kcal
- Lunch 860 ± 65 Kcal
- Dinner 660 ± 45 Kcal

Food Composition

- Carbohydrate 56%
- Protein 19%
- Fat 25%
-

RESULTS





SUMMARY

Compared to insulin administration with a needle, the Medi-Jector VISION jet injection device demonstrated:

1. The blood glucose profile produced by jet injection of insulin was sustained for one year.
2. HbA1c levels declined throughout the year of using jet injection.

CONCLUSIONS

1. Subjects with reasonable glycemic control as evidenced by HbA1c (≤ 8.0%) were able to achieve meaning improvement after changing mode of insulin administration to jet injection.
2. A needle-free insulin administration regimen may be advantageous in reducing the risk of diabetes complications.