

NEEDLE-FREE INSULIN ADMINISTRATION SIGNIFICANTLY ALTERS NOCTURNAL BLOOD GLUCOSE PROFILE WITH INTERMEDIATE-ACTING INSULIN IN TYPE 1 DIABETIC SUBJECTS

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ABSTRACT

Introduction: The management of nocturnal NPH insulin is commonly a problem for type 1 diabetic patients because of hypoglycemia risk. **Aim of the study:** To compare nocturnal blood glucose after NPH insulin administered alternatively with a pen device and a needle-free jet-injector (Medi-Jector VISION®). **Materials and Methods** 15 type 1 diabetic subjects (7 males, 8 females), age 31 ± 4 and diabetes duration 9 ± 4 years, BMI 23.5 ± 1.8 Kg/m², systolic BP 130 ± 4 and diastolic BP 78 ± 4 mmHg, intensively treated since diabetes onset (43 ± 5 I.U. insulin - NPH typically 30% of the total). Subjects consented to 72-hour continuous subcutaneous glucose monitoring (CGMS Minimed®) and to use the pen device the first and the third night and a jet injector the second night of the study. All subjects received NPH at 11:00 pm each night. All the patients otherwise maintained consistent activity, insulin dose and diet during the study. **Results:** Blood glucose after using the jet-injector was significantly lower than that with a pen device between 12:45 am to 3:15 am and between 5:30 am and 8:30 am ($p < .01$) (see graph). The pen device produced lower but not statistically different blood glucose levels between 4:00 am and 5:00 am. No hypoglycemic episodes were recorded during the study. **Conclusions:** The nighttime blood glucose profile was improved using the jet-injection compared to a pen device. Blood glucose control with jet injection was superior at the end of the dosing period, and the blood glucose nadir was less pronounced after jet-injection.

AIM OF STUDY

The aim of the study was to compare the efficacy and safety of a needle-free insulin device (Medi-Jector VISION) to an insulin pen device for diabetic patients injecting nocturnal NPH insulin at bedtime.

STUDY DESIGN AND METHODS

Patient Characteristics:

- Type I diabetic patients 15 (7 males, 8 females)
- Diabetes duration 9 \pm 4 years
- BMI 23.5 \pm 1.8 kg/m²
- Systolic BP 130 \pm 4 mm/Hg
- Diastolic BP 78 \pm 4 mm/Hg
- Mean Insulin Need 43 \pm 5 IU/day
- Bedtime NPH Insulin 30% of total
- Mean HbA1c 7.0 \pm 0.4%

Insulin Devices

- Novopen Demipen used by patients on 1st and 3rd night of the study
- Medi-Jector VISON Jet Injector used on 2nd night of the study

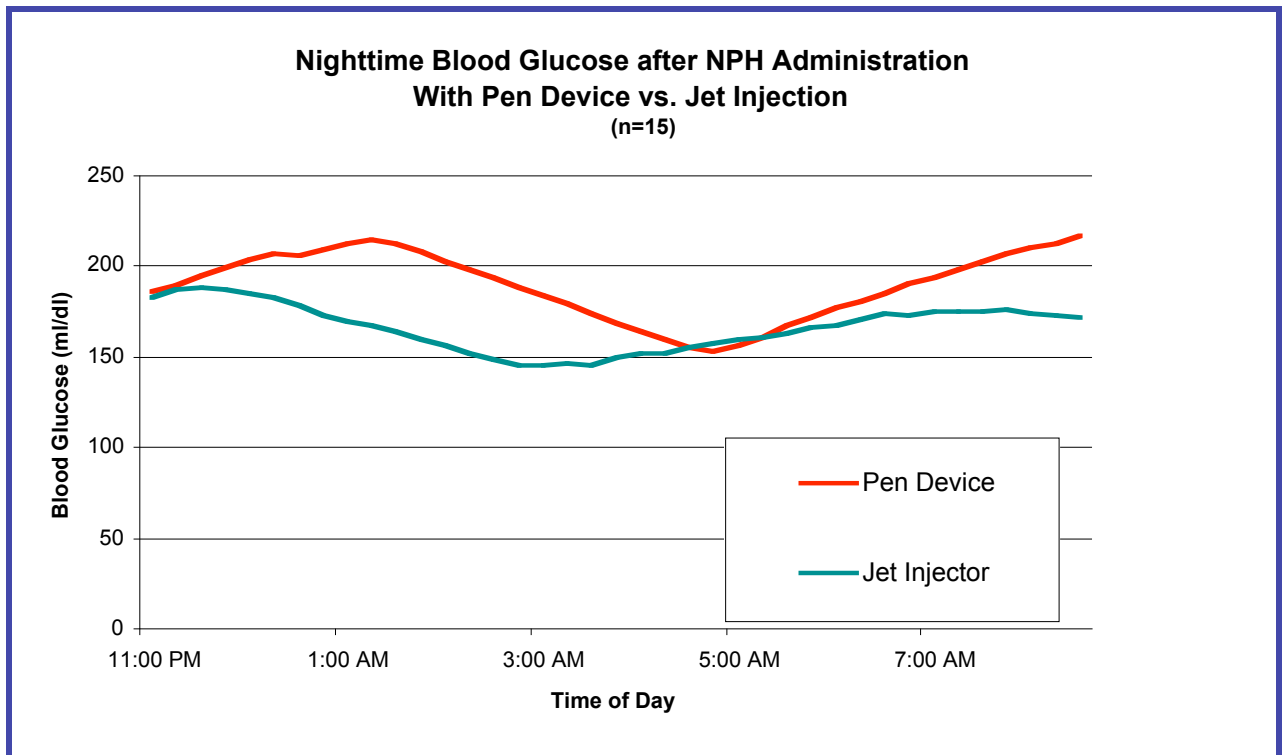
Injection Timing

- NPH Injection at 11:00 PM each night

Injection Site

- Upper arm

RESULTS



SUMMARY

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

Lower average blood glucose level through the night.

1. Less-pronounced glycemic excursions during the night.

CONCLUSIONS

1. Needle-free administration of NPH insulin was well tolerated by all subjects.
2. The Medi-Jector VISION resulted in a superior blood glucose profile compared to that after using needle, as assessed by:
 - area under the curve
 - glycemic excursions
3. Most notably, the risk of nighttime hypoglycemia may be reduced when using the Medi-Jector VISION