

NEEDLE-FREE INSULIN INJECTOR SIGNIFICANTLY AMELIORATES ABSORPTION OF REGULAR INSULIN IN TYPE 1 DIABETIC SUBJECTS

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ABSTRACT

Introduction: many patients with diabetes want alternatives to needles as a means to administer insulin. **Aim of the study:** to compare blood glucose profile after administering insulin with a pen device vs. a needle-free insulin injector. **Materials and Methods:** 15 type 1 diabetic subjects (8 females, 7 males; mean age 30 ± 6 years; diabetes duration 10 ± 5 years; BMI 24.3 ± 2.2 Kg/m²; BP 125 ± 4 systolic, 75 ± 5 mmHg diastolic; intensively treated since diabetes onset; mean daily insulin dose 33 ± 6 U.I.) were accepted, after written informed consent, to undergo 48 hours of continuous subcutaneous glucose monitoring (Minimed® CGMS). Subjects used a pen device (Novopen® Demi) to inject regular human insulin 30 minutes before breakfast, lunch and dinner on the first monitoring day and a jet injection device (Medi-Jector VISION®) during the second monitoring day. The insulin/carbohydrates ratio was 1/15 CHO, and the mean Kcal content of the diet was 430 ± 30 at breakfast, 860 ± 55 at lunch, 660 ± 45 at dinner (all composed by 56% CHO, 19% proteins, 25% fats). **Results:** insulin administered by jet injection device, in comparison to pen device, produced a significantly lower ($p<0.01$) glucose profile from 45 to 255 minutes after breakfast-time injection, 45 to 270 minutes after lunchtime injection and 45 to 240 minutes after dinner-time injection (maximum blood glucose difference at 105 minutes after breakfast and dinner, and 150 minutes after lunch) with a significant reduction ($p<0.01$) in area under the blood glucose curve, without lesions in the injection site (abdominal wall) and without a loss in blood glucose control at the end of the dosing period. **Conclusions:** Medi-Jector jet

injection device produces quicker absorption of regular insulin compared to absorption profile using the pen device and a significantly lower blood glucose profile without an increase in hypoglycemia after food ingestion.

AIM OF STUDY

The aim of the study was to compare the efficacy and safety of a new needle-free insulin device (Medi-Jector Vision) to an insulin pen device for diabetic patients injecting human regular insulin three times per day (breakfast, lunch and dinner) and intermediate-acting insulin at bedtime.

STUDY DESIGN AND METHODS

Patient Characteristics

- Type 1 Diabetic Patients 15 (8 females, 7 males)
- Diabetes duration 10 ± 5 years
- BMI 24.3 ± 2.2 Kg/m²
- Systolic BP 125 ± 4 mmHg
- Diastolic BP 74 ± 5 mmHg
- Regular insulin 0.5 ± 0.2 IU/Kg
- Bedtime insulin 0.2 ± 0.1 IU intermediate
- Mean insulin need 33 ± 6 IU per day
- Mean HbA1c 6.7 ± 0.3 %
- Physical activity 1032 ± 215 Kcal

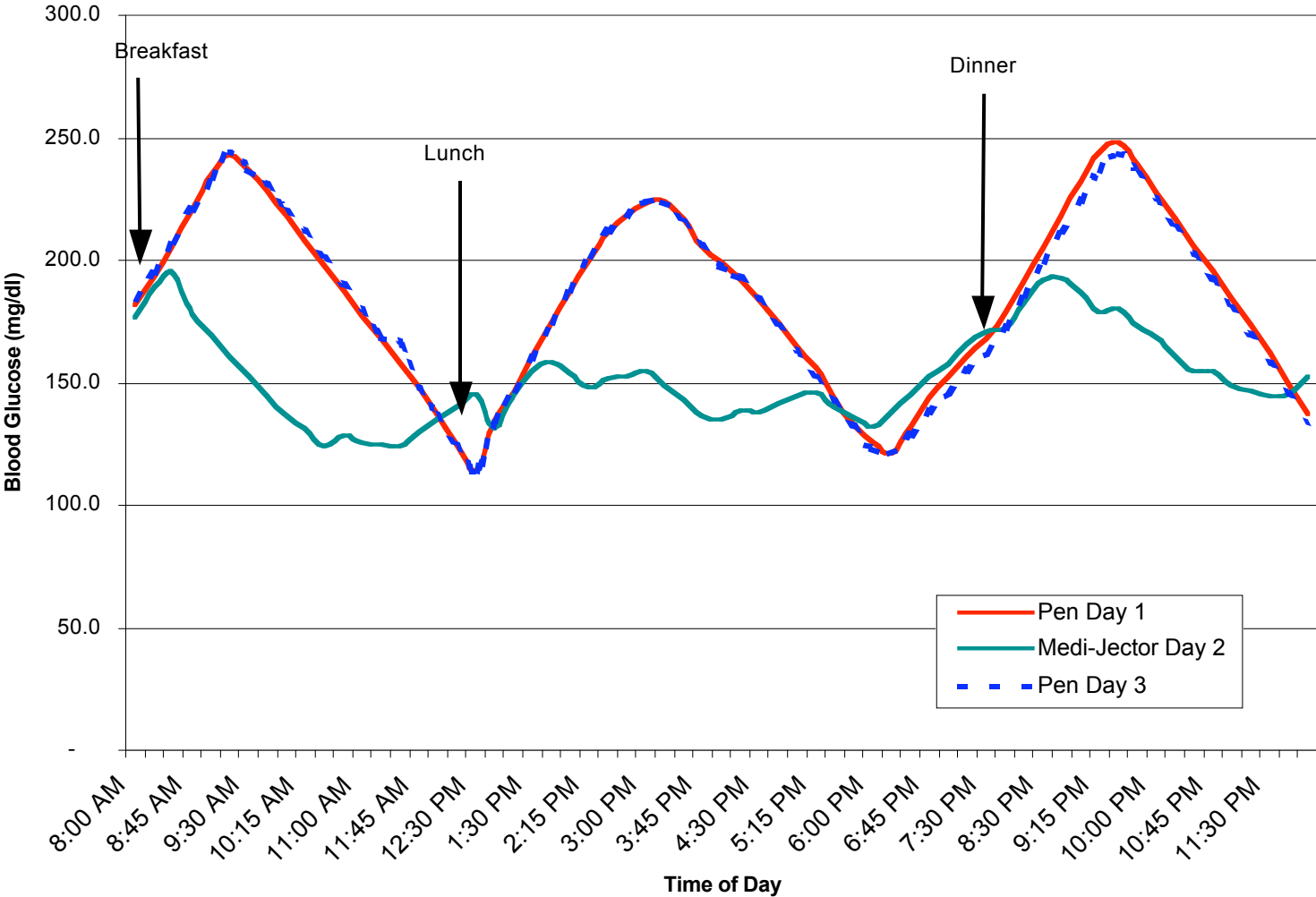
Study Design

Continuous Glucose Subcutaneous Monitoring (MiniMed CGMS) for a period of 72 hours during normal job activity and lifestyle (no weekends).

- Insulin devices:
- Novopen Demi pen used by patients on first and third day of the study.
 - Medi-Jector Vision jet injector used on second day of the study.
- Injection timing:
- 30 minutes before meal with pen,
 - immediately before meal with Medi-Jector Vision
- Injection site:
- abdominal wall for regular insulin
 - upper arm for intermediate acting insulin
- Food consumption:
- breakfast 430 ± 30 ,
 - lunch 860 ± 55 ,
 - dinner 660 ± 45 Kcal
- (for each of the three days)
- Food composition:
- CHO 56%,
 - proteins 19%,
 - fats 25%
- (for each meal)
- Insulin/CHO ratio: 1 ± 0.3 IU/15 grams CHO

RESULTS

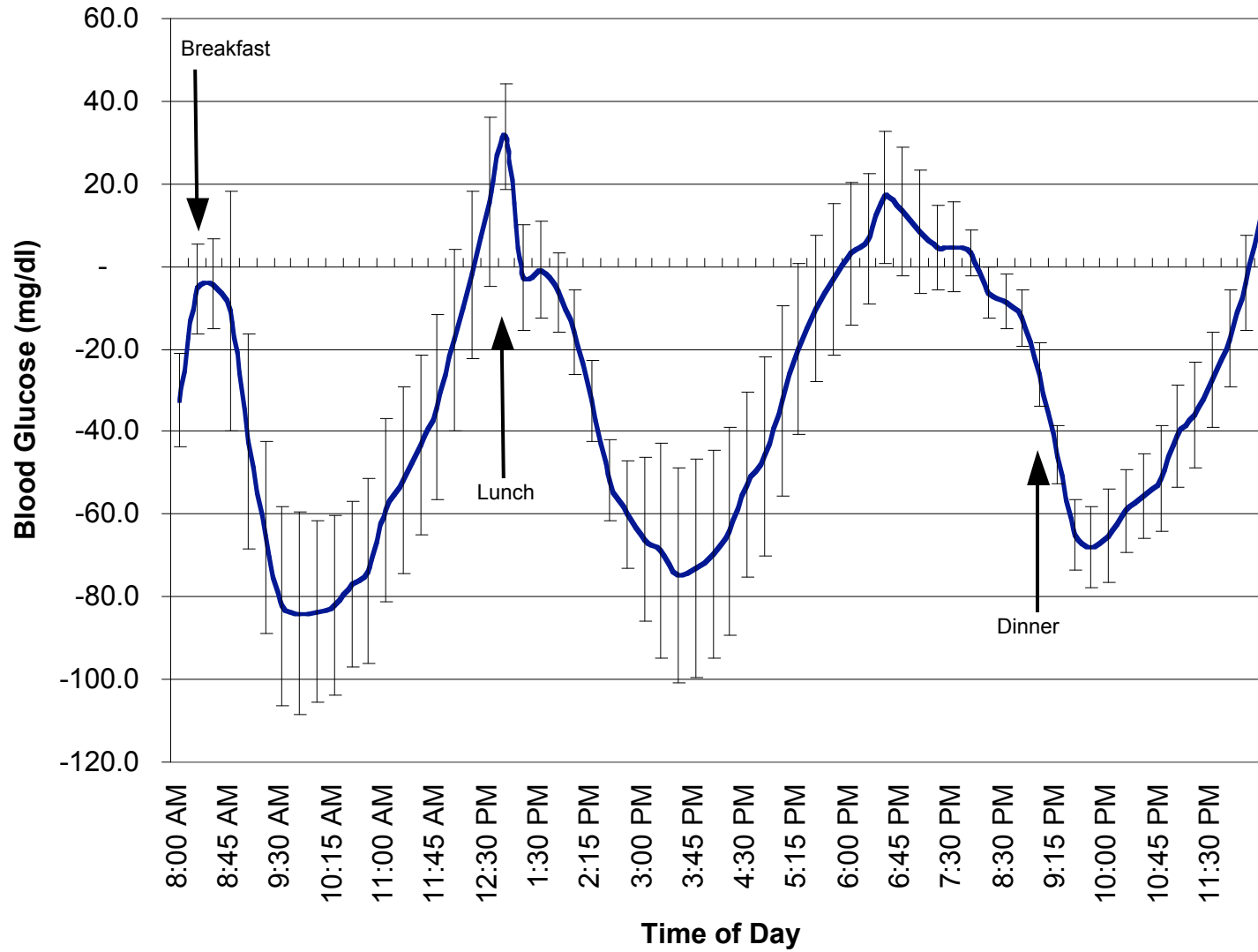
Blood Glucose after Insulin Administration Pen vs. Medi-Jector (n=15)



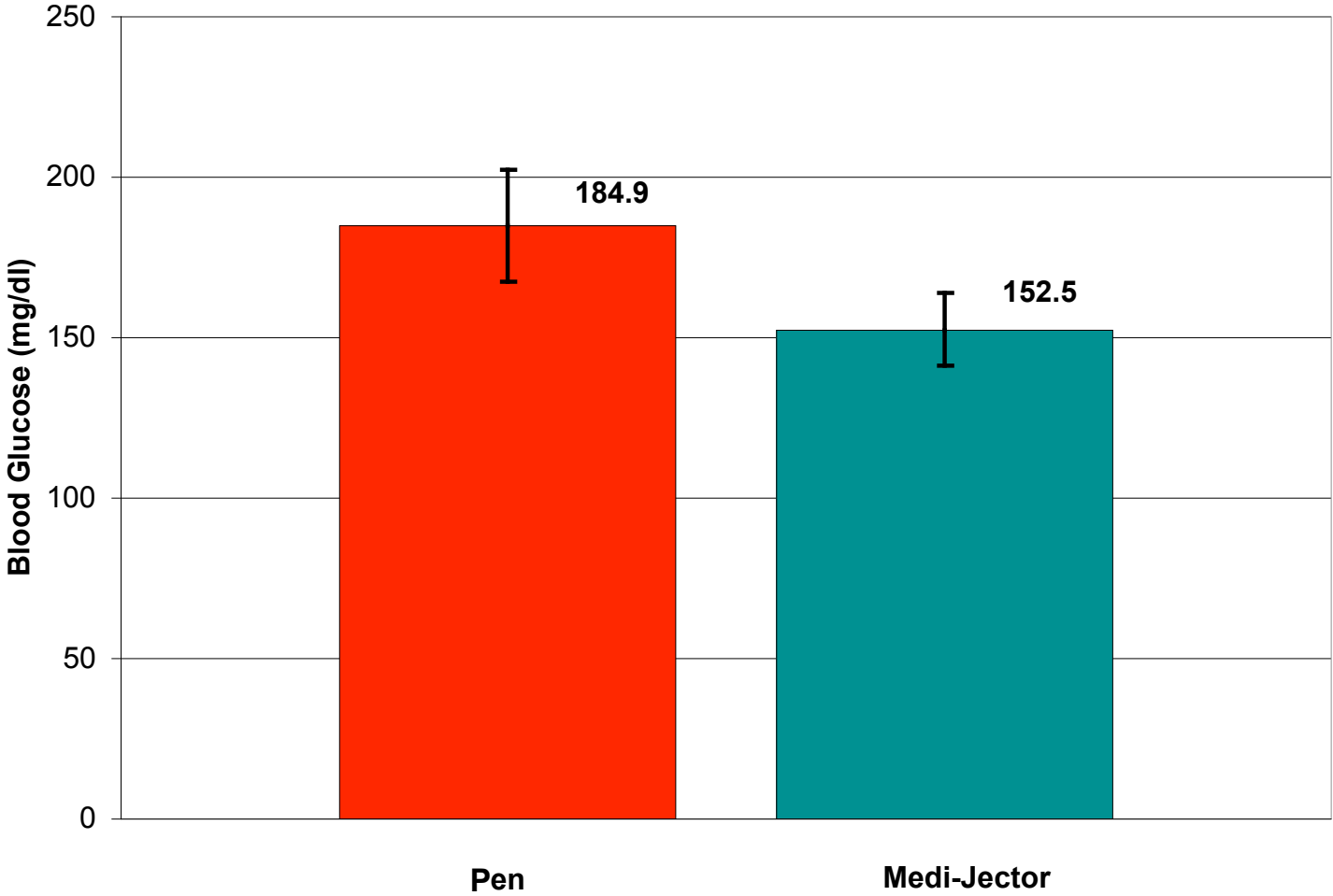
Note: Insulin administered 30 minutes prior to meal when using Pen and immediately prior to meal when using Medi-Jector.

Difference in Blood Glucose Levels Medi-Jector - Pen

n=15



**Mean Blood Glucose
Pen vs. Medi-jector
(n=15)**



SUMMARY

Under continuous subcutaneous glucose monitoring for 72 hours, the Medi-Jector Vision device demonstrated:

1. Quicker absorption of human regular insulin, injected in the abdominal wall, in comparison to that using pen device.
2. Significant lower blood glucose profile, particularly in the postprandial period of time.
3. No increase of hypoglycemic episodes after food ingestion.
4. A glucose profile similar to insulin analogues without abrupt decrease of glucose blood level and excess of glucose variability.

CONCLUSIONS

1. Needle free insulin device Medi-Jector Vision was well accepted by the 15 type 1 diabetic patients of the study.
2. Neither local adverse reactions nor local pain has been claimed by the patients.
3. The ability to inject regular insulin immediately before food consumption with the Medi-Jector Vision facilitates normal lifestyle routines of the patients.
4. Different effects on blood glucose levels depend on the injection method and quicker bioavailability of the injected insulin.
5. The Medi-Jector Vision was demonstrated in this study to reduce postprandial hyperglycemic peaks better than that achieved by using insulin pens without an increase in hypoglycemic episodes.