

Clinical Performance of a Device That Applies Local Heat to the Insulin Infusion Site: A Crossover Study

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Abstract

Background:

Fast-acting insulin analogs have been available since 1996. The absorption rate of these insulins is still too slow to mimic the physiological insulin action in healthy subjects. This study investigates the clinical performance of InsuPatch™, a local skin-heating device, on postprandial glucose excursion.

Methods:

Twenty-four type 1 diabetes mellitus subjects on continuous subcutaneous insulin infusion were included in this crossover study [10 male, 14 female, age: 43.5 ± 11.3 years, diabetes duration: 18.3 ± 10.5 years, glycosylated hemoglobin: $7.4 \pm 0.8\%$, body mass index: 25.0 ± 3.0 kg/m² (mean \pm standard deviation)]. The impact of local skin heating was measured by dividing the two-hour area under the curve by integration time (AUC/t₁₂₀) for blood glucose (BG) above baseline after two standardized breakfast and dinner meal pairs (with and without heating) per subject. For the first breakfast pair, venous insulin concentration was also measured.

Results:

A significant reduction was found for the AUC/t₁₂₀ after breakfast and after dinner meals (42 breakfast meal pairs, AUC/t₁₂₀ not heated 66.4 ± 32.8 mg/dl vs heated 56.8 ± 34.0 mg/dl, $p = .017$; 38 dinner meal pairs, AUC/t₁₂₀ not heated 30.8 ± 31.0 mg/dl vs heated 18.4 ± 23.9 mg/dl, $p = .0028$). The maximum venous insulin concentration with heating was 27% higher than without heating ($n = 23$). The number of hypoglycemic events on days with heating ($n = 9$) was similar to the number of days without heating ($n = 13$).

Conclusions:

Local heating of the skin around the infusion site significantly reduced postprandial BG by enhancing insulin absorption. The heating device was well tolerated, and it could facilitate development of closed-loop systems.

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Abbreviations: (ADE) adverse device effects, (AUC/t) area under the curve divided by integration time, (BG) blood glucose, (CHO) carbohydrate, (CSII) continuous subcutaneous insulin infusion, (HbA1c) glycosylated hemoglobin, (SD) standard deviation, (T1DM) type 1 diabetes mellitus

Keywords: blood glucose, continuous subcutaneous insulin infusion, insulin pump, postprandial excursion, skin heating

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