

Feasibility of Adjacent Insulin Infusion and Continuous Glucose Monitoring via the Medtronic Combo-Set

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Abstract

Background:

Subcutaneously infused insulin may interfere with the function of nearby glucose-sensing electrodes and *vice versa*. The prototype of the Combo-Set device (Medtronic) incorporates a subcutaneous insulin delivery catheter and continuous glucose monitoring (CGM) sensor assembled on the same platform and separated by 11 mm. We aim to evaluate Combo-Set's insulin delivery and glucose-sensing functions.

Methods:

Ten subjects with type 1 diabetes wore a Combo-Set and a Sof-Sensor inserted subcutaneously in contralateral abdominal areas connected to *iPro* recorders (Medtronic) for 53.25 ± 0.75 h (mean \pm standard deviation). The Combo-Set delivered insulin diluent except during meal tests on days 1 and 3 when insulin lispro was delivered as a meal bolus and postmeal basal. Venous plasma samples were collected at the following time points from meal start: 0, 30, 60, 120, and 180 min for insulin measurements. The accuracy of the Combo-Set sensors was evaluated and compared with that of the Sof-Sensor, with each referenced against capillary glucose values (Contour Link Meter, Bayer).

Results:

Accuracy of the Combo-Set sensor was comparable to that of the Sof-Sensor. Clarke error grid analysis showed that 97% of Combo-Set and 93% of Sof-Sensor values were in the A+B regions ($p = .20$, not significant). The Combo-Set showed the expected postbolus peak insulin time (67 ± 9 min, mean \pm standard error). One "no delivery" alarm occurred during the 21 patient days of use.

Conclusion:

A device providing for simultaneous adjacent placement of an insulin infusion catheter and a CGM sensor is feasible and functions within acceptable limits. The low "no delivery" alarm rate was similar to that of other infusion sets.

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Abbreviations: (CGM) continuous glucose monitoring, (CSII) continuous subcutaneous insulin infusion, (CTU) clinical trial unit, (ISF) interstitial fluid, (MARD) mean absolute relative difference, (RT-CGM) real-time continuous glucose monitoring, (SD) standard deviation, (T1DM) type 1 diabetes mellitus

Keywords: accuracy, colocalization, continuous glucose monitoring, glucose sensing, insulin delivery

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