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 ± 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 ± 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.