Increased time in range observed after introduction of a connected insulin pen

Anne Kaas¹; Niels V Hartvig2; Jarl Hellman³; Nikoline Nygård Knudsen4; Ann-Charlotte Mårdby5; Peter Adolfsson6

Background

Insulin pens have become the most widely used devices for delivering insulin. Despite their convenience, however, there are shortcomings. In particular, for patients with type 1 diabetes (T1D), insulin injection can result in inadequate glycaemic control for patients with diabetes. Smart insulin pens offer automatic access to insulin injection data, and could help overcome barriers of poor adherence, clinical inertia and incorrect dosing.

The smart connected NovoPen® 6 collects and stores data on the time of insulin injections and the number of units administered. These data are then downloaded using near field connectivity to a centralised database. This allows healthcare professionals (HCPs) and patients to look at injection data together when discussing insulin treatment. If the injection data are further combined with continuous glucose monitoring (CGM) data the potential to improve patient-HCP dialogue is thought to be even greater.

The possibility to have a combined view of insulin injections and CGM data gives the HCP and the patient a more complete picture of current glycaemic status. Thus, both patient-HCP dialogue and treatment approaches can be improved.

An engaging and open patient-HCP dialogue has been identified as highly important for optimal disease management. Therefore, the NovoPen® 6 has the potential to improve glycaemic control. 1,2

Aim

The objective of the non-interventional study was to investigate how a smart connected insulin pen (NovoPen® 6) influences glycaemic control in patients with type 1 diabetes (T1D) in a real-world setting.

Methods

This pilot study was a prospective, non-interventional study running from May 2017–Nov 2018. Twelve diabetes clinics from different parts of Sweden participated. Patients with T1D using CGM were included if their treating physicians decided to offer them a NovoPen® 6.

At baseline, patients received a NovoPen® 6 for basal and/or bolus insulin injections. Baseline was then followed by a baseline period between pen introduction and visit 1, during which the patient started to use the NovoPen® 6 but without access to downloads of injection data. The first pen introduction and visit 1, during which the patient started to use the NovoPen® 6 but without access to downloads of injection data. The first visit was always the earliest point for follow-up, as patients would on average have been in the study for ≥180 days, allowing for sufficient interaction with HCPs and discussions of available pen data. Time in range (TIR), time spent in hyperglycaemia and time spent in insulin aspart (≤0.5 mmol/L) and l2 hypoglycaemia (<3.0 mmol/L) were compared between the baseline and follow-up periods, which was defined as any day after the fifth visit.

Figure 1: Study design

Figure 2: Using NovoPen® 6 with the Glooko/Diasend® system

Figure 3: Patient treatment characteristics

Figure 4: Mean difference in the time spent in glycaemic ranges from the baseline period to the follow-up period

Figure 5: Baseline and follow-up TIR

Results

Ninety-four adults with T1D with a mean [min; max] age of 40.1 years (18–67 years) were included in the analysis. A total of 64 patients used NovoPen® 6 for bolus insulin only, 17 for basal and bolus insulin and 5 for basal insulin only. For the majority, insulin degludec was the basal insulin. Seven patients did not have connected pen data in the 14-day periods studied and 1 patient used biphasic insulin aspart 30, multiple bolus basal insulin (Figure 1).

A significant increase of 1.3 hours per day (>21%) of the baseline level in mean TIR from the baseline period to the follow-up period was observed (p<0.001, Figure 4 and Table 1).

Accordingly, a significant reduction in mean time spent in hyperglycaemia (<10.0 mmol/L) and l2 hypoglycaemia (<0.5 mmol/L) of –1.8 hours per day (p<0.001 and >0.3 hours per day (p<0.05), respectively, was also observed (Figure 4 and Table 1).

There was no significant change in mean time spent in l1 hypoglycaemia (0.0–0.9 mmol/L, p=0.181, Figure 4 and Table 1).

While the mean glucose level did not change significantly, the coefficient of variation was reduced 3.8% from the initial level of 9.5% (Table 1). This shows that the improved TIR is obtained primarily by more stable glucose levels over the day.

In terms of bolus insulin dose (bolus), a significant increase from the baseline period to the follow-up period of 29%, to a dose of 32.1 Unitbolus was observed. There was no significant change in mean basal insulin dose (insulin).

Conclusion

The high rates in findings in patients with T1D highlights the potential benefit to glycaemic control when connected pen data contribute to the patient-HCP dialogue.

Patients with a smart connected pen obtained more stable CGM profiles, with more time in range and less time spent in hyperglycaemia and hypoglycaemia.