Technology

Automated algorithms: A useful tool to optimise insulin pump therapy?

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Automated control of insulin delivery is perceived as an increasingly important development in helping optimise glycaemic control for people with type 1 diabetes using pump and sensor technology to manage their condition. After initial suspicion, the US Food and Drug Administration has approved low glucose suspend systems, paving the way for commercialisation of treat-to-target systems and, in due course, closed-loop systems. These are sophisticated and are likely to be expensive, even in comparison to current sensor-augmented pump therapies. Can insulin adjustment algorithms be harnessed in a simpler and more widely applicable way to help optimise existing insulin delivery systems?

The University of Melbourne diabetes team have previously reported the utility of the ALGOS algorithm in assisting people using sensor-augmented insulin pump therapy with adjustments to their insulin delivery settings (Jenkins et al, 2010), and other units have described similar algorithms. These all rely on the user to make the therapy adjustments themselves.

Now, in the article summarised alongside, the team from the University of Toronto have attempted to develop an automated system to adjust insulin pump settings, using an algorithm accessible through a web-based interface to adjust overnight basal insulin delivery on the basis of continuous glucose monitoring (CGM) data obtained during a controlled basal rate assessment. The basal insulin infusion settings were adjusted gradually on the basis of five assessments performed over a period of 2–8 weeks. Glycaemic outcomes were assessed in terms of the change in a 3-day CGM profile performed pre- and post-intervention. The change in overnight basal insulin delivery following these automated adjustments resulted in significantly less time spent in hypoglycaemia and an average HbA_{1c} reduction of 2 mmol/mol (0.2%) despite the short duration of the study. However, perhaps surprisingly in view of these changes, there was no improvement in glycaemic variability overnight.

Does this relatively modest benefit mean that such automated algorithms are unlikely to be a useful adjunct to optimising insulin delivery via a pump? It is worth noting that this was a pilot study and the adjustments made to the infusion rates following each assessment were deliberately conservative. Learning from these pilot data should allow more aggressive adjustments to be made, which would result in greater improvements in blood glucose variability in a shorter period of time. Furthermore, basal rate testing is dependent on a lack of interfering factors, such as active insulin from prior boluses and prolonged glycaemic excursions following fat- and carbohydrate-rich meals, alcohol and exercise. Repeated iterations of this assessment and adjustment process could minimise the impact of such interference, making this automated method of basal rate adjustment more reliable and effective than current systems of basal rate testing, which are usually done once every 3 months at best!

Current guidelines suggest sensor-augmented pump therapy has a limited role over and above stand-alone pump therapy (NICE, 2015), and most pump users are not that keen to add further invasive technology to their existing pump therapy. However, intermittent use of CGM for automated optimisation of insulin pump settings could prove particularly effective, so further development of such systems would be a welcome advance. ■

Jenkins AJ, Krishnamurthy B, Best JD et al (2010) Evaluation of an algorithm to guide patients with type 1 diabetes treated with continuous subcutaneous insulin infusion on how to respond to real-time continuous glucose levels: a randomized controlled trial. *Diabetes Care* **33**: 1242–8

NICE (2015) *Type 1 Diabetes in Adults: Diagnosis and Management* (NG17). NICE, London. Available at: www.nice.org.uk/guidance/ng17 (accessed 09.02.16)

Can J Diabetes

A semiautomated algorithm to adjust overnight basal insulin doses

Readability	✓✓✓✓
Applicability to practice	✓✓✓
WOW! Factor	✓✓✓✓

1 In this pilot study, the authors sought to determine whether a semiautomated, computerised algorithm to test and adjust insulin pump basal rates could improve overnight glucose variability and improve glycaemic control.

2 The study protocol comprised a 3-night baseline evaluation period; a 2–8-week intervention phase, in which the algorithm was used five times to interpret continuous glucose monitoring (CGM) data from an overnight fast to inform dose changes for subsequent nights; and a final 3-night assessment of glycaemic variability and HbA_{1c}.

3 A total of 20 people with T1D, suboptimal HbA_{1c} (mean, 60 mmol/mol [7.6%]) and evidence of at least two overnight glycaemic excursions of >1.7 mmol/L in the previous week were enrolled.

4 Following the intervention, glycaemic variability was unaffected, with neither the standard deviation nor interquartile range of CGM values significantly different from baseline.

5 However, the mean number of hypoglycaemic episodes per night decreased by 1.1 (P=0.01) and the total time spent in hypoglycaemia reduced from 100 to 42 minutes (P=0.07).

6 Furthermore, the mean HbA_{1c} fell by 3 mmol/mol (0.2%; P=0.03).

7 The authors conclude that further research into the efficacy of this algorithm and improvements to make the process more automated are warranted.

Orszag A, Falappa CM, Lovblom LE et al (2015) Evaluation of a clinical tool to test and adjust the programmed overnight basal profiles for insulin pump therapy: a pilot study. *Can J Diabetes* **39**: 364–72

Diabetes Technol Ther

Using CGM to assess glycaemic control in hospitalised people with T2D

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓✓
WOW! Factor	✓✓✓✓

1 These authors sought to test the ability of continuous glucose monitoring (CGM) to assess the effectiveness and safety of an algorithm-based basal–bolus insulin regimen in non-critically ill inpatients with T2D in the general ward.

2 They retrospectively compared capillary measurements with CGM data to assess blood glucose levels in 84 people receiving this regimen.

3 Overall, the regimen improved glycaemic control, with the number of measurements (CGM or capillary) in the range of 3.9–10.0 mmol/L increasing from around 70% on the first day of intervention to around 80% on the last day.

4 CGM and capillary measurements showed high consistency over the whole study period, with 99% of data comparisons in the clinically accurate or acceptable Clarke error grid zones A or B.

5 However, CGM was significantly better at identifying hyper- and hypoglycaemia, particularly at night, when there was a 15-fold increase in the number of hypoglycaemic episodes and a 12.5-old increase in hyperglycaemic episodes detected compared with capillary measurements.

6 The authors conclude that using CGM to assess glycaemic control in this setting is feasible; however, the retrospective analysis does not provide evidence to suggest whether it is superior to capillary measurements in informing treatment decisions.

Schaupp L, Donsa K, Neubauer KM et al (2015) Taking a closer look – continuous glucose monitoring in non-critically ill hospitalized patients with type 2 diabetes mellitus under basal–bolus insulin therapy. *Diabetes Technol Ther* **17**: 611–8

J Diabetes Sci Technol

Non-HbA_{1c} benefits of frequent CGM use

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! Factor	✓✓✓✓

1 These authors surveyed 64 frequent (almost daily usage or 3 weeks per month) users of the Dexcom G4 continuous glucose monitoring (CGM) system in terms of fear of hypoglycaemia and frequency of emergency medical treatment.

2 While 78% reported worrying about hypoglycaemia "most of the time" or frequently prior to CGM initiation, only one (2%) reported worrying frequently after 1 year of use. Although this was a 98% reduction, the difference was not significant).

3 They also reported an 86% reduction in the number of events requiring emergency treatment (P=0.0013), as well as a significant reduction in daily frequency of self-monitoring of blood glucose.

Chamberlain JJ, Dopita D, Gilgen E, Neuman A (2015) Impact of frequent and persistent use of continuous glucose monitoring (CGM) on hypoglycemia fear, frequency of emergency medical treatment, and SMBG frequency after one year. *J Diabetes Sci Technol* **10**: 383–8

Diabetologia

Paediatric pump use and HbA_{1c} in three national registries

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! Factor	✓✓✓

1 In this study, 2011–2012 data from three paediatric registries in Germany/Austria (n=26 198), the US (n=13 755) and the UK (n=14 457) were analysed to compared the rate of insulin pump use and HbA_{1c} levels in children and adolescents between these countries.

2 The rate of pump use was much lower in the UK (14%) than in Germany/Austria (41%; P<0.001) and the US (47%; P<0.001).

3 In contrast, mean HbA_{1c} was higher in the UK (74 mmol/mol [8.9%]) than in Germany/Austria (64 mmol/mol [8.0%]; P<0.001) and the US (68 mmol/mol [8.3]; P<0.001), despite similar participant characteristics and HbA_{1c} targets.

4 Pooled analysis of the data showed that pump use was associated with lower mean HbA_{1c} than multiple daily injections (64 mmol/mol [8.0%] vs 69 mmol/mol [8.5%]; P<0.001).

Sherr JL, Hermann JM, Campbell F et al (2016) Use of insulin pump therapy in children and adolescents with type 1 diabetes and its impact on metabolic control: comparison of results from three large, transatlantic paediatric registries. *Diabetologia* **59**: 87–91

Lancet Diabetes Endocrinol

Overnight use of an artificial pancreas

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! Factor	✓✓✓✓

1 In one of the longest studies of its type reported to date, 32 people with T1D were enrolled in a crossover study to compare overnight use of a closed-loop artificial pancreas (AP) system versus sensor-augmented pump therapy in free-living conditions.

2 After 8 weeks of each treatment, the mean percentage of time spent in the target glycaemic range of 3.9–10.0 mmol/L was greater in the AP group (66.7% vs 58.1%; P<0.001), via reductions in the time spent in both hyper- and hypoglycaemia.

3 Mean HbA_{1c} fell in both groups over the study period, but to a greater extent in the AP group (3.5 mmol/mol [0.3%] vs 1.8 mmol/mol [0.2%]; P=0.047).

4 No serious adverse events were reported.

5 The authors conclude that this AP is a safe and effective option for night-time use at home.

Kropff J, Del Favero S, Place J et al (2015) 2 month evening and night closed-loop glucose control in patients with type 1 diabetes under free-living conditions: a randomised crossover trial. *Lancet Diabetes Endocrinol* **3**: 939–47

> ***"The rate of pump use was much lower in the UK than in Germany/Austria and the US. In contrast, mean HbA_{1c} was higher in the UK than in Germany/Austria and the US, despite similar participant characteristics and HbA_{1c} targets."***