Safely finishing a half marathon by an adult with type 1 diabetes using a commercially available hybrid closed-loop system

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ABSTRACT
Glycemic targets are often difficult to achieve in people with type 1 diabetes, especially during exercise. Consequently, many people with type 1 diabetes avoid sports as a result of fear of hypoglycemia. Strenuous physical activity, such as a half marathon, imposes difficulties on people with type 1 diabetes. The first commercial hybrid closed-loop (HCL) system with the potential to facilitate better diabetes management during exercise has recently been marketed. So far, no data on HCL performance during strenuous exercise have been published. A woman with well-controlled type 1 diabetes participated in and safely finished a half marathon while undergoing HCL therapy. HCL could safely establish glycemic control without causing either hypo- or relevant hyperglycemia, and without the need for rescue carbohydrates while running. In the days after the half marathon, there was no change in glycemic control compared with the period before.

INTRODUCTION
Type 1 diabetes management presents an enormous challenge in everyday life. The first goal is to achieve and maintain good glycemic control while avoiding both hypo- and hyperglycemia. Special situations, such as exercise, are even more challenging. Hypo- and hyperglycemia are often hard to avoid during physical activity. As a result, many people with type 1 diabetes subsequently avoid doing sports. Treatment with an insulin pump in combination with a continuous glucose monitoring (CGM) system facilitates better diabetes management in general and especially during exercise, but is not a guarantee for avoidance of hypoglycemia during exercise. People with type 1 diabetes have to therefore consider insulin on board after the last bolus insulin dose, and have to adjust the basal rate for a certain length of time and to a certain extent when exercising. However, despite the difficulties, it has been shown that physical exercise, even extreme and professional sports, are possible for people with type 1 diabetes1.

High endurance sports competitions (e.g., a half marathon) present a big challenge for people with type 1 diabetes, as they have to maintain a stable glucose level over a long period of time. Any hypo- or hyperglycemia can affect performance in a negative way, and lead to the person requiring emergency care or even discontinuing the competition7.

In 2017, the world’s first commercially available hybrid closed-loop system (HCL) came to the market, and it has been available in Germany since September 2019. The HCL system comprises an insulin pump, a continuous glucose monitor and a control algorithm that automatically adjusts basal insulin delivery according to insulin requirements derived from the CGM signal enabling patients to individualize glycemic targets to a certain extent. To prevent hypoglycemia during exercise for instance, the glycemic target is set at 120 mg/dL and can be increased to 150 mg/dL for up to 12 h.

It has been shown that the HCL system was safe during moderate exercise and was able to prevent hypoglycemia5. We present the case of a woman with type 1 diabetes who was using the HCL system for 6 months before competing in a half marathon.

CASE REPORT
The woman was aged 43 years, and had been living with type 1 diabetes for 16 years at the time of competing. She runs regularly (training volume 40 km, competition preparation 50–60 km per week), but she had never participated in a competition due to fear of hypoglycemia and, in many cases, rebound hyperglycemia.
On 13 October 2019, she participated in the Cologne Marathon (category: half marathon; Figure 1). One hour before the competition, the temporary glycemic target was set to 150 mg/dL. Immediately before competition start, she ingested 3 g of carbohydrates and administered a 0.4 IU insulin bolus. One hour after the start, another 4 g of carbohydrates and 0.5 IU of insulin were administered. In both cases, carbohydrates were consumed to build energy reserves and not to treat (impending) hypoglycemia. During the marathon, a total of 90 g of carbohydrates were consumed. The woman successfully and safely completed the half marathon using the HCL system. The total running distance was 21.1 km, altitude 39 m, finishing time 2.17.13 h. The average pace was 6.27 min/km and average heart rate 156 b.p.m.

Data from the HCL system were uploaded to the Medtronic Carelink server, and subsequently analyzed using Python and Microsoft Excel. Detailed data on glycemic control, insulin dose and carbohydrate consumption before, during and after the competition are shown in Table 1. Average glucose during the marathon was 184 mg/dL (range 118–247 mg/dL). Detailed information on HCL therapy on the day before the marathon, as well as the day of the marathon, can be found in Figure 2.

The patient provided written informed consent to publish data of her case.

DISCUSSION

The woman’s diabetes was well-controlled. She easily fulfilled the current recommendations for glycemic control, as assessed by the CGM: she spent most of the time in the target range (90%), with only limited time below and above the target range (approximately 2% and 8%, respectively)4. So far, she never experienced a severe hypoglycemic episode. Her glycated hemoglobin was within the target range (6.2%/44 mmol/mol) and in line with CGM data.

Before and throughout the first hour of the competition, the glucose values were slightly above the target range (180 mg/dL). This hyperglycemic episode can be attributed to stress (adrenaline release), and could be resolved by a small bolus insulin dose. Throughout the competition, the glucose did not rise above 250 mg/dL. The HCL algorithm was able to manage the glucose fluctuations without any hypoglycemia (<70 mg/dL) during the whole competition and afterwards. The woman consumed a total of 90 g of carbohydrates (before the start, during and after the run) to maintain energy levels and not to treat (impending) hypoglycemia.

During the 2 days after the competition (14 and 15 October 2019), glucose remained stable between 70 and 180 mg/dL without subsequent hypo- or hyperglycemic events.

Participating in sports competitions, such as a half marathon, is also possible for people with type 1 diabetes on other established therapy regimens (e.g., basal–bolus therapy using a pen or an insulin pump with or without CGM), but with a great deal more effort, precautions and alertness1,5. Within the past couple of years, do-it-yourself artificial pancreas systems (DIYAPS) have become increasingly popular among people with type 1 diabetes, as commercial HCL systems were not yet available. In DIYAPS, commercially available insulin pumps and CGM systems are connected and remotely controlled by open-source algorithms running as smartphone apps to automate insulin delivery. As DIYAPS are not commercially regulated, but are completely self-made, they require – at least during the initialization phase – a great deal of

Figure 1 | Course of the half marathon, distance covered and performance parameters.
Table 1 | Glycemic control, insulin dose and carbohydrate consumption before (48 h/24 h), during (day of competition and competition itself) and after the competition (24 h/48 h)

|                          | 48 h before running competition | 24 h before running competition | Day of running competition | 24 h after running competition | 48 h after running competition | During running competition |
|--------------------------|---------------------------------|---------------------------------|---------------------------|-------------------------------|-------------------------------|----------------------------|
| Time in range (70–180 mg/dL) | 82.9%                          | 87.5%                          | 89.0%                      | 94.2%                         | 95.9%                         | 44.4%                      |
| Time below range (<54 mg/dL) | 0.4%                           | 0.8%                           | 0.0%                       | 0.0%                          | 0.2%                          | 0.0%                       |
| Time below range (<70 mg/dL) | 3.3%                           | 4.7%                           | 3.1%                       | 0.7%                          | 1.4%                          | 0.0%                       |
| Time above range (>180 mg/dL) | 13.9%                          | 7.8%                           | 7.9%                       | 5.1%                          | 2.7%                          | 55.6%                      |
| Time above range (>250 mg/dL) | 0.9%                           | 0.4%                           | 0.0%                       | 0.0%                          | 0.0%                          | 0.0%                       |
| Basal insulin dose (IU)    | 24.5                           | 12.7                           | 16.0                       | 14.8                          | 26.5                          | 1.4                        |
| Bolus insulin dose (IU)    | 61.6                           | 26.8                           | 35.6                       | 31.3                          | 74.6                          | 0.5                        |
| Carbohydrates (g)         | 574                            | 325                            | 333                        | 314                           | 520                           | 90                         |

Figure 2 | Graphic illustration of the hybrid closed-loop on the day before the half marathon (upper panel) and of the day of the half marathon (lower panel). The green area indicates the glucose target (70–180 mg/dL). The black line indicates the continuous glucose monitoring trace, the pink dots indicate the capillary glucose values. Carbohydrates (orange) as well as basal (pink) and bolus (violet) insulin are shown below the glucose trace. The marathon is highlighted in red.

experience, time and effort on the user’s part. As the algorithms are customized, they optimally fit individual requirements and can improve glycemic control6–8. The first data on successful participation in a sports competition (a half marathon) on DIYAPS are available9. Because of the ease of use and approval by regulators, many people with type 1 diabetes still prefer the commercially available insulin delivery systems, despite all their restraints (prespecified target ranges and type of algorithm, no individual selection of sensor and/or insulin pump). The present case report shows that competing and finishing a half marathon when using a commercially available HCL system is easily possible and feasible for people with type 1 diabetes.
**DISCLOSURE**

LvdB is a member of the advisory board of Medtronic and Abbott Diabetes Care, and received speaker honoraria from Astra Zeneca, Medtronic and Johnson & Johnson. JKM is a shareholder of decide Clinical Software Ltd., a member of the advisory board of Boehringer Ingelheim, Eli Lilly, Medtronic, Prediktor A/S, Roche Diabetes Care and Sanofi-Aventis, and received speaker honoraria from Abbott Diabetes Care, Astra Zeneca, Dexcom, Eli Lilly, Novo Nordisk A/S, Roche Diabetes Care, Servier and Takeda. HZ declares no conflict of interest.

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