A JOURNEY FROM BECOMING A DIABETES TYPE 1 PATIENT TO REALIZING A CE-MARKED ARTIFICIAL PANCREAS

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Introduction

This abstract unites 2 perspectives: from a patient and from an inventor/entrepreneur. When diagnosed with diabetes type 1, my quality of life drastically decreased. As a technologist I wanted to understand what was happening to me. And the more I started to understand the mechanisms of my disease (helped by wonderful medical doctors), the more I got convinced there should be a way to replace the natural blood glucose regulation of the pancreas with an artificial device. As I used to run a small firm designing and building custom machines, I decided to use my engineering & entrepreneurial skills to design & build an AP (starting in my garage).

Methods

From 2004 on, I built several AP iterations, starting with a laptop-controlled setup. As a patient I could experiment on myself, which facilitated quick iterations. This resulted in a CE-marked bihormonal (insulin & glucagon) fully closed-loop (FCL) automated AP. We assessed long-term performance & safety in a 1-year, multicentre (8 Dutch outpatient clinics), prospective, single-arm intervention trial in adults (18–75y) with type 1 diabetes who, as a baseline, had used flash or continuous glucose monitoring ≥ 3 months. Primary endpoint was time in range (TIR; glucose concentration 3.9–10.0 mmol/L) after 1 year, also Problem Areas in Diabetes (PAID) questionnaires quantified the patient burden [1]. Dutch Trial Register study ID: NL9578.

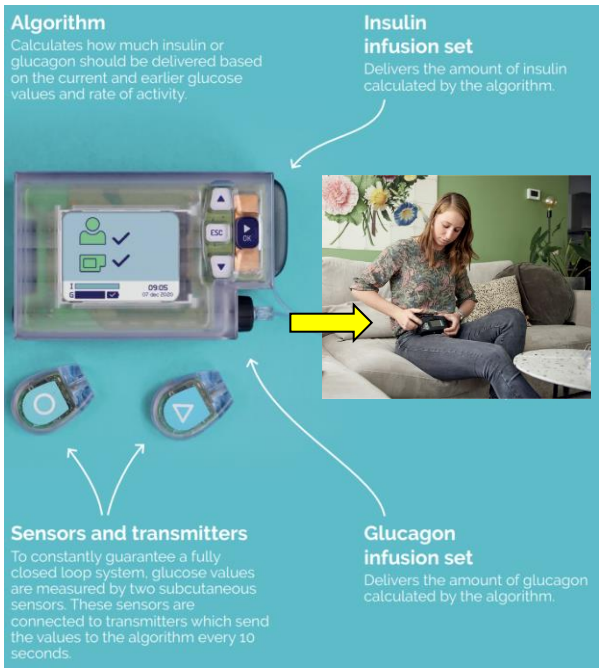

Figure 1: The belt clip-on artificial pancreas system.

Results

Time *in* Range (TIR, desired) improved from 55.5% to 80.3%, while Time *below* Range (TBR, to be avoided) was reduced from 3.2% to 1.5%. Time *above* Range (TAR, also to be avoided) was reduced from 41.3% to 18.2%. See also Fig. 2. PAID-scores strongly improved from 30.0 (IQR 18.8–41.3) at preintervention to 10.0 (IQR 3.8–21.3; p<0.0001) at 12 months.

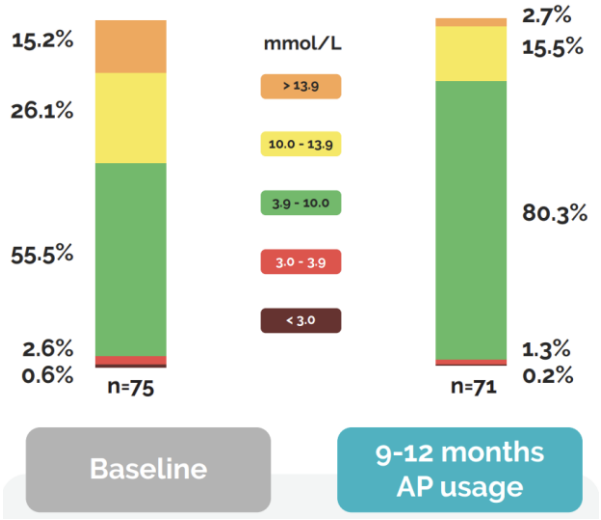

Figure 2: Left the ≥ 3 months baseline. Right the results observed after 9-12 months AP usage in daily life.

Discussion

This 1-year trial demonstrates that the tested bihormonal FCL system facilitated very good glycaemic control in a real-world daily-life setting and could be safely used by patients who completed 1 year of treatment. The FCL system offers a strong potential to relieve individuals with diabetes type 1 from constantly making treatment decisions and burdensome carbohydrate counting.

References

1. AC van Bon et al. Bihormonal fully closed-loop system for the treatment of type 1 diabetes: a real-world multicentre, prospective, single-arm trial in the Netherlands. Lancet Digit Health 2024; 6: e272–80. Published Online March 4, 2024. https://doi.org/10.1016/S2589-7500(24)00002-5

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