Diabetes and Metabolism 50 (2024) 101510

Contents lists available at ScienceDirect

Diabetes & Metabolism

journal homepage: www.elsevier.com/locate/diabet

Editorial

Hope, hype and present limitations of hybrid closed loop systems for persons with type 1 diabetes

Hybrid closed loop (HCL) systems represents an important step forward in insulin management for persons with type 1 diabetes (PwT1D). These solutions utilize an algorithm that automatically adjusts insulin delivery via an insulin pump based on real-time sensor glucose levels. The hope for PwT1D to reduce the daily burden of insulin therapy usually associated with fear of recurrent hypoglycemic episodes and diabetes complications associated with hyperglycemia, is an important driving factor for innovations. Despite improvements of insulin therapy during these last 20 years, the needs to anticipate blood glucose variations with many decisions to take according to meals or physical exercise, largely interfere with quality of life which may lead to diabetes distress. Before HCL, less than 25 % of PwT1D reached target CGM values using multiple daily injections or stand-alone insulin pumps [1,2]. All pivotal studies demonstrated safety and effectiveness of HCL systems in reducing hyperglycemia without increasing hypoglycemia in comparison to conventional insulin therapy, which led to several recommendations for use in clinical practice [3,4]. Real life observations extended these results with an increase by 14 percentage points in time in range (TIR, 3.9–10 mmol/L) of glucose levels after 360 days with a mean decrease of 0.7 % in HbA1C levels [5]. AID is also expected to be an answer to the negative emotions that arise from living with and managing diabetes. Several HCL systems are commercially available, and this field is now very competitive. This includes the 780G- smartguard G4® advanced hybrid closed loop (AHCL) system (Medtronic, Northridge, California), the Tandem T:slim X2™ pump with Control-IQ® system (Tandem Inc., San Diego, California), the CamAPS FX™ interoperable app (CamDiab, Cambridge, UK) with Ypsopump mylife loop®, the Omnipod 5™ solution (Insulet, Acton, MA) and the DBLG1® interoperable algorithm with the Kaleido™ pump (Diabeloop, Grenoble France). Additional systems are in development with pivotal trials under way and several do-it-yourself (DIY) artificial pancreas systems with open-source algorithms are also available.

Despite both hope and hype with automated insulin delivery (AID), real life observations showed the lack of incremental improvements of efficacy in the long-term, especially in those subjects with poor results initially, who still need additional supports to maximize benefits. Normalization of blood glucose levels remains linked to three broad issues. The first, is efficacy rates for glucose outcomes. Since all HCL systems still require user-initiated prandial insulin boluses, results may remain suboptimal in those individuals with difficulties in precise evaluation or inobservance in carbohydrate announcements. Second, closed loop systems may increase on some occasions, or at least do not decrease, diabetes burden. The necessity to wear permanently both an insulin pump and a glucose sensor to optimize the automode delivery, skin reactions, occurrence of either low or high blood glucose alerts, system alarms, tubing issues, sick day management rules, are situations that still require full personal involvement to get optimal disease control. The dream to forget the constraints of everyday life with diabetes is therefore not yet achieved. Third, the personal smartphone can be another challenge for PwT1D. It appears to be a key element to serve as a link between the sensor and the pump, and in some cases can also harbor the algorithm and the pump application for bolusing capacities. Transmission of data to health care professionals either through a dedicated solution or to an integrative platform may also require a compatible smartphone. It is sometimes awkward to face obstacles to AID technology either because an obsolete mobile device or if the system i.e. IOS vs Android is incompatible with the required applications. Moreover, updating the mobile system is often not recommended to maintain compatibility with sensor, pump and/or algorithm apps. The choice for manufacturers not to develop internal communicating solutions is understandable but may lead to a digital divide with unequal access to care, security, or performance of insulin administration.

In conclusions, access to AID in real life with commercially available systems is a real breakthrough in insulin management, allowing many users to improve diabetes control. To go beyond the present limitations and to improve both efficacy and safety, it is expected that most systems will progress toward full closed loop without meal announcements with new algorithms and faster insulin formulae. Technical innovations with implantable sensors and/or implantable pumps will also further improve quality of life with an expected reduction of diabetes burden. The AID landscape is developing rapidly. This requires vigilance from healthcare professionals with the help of patients, on the various steps to take for success.

CRediT authorship contribution statement

Charles Thivolet: Conceptualization, Writing – original draft, Writing – review & editing.

Declaration of competing interest

CT reports personal fees from Abbott Diabetes Care, Glooko, Lilly, Novo-Nordisk, Medtronic, and Sanofi and is an advisory board member for Insulet and Medtronic.

https://doi.org/10.1016/j.diabet.2024.101510
Received 6 January 2024; Accepted 14 January 2024
Available online 15 January 2024

References

[1] El Sayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. Glycemic targets: standards of care in diabetes—2023. Diabetes Care 2023;46 (Supplement 1):S97–110.
[2] Renard E, Ikegami H, Daher Vianna AG, Pozzilli P, Brette S, Bosnyk Z, et al. The SAGE study: global observational analysis of glycaemic control, hypoglycaemia and diabetes management in T1DM. Diabetes Metab Res Rev 2021;37:e3430. https://doi.org/10.1002/dmrr.3430.
[3] Tubiana-Rufi N, Schaepelynck P, Franc S, Chaillous L, Joubert M, Renard E, et al. Practical implementation of automated closed-loop insulin delivery: a French position statement. Diabetes Metab 2021;47:101206. https://doi.org/10.1016/j.diabet.2020.10.004.
[4] Phillip M, Nimri R, Bergenstal RM, Barnard-Kelly K, Danne T, Hovorka R, et al. Consensus recommendations for the use of automated insulin delivery technologies in clinical practice. Endocr Rev 2023;44:254–80.
[5] Henry Z, Villar Fimbel S, Bendelac N, Perge K, Thivolet C. Beneficial effects of automated insulin delivery over one-year follow-up in real life for youths and adults with type 1 diabetes irrespective of patient characteristics. Diabetes Obes Metab 2023. https://doi.org/10.1111/dom.15344.

Charles Thivolet
Center for Diabetes DIAB-eCARE, Hospices Civils de Lyon, 64 Avenue Rockefeller, Lyon 69008, France
E-mail address: Charles.thivolet@chu-lyon.fr.