



COMMENT ON HAIDAR ET AL.

A Randomized Crossover Trial to Compare Automated Insulin Delivery (the Artificial Pancreas) With Carbohydrate Counting or Simplified Qualitative Meal-Size Estimation in Type 1 Diabetes. *Diabetes Care* 2023;46:1372–1378

Diabetes Care 2023;46:e207–e208 | <https://doi.org/10.2337/dc23-1243>

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Haidar et al. (1) report a crossover trial that compares quantitative carbohydrate (CHO) counting with simplified qualitative meal-size estimation (QMSE) in 30 adult patients with type 1 diabetes (T1D) who used an automated insulin delivery system for 3 weeks. They found that the mean (SD) time in the 3.9–10.0 mmol/L range (TIR) was 74.1% (10.0%) with CHO counting and 70.5% (11.2%) with QMSE. Although the difference (–3.6% [8.3%]) did not confirm noninferiority (predefined margin of 4%), the authors concluded that the TIR achieved with QMSE was still satisfactory and suggested that QMSE is appropriate in a subset of patients.

We randomly selected a 20% sample within the commercial database built from all the patients with type 1 diabetes equipped with DBLG1 (Diabeloop) (2). This closed-loop system combined a Roche Insight pump, a Dexcom G6 sensor, and a dedicated smartphone. The algorithm allowed the patient to enter meals in a semiquantitative fashion (small, medium, and large), according to an assessment performed by a dietitian at initiation of the system, for each of the three daily meals (3).

To discriminate between the two types of meal declarations, we assumed that when the CHO count was identical to the predefined average meal value, the patient had used the semiquantitative method, and the corresponding meals were assigned to the QMSE group. The other meals were assigned to the CHO counting group. The different glucose metrics were extracted in the postprandial period, defined as [t meal; t meal + 4 h], provided that there was no other meal during this 4-h period or during the previous 4 h. Because patients sometimes used both methods of meal declaration on a given day, we focused on days when all meals were declared with a single method.

A total of 1,958 patients from seven Western European countries were included (mean [SD] age 45.4 [14.7] years). Overall, 299,387 meals were declared with the CHO counting method and 315,432 with the QMSE method. During the postprandial period, mean (SD) TIR was 63.0% (30.7) in the CHO counting group and 62.6% (30.8) in the QMSE group ($P < 0.05$), mean (SD) glucose was 166.4 (42.9) vs. 166.9 (43.4) mg/dL, and significant but not clinically relevant differences were observed

in time in low glucose (<70 mg/dL) and time in very low glucose (<54 mg/dL). We then analyzed days with the same declaration mode. From a total of 81,173 days with the CHO counting method and 85,554 days with the QMSE method, we observed a mean (SD) TIR of 70.7% (16.7%) vs. 69.7% (17.3%) ($P < 0.01$), a time in low glucose (<70 mg/dL) of 1.2% (2.4%) vs. 1.2% (2.4%) (not significant), and a mean (SD) glucose of 157.6 (24.5) vs. 159.2 (25.5) mg/dL ($P < 0.01$).

Our interpretation is that, despite a slight deterioration in TIR when using QMSE, to a lesser extent (1%) than the one observed by Haidar et al. (1), the overall glucose metrics remained similar without clinically meaningful differences. This qualitative method may reduce diabetes burden and can be proposed to patients reluctant to perform CHO counting. This has implications for patient management and education on closed-loop therapy.

Funding. The study was funded by Diabeloop SA.

Duality of Interest. P.Y.B. is chief medical officer for Diabeloop SA, S.L. served on an advisory board panel for Diabeloop SA, H.R.-U. and A.A.

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are employees of Diabeloop SA, and G.C. owns shares in Diabeloop SA. No other potential conflicts of interest relevant to this article were reported.

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