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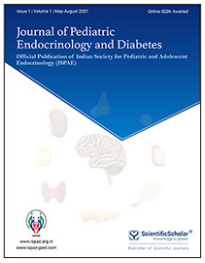

Editorial Commentary

Hybrid closed-loop insulin pump system: Creating real-world evidence on handling high-protein and high-fat meals

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Management of type 1 diabetes mellitus (T1D) has seen significant technological advances in the past few years in the form of smaller and more accurate continuous glucose monitors and semi-automatic or hybrid closed-loop (HCL) insulin pump systems. These newer technologies have demonstrated an improvement in glycemic control compared to insulin regimens using multiple daily injections and standard/manual-mode insulin pumps. However, much of the early data comes from the use of these technologies under controlled settings of research protocols. The outcomes of real-world use of these technologies are only beginning to be assessed. Several challenges exist in the seamless use of these advanced technologies on a regular basis including the ability to stay in auto-mode consistently; the effect of different meal compositions such as those with high-protein and high-fat (HPHF) content or ones with variable glycemic index; various real-life situations such as physical activity, sports, menstrual cycles, and episodes of intercurrent illness. This study by Lim *et al.* compares the efficacy of an automated HCL system (Medtronic MiniMed™ 670G) in managing glucose excursions after consuming a standardized HPHF meal to that with the use of manual mode standard insulin pump therapy.[1]

With the widespread use of the Western diet, there has been an increase in the consumption of foods that are rich in processed carbohydrates and meats, saturated fats, high-fat dairy products, often in the form of pre-packaged meals and fast foods. Frequent and long-term consumption of these foods has significant negative effects on cardiovascular health.[2] In a patient with T1D, the consumption of these foods offers the additional challenge of late and prolonged glycemic excursions that can last up to 10–12 hours after consumption of an HPHF meal. Various techniques have been developed to minimize these glycemic excursions albeit with mixed success. These have included square-wave or dual-wave bolus in a standard insulin pump, giving an additional insulin bolus after the initial bolus, or adjusting insulin dosing based on fat–protein counting method.[3,4] Of course, all these strategies have to be balanced against the risk of hypoglycemia.

To date, there is minimal literature on the efficacy of the HCL system in managing postprandial glucose excursions after HPHF meals. Hence the study by Lim *et al.* is a significant addition to this field. This clinical study uses a cross-over model to compare the HCL system and manual mode insulin pump for efficacy in addressing glycemic excursion up to 7 h after two standardized

HPHF meal types (pasta and pizza). The primary outcome was the net incremental area under glucose × time curve compared to the pre-meal baseline. While a total of 61 meals were ingested by 10 study participants over the course of the study, only 38 meals (by 7 participants) were included in the final analysis. The others were excluded for a variety of reasons including protocol deviations, hypoglycemic events, and technical issues. While using manual mode, three of the seven participants used the dual-wave bolus. Hypoglycemic events occurred similarly between the two groups and there was no severe hypoglycemia. The authors did not find any statistical difference between the two groups for net incremental and absolute incremental area under curve, time in range, or peak sensor glucose levels. In addition, when the families were interviewed for their lived experiences of manual versus auto-mode 1 week after the study, six of the seven families reported subjectively that for a HPHF meal auto-mode was overall better in managing glucose levels and it provided them a better sense of security and reassurance.

The final reported numbers were rather small, and the study was not adequately powered to detect small differences between the two groups. While the authors intended to evaluate patients under free-living conditions, they did not do an intention-to-treat analysis and thus excluding patients or meals for protocol violations could have undone the randomization efforts. The study participants were using auto-mode for about 8 months before the study and hence may have had inherent preference/bias toward this system or a sense of discomfort at using the manual system, especially the square-wave meal bolus feature.

There have been several newer HCL systems that are now commercially available since the one used in the study that have further modified and enhanced algorithms and these may be better at addressing postprandial BG excursions after HPHF meal but that remains yet to be studied further.

In summary, this study serves as a pilot study for investigation in the field of HCL systems for the management of glycemic excursions after HPHF-containing meals. Further studies with newer HCL systems, involving a larger number of subjects/meals and longer duration of follow-up, up to 12 h after the meal, are needed to further assess their efficacy. These data will be key to further guide the development of improved HCL algorithms in the near future to address not only the consumption of a variety of meal types but also other daily life activities that influence glycemic excursions with the global aim of providing improved and safe glycemic management in patients with T1D.

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