COMMENT ON LITTLE ET AL.

Recovery of Hypoglycemia Awareness in Long-standing Type 1 Diabetes: A Multicenter 2 × 2 Factorial Randomized Controlled Trial Comparing Insulin Pump With Multiple Daily Injections and Continuous With Conventional Glucose Self-monitoring (HypoCOMPaSS). Diabetes Care 2014;37:2114–2122

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I appreciate the intent of the study by Little et al. (1) to determine whether hypoglycemia awareness can be improved and severe hypoglycemia prevented through rigorous avoidance of biochemical hypoglycemia. However, I am troubled by the methodology and conclusions.

The authors concluded that impaired awareness of hypoglycemia can be improved and recurrent severe hypoglycemia prevented in adults with long-standing type 1 diabetes through strategies deliverable in routine clinical practice. The care provided in the protocol could not be termed "routine" as none of the four study arms received conventional treatment. All arms received extensive interventions that included weekly contact, monthly follow-up visits, and use of a bolus calculator to determine the insulin dose, whether or not an insulin pump was used. The intensive follow-up and required bolus calculator use prevents these results from being generalizable outside the study confines.

There was an absolute focus in providing similar education to all cohorts, a useful approach in trials comparing pharmacotherapies. However, device and glucose management education should differ for different devices. There was no comment about the continuous glucose monitor (CGM) and pump training provided and whether subjects were instructed to use the rate of change data, trending information, or alert settings or whether insulin dosing adjustments were recommended in response to glucose patterns. Similarly, it is unknown if pump infusion rates adjustments based on glucose patterns were recommended or if patients were instructed to reduce or suspend insulin delivery based on impending or actual hypoglycemia. The lack of glycemic benefit observed in the subjects who used pumps and CGM may be related to device features, device performance, or the subjects' or clinicians' underutilization of information.

One of the most important issues impacting the study results is that subjects in the CGM arms had very low rates of adherence to CGM. Sensors were used a median of 57% of the time; only 17 of the 42 individuals achieved 80% sensor usage threshold, which is often considered the frequency required for meaningful benefit. This poor CGM adherence rate markedly differs from my experience (and others') using different devices (2). In fact, these results are inconsistent with the majority of literature in this field, excepting that if one does not wear the CGM device, it does not seem to have benefit! Further, in clinical practice we rarely see the problem with sensor discomfort and irritation that was described as fairly common in this study.

Prior studies demonstrate that patients' trust in their CGM device is a critical component to sustained use (3). As the consistency of use of the CGM device is a known key determinant for clinical benefit, the lack of benefit with the limited wear time observed is not surprising (4). It is unclear why CGM wear time of 50% was considered a priori as high CGM use. A study to reverse hypoglycemia unawareness using intensive education on hypoglycemia avoidance, comparing outcomes with or without the use of technology, should ensure proper device training and require stricter requirements for device utilization.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

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