The InPen™ System Identifies Missed Correction Dosing Opportunities- Impact on Real-World Glycemia and Potential for Actionable Reminders

Robert Vigersky, MD; Glen Im, MS; Madison Smith, PhD, RN, CDCES; Janice MacLeod, MA, RD, CDCES, FADCES
Medtronic, Northridge, California, USA

1. INTRODUCTION

The InPen™ Smart Insulin Pen (SIP) can track active insulin, enabling opportunities to safely calculate correction doses after boluses. Analysis of preliminary real-world InPen data has shown that when an initial sensor glucose (SG) alert occurs, less than half of alerts are actionable (i.e., allow for a correction dose that can be safely delivered). Alerts without an associated action may, in turn, drive alert fatigue and risk of insulin stacking.

2. AIM

This study identifies missed correction opportunities and investigates the relationship of the duration of missed correction dose opportunities to glycemia in adult and pediatric users of InPen with CGM (InPen+CGM) who have type 1 or type 2 diabetes.

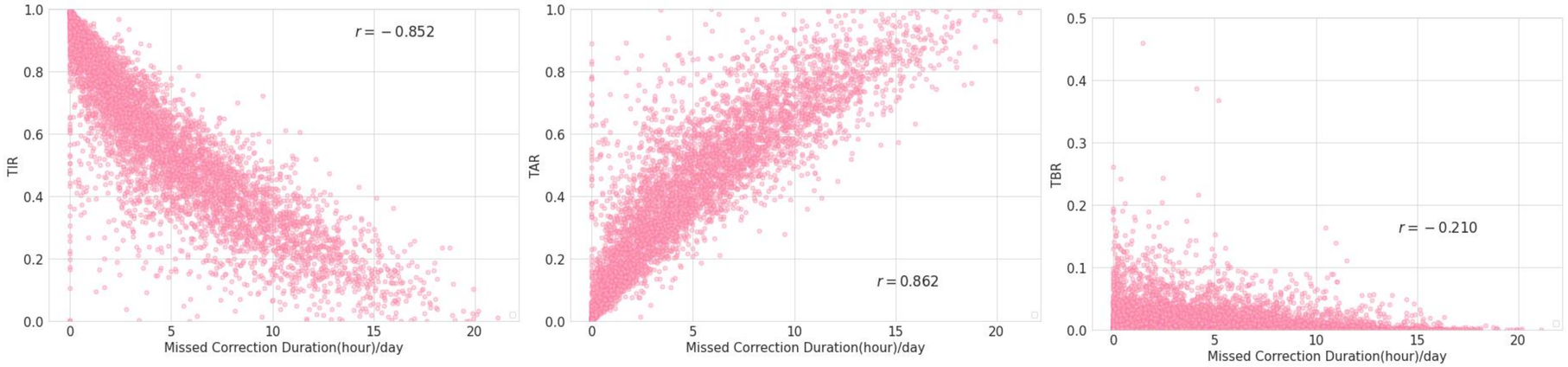
3. METHODS

A retrospective cohort analysis used deidentified SG data from N=5,153 individuals during the latest 14 days of use 30-to-59 days after starting InPen January 2020-December 2021. Missed correction opportunities were defined as elevated SGs in which dose recommendations were no less than each user's correction threshold (180 mg/dL–target glucose/Insulin Sensitivity Factor). Pearson's r was used to evaluate correlation between variables and a *p-value <0.05 indicated* significant difference.

4. RESULTS

Users in the analysis averaged 5.3±4.1 hours of missed correction opportunities per day. The durations of the daily missed correction opportunities showed strong negative correlation with time in range (TIR, r=-0.85, *p<0.0001*) and strong positive correlation with time above range (TAR, r=0.86, *p<0.0001*) as well as with glucose management indicator (GMI, r=0.85, *p<0.0001*), but only weak negative correlation with time below range (TBR, r=-0.21, *p<0.0001*).

Figure 1. Correlation of Duration of Missed Correction Opportunities (Hours) to TIR, TAR, and TBR (%)



5. CONCLUSIONS

- Combined insulin dosing and SG data from real-world InPen+CGM users demonstrate a high number/duration of missed correction dose opportunities negatively impacting glycemia. This study unveils the capability of a SIP, when paired with CGM, to determine the need for timely correction doses. This, in turn, might indicate its possibility for giving actionable alerts only when in need.
- Given its weak negative correlation with TBR, reducing missed correction opportunities should not lead to significant increase in TBR.
- While SG alerts are important in detecting missed and miscalculated insulin dose events, over half are not actionable for dosing. Future research is needed to minimize non-actionable SG alerts combined with dosing guidance.

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