

The artificial pancreas ski camp: real-time monitoring and glucose control in youth with type 1 diabetes

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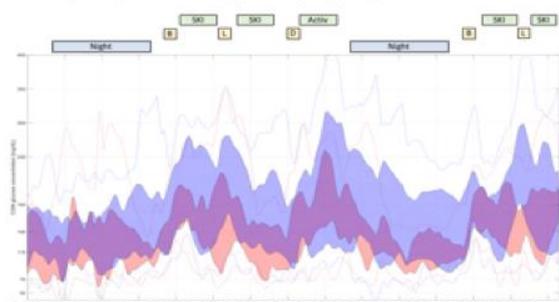
Background and aims: In Type 1 Diabetes (T1D) prolonged moderate/intense physical activity (PA) may result in hypoglycemia and is generally hard to manage. Winter-sport activities add external factors, e.g. cold and altitude, which make them most challenging to patients, health-care providers, and diabetes technologies such as insulin pumps, continuous glucose monitoring (CGM), and the emerging Artificial Pancreas (AP) systems. While AP has been shown to improve glycemic control during and after exercise, AP systems have been tested during structured winter-sport studies only once - in our recently reported 2016 skiing camp trial. Building on this previous experience, we now present the testing of a new system - the Tandem X2 with Control IQ Technology - in a series of ski studies in the winter of 2018. The premise of these studies is that the challenges of skiing provide great environment to test the AP in extreme real-life conditions.

Materials and methods: A sequence of three winter camp trials at ski resorts in Virginia, Colorado and California enrolled N=48 children, ages 6-18, N=24, N=12, and N=12 at each of these sites, respectively. All participants are randomized to the Tandem X2 Insulin Pump with Control IQ Technology (AP group) vs. sensor augmented pump (SAP control group). This new system consists of a G6 CGM (Dexcom, Inc.) and an X2 pump with embedded Control IQ algorithm (Tandem Inc. and Typezero, Inc.), which is identical to the AP algorithm originally developed at the University of Virginia (UVA) and tested in a number of UVA studies. The AP and SAP groups were matched by age and HbA1c. The studies continued for 2 days and on each day the participants had 3 hours of morning and 3 hours of afternoon skiing with instructors. For added safety, all subjects (AP and SAP) were monitored by a physician 24/7 using Dexcom Share G5 CGM. At the time of this writing, the results from the first ski camp in Virginia are ready and presented here; the study in Colorado is completed, and the study in California is scheduled for April 8-10.

Results: The participants in the first camp were teenagers ages 13-18 (14 males). Compared to SAP, glycemic control was significantly better in the AP group, including: percent time between 3.9-10mmol/L of 55.4% (SAP) vs 73.1% (AP), $p=0.032$; percent above 10mmol/L and above 13.9mmol/L of 41% (SAP) vs 21.6% (AP), $p=0.026$ and 14.8% (SAP) vs 5.6% (AP), $p=0.02$; mean blood glucose of 9.4mmol/L (SAP) vs 7.8mmol/L (AP), $p=0.03$, and no increase in hypoglycemic events on AP. Hyperglycemia post meals was reduced on AP, thus reducing glucose variability (Figure 1).

Conclusion: During its first winter/ski camp, the new X2 Insulin Pump with embedded Control IQ AP algorithm improved significantly the glycemic control in children with T1D, without adverse events, and with overwhelmingly positive patient feedback.

Figure 1: interquartile plots: Sensor-augmented pump (blue); Tandem X2 with Control IQ (purple)



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