Insulin Infusion Pump Dose Precision Performance at Different Delivery Phases
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BACKGROUND
- Insulin pump manufacturers specify ±5% accuracy according to international standard EN60601-2-24. The standard calls for a 24-hour stabilization period followed by the measurement and averaged calculation of 100 consecutive basal doses.
- However, the ±5% accuracy calculation over 100 doses provides limited information on the significance of delivery precision during the time of use of the pump by the patient. The delivery performance of a pump can be represented in terms of accuracy and precision as shown in Figure 1.
- Due to the recommended usage limit of infusion sets, cartridges, and patch pumps, insulin pump sessions are typically re-started every 2-3 days. Therefore, understanding pump delivery performance over the first 24-hour of pump therapy may be instrumental in achieving a reliable insulin delivery regimen and thereby minimizing glycemic excursions.
- As we move towards closed-loop control, the need for insulin infusion pumps to be characterized in terms of precision may become increasingly important.

OBJECTIVE
- To compare the dose precision performance of the durable Animas Vibe™ and Tandem t:slim pumps and the patch Insulet OmniPod® pump over three delivery phases in a 20 hour test duration: 1. Start-up (0th-2nd hour), Transition-to-Stability (2nd-4th hour), and Stabilization (14th-20th hour).

SETUP AND METHODS
- Pumps were tested using a time-stamped micro-gravimetric system (Sartorius ME-5 microbalance with a load limit of 5 grams and resolution of 0.000001 grams). Pump settings were programmed according to manufacturer’s instructions.
- Dose precision was characterized at 0.5 Uhr basal rate. For each pump manufacturer, data were compared from 20 hour test runs (n=30 sets per pump brand): 5 runs each on 6 different durable pumps and 2 runs each on 15 patch pumps.
- The Animas Vibe pumps delivered in smaller dose increments (0.02SU at 3 minute intervals) more frequently than the Tandem t:slim (approximately 0.042U at 5 minute intervals) and the Insulet OmniPod (0.05SU at 6 minute intervals).
- The relative percent error was calculated for each dose over the defined delivery phases. Test-time-dependent polat plots with concentric circles representing constant error levels (i.e. ±10% through ±150%) were created using the dose percent error for each pump manufacturer. For each single point, the distance from the origin represents the magnitude of the error.
- Errors less than -100% may represent delivery of an air bubble or the system retracting insulin. Errors greater than +100% represent over dosing.

RESULTS

Figure 2. Setup of the durable (A) and disposable (B) pumps.

Figure 3. Polar plots of single dose deliveries for (A1, B1, C1) Animas Vibe, (A2, B2, C2) Tandem t:slim and (A3, B3, C3) Insulet OmniPod for the start-up, transition-to-stability and stabilization delivery phases. The Animas Vibe pump delivered with statistically significant higher precision even when delivering a smaller dose (i.e. 0.025U) than the Tandem t:slim (0.042U) and Insulet OmniPod (0.05U).

Start-up Phase (0th through 2nd hour)

Transition-to-Stability Phase (2nd through 4th hour)

Stabilization Phase (14th through 20th hour)

CONCLUSIONS
- The Animas Vibe demonstrated statistically better precision per dose than the Tandem t:slim and Insulet OmniPod across all delivery stages.
- The Tandem t:slim and Insulet OmniPod demonstrated significantly higher dose variability than the Animas Vibe.
- The Animas Vibe was superior at reaching delivery stability after 2 hours from delivery start-up and significantly increased delivery precision through the remaining of the test duration.
- As we anticipate the emergence of closed-loop systems and newer insulins with improved pharmacokinetics, increased dose precision may be critical.
- Further research on the critical relevance of these findings is warranted.

Animas vs Tandem, Insulet < P < 0.001 across all delivery phases at ±5%, ±10%, and ±15% thresholds.

Presented at the 8th International Conference on Advanced Technologies & Treatments for Diabetes (ATT21), Milan, Italy, February 3rd – 8th, 2016