Real World Experience with Bigfoot Unity: A Twelve-Month Retrospective Analysis

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Background

- The Bigfoot Unity® Diabetes Management System is a smart pen cap system that incorporates data from the Abbott FreeStyle Libre 2 Sensor, real-time alerts, and clinician-directed dose recommendations.
- The objective was to analyze real world 12-month data for a large MDI cohort using the System.

Methods

- De-identified data and a prespecified analysis plan was reviewed by a central institutional review board (IRB) and deemed exempt from IRB oversight.
- A retrospective analysis for a 12-month System use cohort (N=303) was conducted. Outcomes are also reported for 3- (0-90 days) and 6-month (91-180 days) periods.
- Selection criteria were 1) persons with diabetes completing training and initiating System use (Day 0), 2) at least 45 use-days and >45 CGM or BGM readings within the 12-month period (276-365 days) to represent real-world use and avoid bias towards highest System users, and 3) baseline A1C from clinic records, prior to starting the System (-120 to 0 days).
- Post-market surveillance data was reviewed for FDA medical device reports for malfunctions or serious adverse events occurring in a broader safety cohort (N=402) who also met minimum requirements (baseline A1C and ≥45 use-days and ≥45 glucose readings) in the 90-day period ending at day 90 or 180.
- Due to the retrospective nature, sample size was not based on statistical power.
- Given the limitation of having only baseline A1Cs, estimated A1C (GMI) was used as a proxy for A1C to perform statistical comparisons of A1C data at baseline and GMI in the 12-month period of use. Differences between median baseline A1C and the median estimated A1C (GMI) in the 12-month period was tested with the Wilcoxon signed rank test; a P-value <0.05 was considered statistically significant.

Results

- Mean age was 63.7 years and 86.5% had T2D (Table 1).
- A small number (4.9%) were not new to taking insulin and a larger number (62.3%) were new to taking correction insulin (Table 1).
- Using estimated A1C (GMI), improvement from baseline A1C was 1.3 ± 1.7% at 12 months and statistically significant (Table 2 & Figure 1; p<0.0001). Similar improvement was observed at 3, 6 and 12 months (Figure 1).
- TIR was 61.3 ± 22.1% and 46.3 ± 19.0% for T2D and T1D, respectively; total time below range was 1.2 ± 1.7% and 2.9 ± 3.0%, respectively (Table 2).
- During the 12-month period, Bigfoot Unity was used, on average, for 95.5% of days (Table 2).
- Doses for long-acting insulin were recorded on 72.7% of days; 2 or more rapid-acting insulin doses were recorded on 65.8% of days (Table 2).
- Figure 2 shows change in glycemic control within subgroups.
- Within the safety cohort (N=402), using post-market surveillance data of medical device reports to FDA, 5 severe hypoglycemia events, 1 serious hypoglycemia, 1 DKA and 1 other severe hyperglycemic event occurred and were not related to System malfunction; 4 malfunctions occurred without a reported adverse event.

Table 1: Demographics

	Total (N=303)
Age, mean (SD)	63.7 (12.2)
Type 2 diabetes, n (%)	262 (86.5)
New to Insulin, n (%)[a]	14 (4.9)
New to CGM, n (%)[b]	92 (31.1)
New to corrections, n (%)[c]	147 (62.3)
Baseline A1C, mean (SD)	8.8 (1.8)

[a]16 missing new to insulin status; [b]7 missing CGM status; [c]67 missing new to corrections status.

Table 2: Sensor and Use Parameters in 12-Month Period

	Total (N=303)	T2D (N=262)	T1D (N=41)
Change of estimated A1C (GMI) from baseline A1C (%), mean (SD)	-1.3 (1.7)[a]	-1.4 (1.7)[a]	- 0.8 (1.8)[a]
Glucose Management Indicator (GMI), mean (SD)	7.5 (0.9)	7.4 (0.9)	8.0 (1.0)
Average glucose (mg/dL), mean (SD)	175.8 (38.1)	172.7 (36.6)	195.7 (41.4)
Coefficient of variation, mean (SD)	31.9 (6.7)	31.0 (6.4)	37.4 (5.6)
Percent Sensor time in ranges:			
70-180 mg/dL, mean (SD)	59.3 (22.3)	61.3 (22.1)	46.3 (19.0)
>180 mg/dL, mean (SD)	39.3 (22.5)	37.4 (22.4)	50.8 (20.0)
>250 mg/dL, mean (SD)	14.4 (15.7)	12.8 (14.8)	24.4 (17.7)
<70 mg/dL, mean (SD)	1.5 (2.0)	1.2 (1.7)	2.9 (3.0)
<54 mg/dL, mean (SD)	0.2 (0.4)	0.1 (0.2)	0.5 (1.0)
Percent of days of System use, mean (SD)[b]	95.5 (9.3)	95.1 (9.7)	97.7 (5.6)
Percent of days with a long-acting insulin dose, mean (SD)[b]	72.7 (29.6)	71.4 (30.2)	80.5 (23.9)
Percent of days with ≥2 rapid-acting insulin dose, mean (SD)[b]	65.8 (30.4)	64.6 (30.8)	73.8 (26.9)
Glucose readings/day, mean (SD)	65.2 (21.1)	64.8 (21.0)	67.9 (22.0)

[a]Indicates statistically significant difference of 12-month period result from baseline (p < 0.0001).
[b]Parameter is expressed as a percentage, using the 90-day analysis period as the denominator.

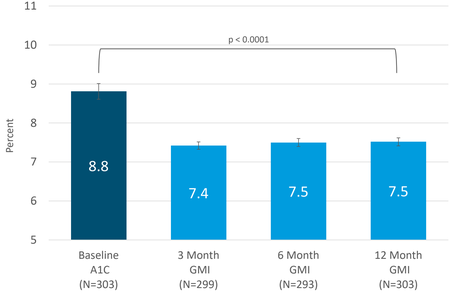

Figure 1: GMI compared with baseline A1C. Mean and 95% CI are shown for baseline A1C and GMI in the 3-, 6- and 12-month analysis periods. The baseline A1C was compared to 12-month GMI using the Wilcoxon signed rank test.

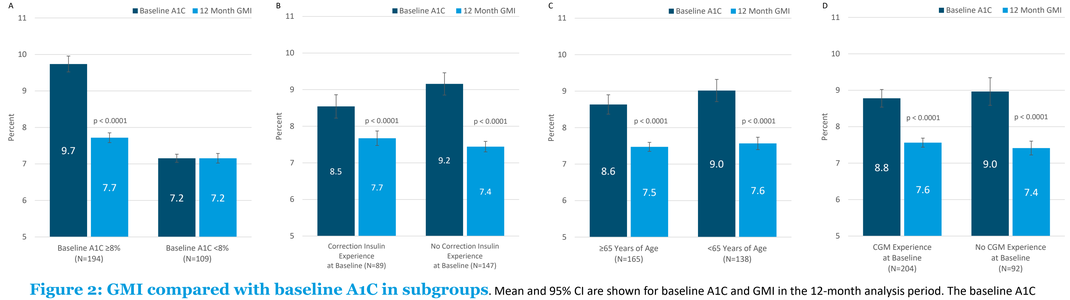

Figure 2: GMI compared with baseline A1C in subgroups. Mean and 95% CI are shown for baseline A1C and GMI in the 12-month analysis period. The baseline A1C was compared to 12-month GMI using the Wilcoxon signed rank test. Baseline status was not available for all 303 people. The N below each bar reflects the available data.

Conclusions

- Using GMI as a proxy of A1C, ~1.3% improvement was observed at 3 months and sustained through 12 months.
- Considering the mean older age, results demonstrate close adherence to established glycemic targets.[1-3]
- Magnitude of improvement was larger (2%) in a subset with suboptimal glycemic control (baseline A1C ≥8%).
- Those new to taking correction insulin also had larger improvement compared to those who had experience (1.7% vs. 0.9%). The fact that over 60% had not used correction insulin before supports the conclusion that the System may be a useful tool to overcome a common barrier of implementing insulin intensification;[4] we have demonstrated previously that when the system displays an HCP-recommended correction dose, on average, 2-hour postprandial glucose was below 180 mg/dL in accordance with ADA guidelines.[2,5]
- Those without prior CGM experience had slightly more improvement (1.6%) compared to those using CGM previously (1.2%). Glycemic improvement was similar in those ≥65 (1.2%) versus <65 (1.4%) years of age.
- There was an average of ~73% of days with a recorded long-acting dose and 66% of days with ≥2 rapid-acting doses. Although encouraging, this leaves room for improvement in missed injections with HCP coaching, given that missed injections is a leading contributor of not meeting glycemic targets.[6,7] Missed injections may be due to not using the System at all on those days or taking insulin outside of the System. Regardless, these data are similar to other literature demonstrating compliance of injections ranging from 58-78%.[8,9]
- The rate of severe hypoglycemia and DKA events was relatively low but may be underestimated due to the retrospective nature of the study using post-market surveillance. Please see poster LB-4690 for further prospective safety and other data from System users.
- Limitations of this report include the retrospective design, lack of a control group and self-reported adverse event data. A1Cs during System use were not available, but strong correlation between A1C and GMI support using GMI as a proxy of A1C[10,11] although there are reports of potential mismatch between A1C and GMI.[12]

References

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Acknowledgements

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