

iHart CGM published in Diabetic Medicine: head-to-head G5 vs. FreeStyle Libre favors G5 for reducing hypoglycemia in type 1s at high risk - February 15, 2018

Full results from the eight-week, investigator-initiated [iHart CGM study](#) (n=40) comparing Dexcom's G5 and Abbott's FreeStyle Libre were recently published in [Diabetic Medicine](#) - in line with the interim [EASD 2016](#) data. The single-site UK study (funded by Dexcom) had a primary endpoint of time in hypoglycemia (<3.3 mmol/l; 60 mg/dl) in a higher-risk study population - type 1s with impaired hypoglycemia awareness (Gold score of ≥4) or at least one severe hypoglycemia event in the preceding year. Following two weeks of blinded CGM in both groups (with the Dexcom G4), CGM-naïve patients on MDI (baseline A1c: 7.5%) were randomly assigned to Dexcom G5 or Abbott Freestyle Libre for eight weeks.

G5 beat FreeStyle Libre on the primary hypoglycemia endpoint, which compared baseline vs. 4-8 weeks. Those using G5 decreased time spent <3.3 mmol/l from 4.5% to 2.4% (-30 minutes per day), while those using Libre saw no meaningful change from 6.7% to 6.8% (between group difference: -4.3%, p=0.006). The advantage for G5 held at all other hypoglycemia thresholds (<2.8, <3.5, <3.9 mmol/l), including for overnight data. Both groups improved time-in-range (70-180 mg/dl), though the difference was numerically larger for G5: Dexcom users increased time-in-range from 50% to 66% (a whopping +3.8 hours per day), while Libre users increased from 54% to 60% (+1.4 hours per day) (p=0.05). Changes in time >180 mg/dl were comparable: from 33% to 27% with G5 (-1.4 hours per day) vs. 35% to 28% with FreeStyle Libre (-1.7 hours per day) (p=0.71).

As we noted at [EASD 2016](#), one way to read this small study is evidence of G5's superiority, but that misses a larger point - it's not a question of either-or, but for which patients which technology is best suited. This study indicates that high-risk patients with hypoglycemia unawareness should have the benefit of CGM alarms, assuming equal access and patient preferences - we don't think anyone would argue with this. And, of course, access and patient preferences vary, making the availability of different device form factors, cost, and features essential. Given Abbott's plans for a next-gen FreeStyle Libre with continuous communication, we'd guess the products could become more comparable in the not-too-distant future (our speculation). Of course, Dexcom is also driving hard on decision support, AID, and dose titration, so it too will drive further improvements beyond the current system. Overall, we're elated to see a head-to-head study addressing a clinically important question, and we hope to see more studies like it in different populations.

Glucose Range	Dexcom G5 (n=19) Median % Time		Abbott FreeStyle Libre (n=20) Median % Time		P-value for between-group difference
	Baseline	Endpoint	Baseline	Endpoint	
<60 mg/dl (3.3 mmol/l)	4.5%	2.4%	6.7%	6.8%	0.006 (in favor of Dexcom)
<70 mg/dl (3.9 mmol/l)	8.8%	6.2%	11.9%	11.0%	0.01 (in favor of Dexcom)
70-180 mg/dl (3.9-10 mmol/l)	50%	66%	54%	60%	0.05
>180 mg/dl (10 mmol/l)	33%	27%	35%	28%	0.71

- **The iHART CGM results differ from Abbott's [IMPACT](#) data, which found Libre reduced time in hypoglycemia (<70 mg/dl) by over one hour per day at six months.** Relative to the control group on SMBG, type 1s using FreeStyle Libre in IMPACT spent ~74 minutes fewer per day <70 mg/dl (a 38% reduction; p<0.001), ~49 minutes fewer per day <55 mg/dl (a 50% reduction; p<0.0001) and ~33 minutes fewer per day <45 mg/dl (a 60% reduction; p<0.0001). These are far more robust reductions than noted above. As we noted when IMPACT came out, however, there was still room to improve: patients on Libre were still spending two hours (!) <70 mg/dl per day at six months. Hypoglycemia reduction will be an important next-gen product frontier for FreeStyle Libre.
- **Now that both G5 and Libre have Medicare reimbursement, might these results sway US prescribing in older users? Which system will see faster uptake?** Given the unacceptable rates of hypoglycemia (and unawareness) in the Medicare population, alarms may be a key differentiator as both systems begin their launch into the large, unpenetrated Medicare market. iHart CGM participants had a mean age of 49.5 years, meaning a younger group than Medicare users, but not by much.

-- by Maeve Serino, Brian Levine, Adam Brown, and Kelly Close