

Online Appendix

The JDRF Continuous Glucose Monitoring Study Group

Clinical Centers: Listed in order of number of patients enrolled with clinical center name, city, and state. Personnel are listed as (PI) for Principal Investigator, (I) for co-Investigator and (C) for Coordinators:

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Supplemental Table 1. Baseline Characteristics of the Six Subjects who never had Nocturnal Hypoglycemia during the Study.

Patient	1	2	3	4	5	6
#Eligible* nights in study	55	69	85	196	220	235
Age (years)	17.1	18.1	12.8	10.7	8.4	43.2
Diabetes Duration (years)	1.3	15.6	1.3	8.2	2.8	21.7
Gender	Female	Male	Male	Male	Female	Female
# Severe hypoglycemia events in 6 months prior to study (self-reported)	0	0	0	0	0	0
#Nights with hypoglycemia during blinded use at baseline[†]	0	0	0	0	0	0
Home blood glucose meter measurements per day (self-reported at baseline)	4.0	5.0	4.0	10.0	8.0	7.0
Insulin delivery	Pump	Pump	Pump	Pump	Pump	Pump
HbA1c (%)	8.9	7.7	8.0	7.7	8.2	7.7
Hypoglycemia Fear Scale Score[‡]	27	40	7	12	15	37
Baseline % of CGM values ≤ 60 mg/dL[†]	0.0%	0.1%	0.0%	0.3%	0.0%	0.0%
Baseline % of CGM values 71-180 mg/dL[†]	32%	63%	32%	31%	67%	31%
Baseline % of CGM values >250 mg/dL[†]	35%	8%	38%	26%	9%	28%
Baseline absolute rate of change (mg/dL/minute)[†]	0.60	0.40	0.60	0.88	0.69	0.69

*With at least 4 hours of glucose readings between midnight and 6 a.m.

[†] From use of a blinded CGM device for one week at baseline.

[‡] The Hypoglycemia Fear Scale consists of 15 5-point Likert scale items, with scores scaled to a 0 to 100 range with higher scores indicating more fear of hypoglycemia.

Supplemental Table 2. Association of Baseline Factors and Nocturnal Hypoglycemia According to Age Group

	All Subjects				Age Group											
					8-14 Years				15-24 Years				≥ 25 Years			
	N	% Hypo Median	% nights per (25 th , 75 th percentile)	% nights with subject (25 th , 75 th percentile)	N	% Hypo Median	% nights per (25 th , 75 th percentile)	% nights with subject (25 th , 75 th percentile)	N	% Hypo Median	% nights per (25 th , 75 th percentile)	% nights with subject (25 th , 75 th percentile)	N	% Hypo Median	% nights per (25 th , 75 th percentile)	% nights with subject (25 th , 75 th percentile)
Total	176	7.4%	(3.7%, 12.1%)		64	6.3%	(2.0%, 11.4%)		42	8.8%	(3.9%, 16.1%)		70	7.4%	(4.6%, 10.8%)	
Gender																
Female	94	7.2%	(3.7%, 10.8%)		34	6.6%	(2.4%, 9.6%)		21	9.0%	(5.3%, 13.7%)		39	7.3%	(4.1%, 10.8%)	
Male	82	7.8%	(3.7%, 14.2%)		30	4.9%	(1.6%, 14.2%)		21	8.7%	(3.9%, 18.4%)		31	7.5%	(5.5%, 11.2%)	
# Severe hypoglycemia events in 6 months prior to study (self-reported)																
0	164	7.2%	(3.7%, 12.2%)		61	6.3%	(2.0%, 10.3%)		39	11%	(4.5%, 17.2%)		64	7.2%	(4.5%, 11.0%)	
≥ 1	12	8.3%	(4.3%, 10.5%)		3	12%	(3.3%, 15.2%)		3	3.9%	(2.3%, 8.7%)		6	8.3%	(7.5%, 9.6%)	
#Nights with hypoglycemia during blinded use at baseline*																
0	102	6.0%	(2.8%, 10.5%)		42	4.1%	(1.8%, 9.0%)		21	5.3%	(2.4%, 11.2%)		39	7.0%	(4.5%, 10.8%)	
≥ 1	68	9.4%	(5.1%, 15.9%)		21	9.8%	(4.6%, 15.0%)		20	14%	(8.4%, 19.1%)		27	8.5%	(4.9%, 12.0%)	
Home blood glucose meter measurements per day (self-reported at baseline) †																
≤5	43	8.1%	(4.1%, 13.7%)		12	9.0%	(2.8%, 15.5%)		16	6.6%	(4.0%, 16.0%)		15	9.3%	(6.6%, 11.2%)	
6-8	78	8.8%	(3.7%, 12.2%)		31	8.4%	(2.9%, 11.7%)		12	10%	(3.8%, 17.2%)		35	8.7%	(4.7%, 14.7%)	
>8	26	5.4%	(3.2%, 12.4%)		9	2.0%	(1.2%, 6.9%)		3	15%	(13.7%, 23.0%)		14	5.4%	(4.2%, 8.5%)	

<u>Insulin delivery</u>	163	7.4%	(3.9%,	12.0%)	57	6.4%	(2.7%,	11.5%)	38	8.6%	(3.8%,	14.8%)	68	7.4%	(4.6%,	11.0%)
Pump																
Injections	13	5.1%	(1.8%,	12.6%)	7	1.9%	(1.3%,	11.4%)	4	16%	(8.9%,	22.1%)	2	5.6%	(1.8%,	9.3%)
<u>HbA1c</u>																
<7.0%	57	9.0%	(5.3%,	14.7%)	17	10%	(7.4%,	15.0%)	11	9.0%	(5.3%,	23.0%)	29	8.1%	(4.9%,	12.2%)
7.0%-<8.0%	72	8.2%	(4.5%,	12.0%)	22	5.5%	(3.3%,	9.6%)	16	13%	(6.1%,	18.7%)	34	8.8%	(5.0%,	10.7%)
≥ 8.0%	47	3.9%	(1.6%,	8.7%)	25	3.9%	(1.4%,	8.4%)	15	6.1%	(2.4%,	14.8%)	7	2.8%	(1.8%,	5.3%)
<u>Hypoglycemia Fear Scale Score[‡]</u>																
<20	65	7.5%	(3.3%,	10.3%)	27	6.8%	(1.9%,	10.3%)	15	8.5%	(3.8%,	19.0%)	23	7.3%	(3.9%,	9.5%)
20-<30	32	7.7%	(4.6%,	11.0%)	14	9.5%	(5.2%,	11.8%)	8	6.6%	(4.2%,	10.1%)	10	6.5%	(4.5%,	9.4%)
30+	78	7.0%	(3.7%,	13.5%)	22	3.7%	(1.8%,	6.9%)	19	12%	(3.7%,	16.1%)	37	8.3%	(4.9%,	12.4%)
<u>Baseline % of CGM values ≤ 60 mg/dL*</u>																
<1% (14.4 minutes per day)	90	4.8%	(2.0%,	8.7%)	40	4.0%	(1.6%,	8.7%)	20	5.2%	(2.9%,	9.7%)	30	5.2%	(3.3%,	8.7%)
1% - 3% (14.4 – 43.2 minutes per day)	36	8.8%	(4.9%,	12.0%)	11	6.4%	(3.7%,	15.2%)	8	11%	(5.4%,	16.4%)	17	7.5%	(5.0%,	10.2%)
≥3% (≥ 43.2 minutes per day)	44	14%	(8.3%,	18.3%)	12	14%	(9.1%,	16.7%)	13	15%	(9.0%,	18.4%)	19	12%	(7.1%,	19.7%)
<u>Baseline % of CGM values ≤ 60 mg/dL - Daytime (6 a.m. - midnight)*</u>																
<1% (10.8 minutes in 18hrs)	98	5.1%	(2.4%,	9.0%)	43	4.6%	(1.8%,	9.0%)	20	5.2%	(2.9%,	9.7%)	35	5.0%	(3.4%,	9.2%)
1% - 3% (10.8 – 32.4 minutes in 18hrs)	33	9.0%	(5.3%,	14.0%)	11	6.3%	(3.7%,	14.0%)	8	10%	(3.0%,	16.4%)	14	9.3%	(7.4%,	12.2%)
≥3% (≥32.4 minutes in 18hrs)	39	14%	(8.3%,	18.2%)	9	15%	(9.8%,	16.8%)	13	15%	(10.7%,	18.4%)	17	12%	(6.9%,	18.2%)

<u>Baseline % of CGM values ≤ 60 mg/dL - Nighttime (midnight-6 a.m.)*</u>														
<1% (3.6 minutes in 6hrs)	106	5.5%	(2.4%, 9.8%)	43	3.9%	(1.6%, 8.4%)	21	5.3%	(2.4%, 11.2%)	42	7.0%	(4.2%, 10.5%)		
1% - 3% (3.6 – 10.8 minutes in 6hrs)	21	9.0%	(4.9%, 12.2%)	5	6.4%	(4.6%, 11.7%)	10	12%	(8.2%, 19.0%)	6	7.0%	(3.0%, 9.3%)		
≥3% (≥10.8 minutes in 6hrs)	43	10%	(8.3%, 16.7%)	15	12%	(8.9%, 16.7%)	10	14%	(8.5%, 17.2%)	18	9.4%	(6.1%, 13.7%)		
<u>Baseline % of CGM values 71-180 mg/dL*</u>														
<50% (12hrs per day)	54	4.9%	(1.9%, 11.4%)	28	3.8%	(1.8%, 9.8%)	17	6.1%	(3.7%, 11.8%)	9	4.7%	(1.8%, 12.4%)		
50-<65% (12-<15.6 hrs per day)	51	7.5%	(3.9%, 11.5%)	22	6.6%	(3.7%, 9.8%)	12	13%	(6.6%, 19.3%)	17	7.0%	(4.1%, 9.6%)		
≥ 65% (≥15.6 hrs per day)	65	8.7%	(5.0%, 14.3%)	13	10%	(5.6%, 15.2%)	12	12%	(5.1%, 21.0%)	40	8.2%	(4.9%, 11.4%)		
<u>Baseline % of CGM values >250 mg/dL^x</u>														
≥ 15% (≥3.6 hrs per day)	61	6.3%	(2.4%, 10.7%)	33	4.0%	(1.9%, 9.0%)	18	6.6%	(3.4%, 11.8%)	10	8.4%	(2.8%, 12.4%)		
5-<15% (1.2-<3.6 hrs per day)	53	7.5%	(3.9%, 12.2%)	19	7.4%	(2.9%, 11.8%)	13	12%	(5.3%, 17.2%)	21	5.5%	(4.1%, 9.8%)		
<5% (<1.2 hrs per day)	56	8.8%	(5.3%, 14.9%)	11	10%	(5.6%, 16.7%)	10	15%	(6.5%, 24.4%)	35	7.3%	(4.9%, 10.8%)		
<u>Baseline absolute rate of change (mg/dL/minute) *</u>														
<0.65	78	7.7%	(4.6%, 12.4%)	16	11%	(6.8%, 14.6%)	18	8.9%	(2.4%, 18.4%)	44	6.7%	(4.6%, 10.6%)		
0.65-<0.75	43	7.5%	(3.4%, 13.7%)	17	3.4%	(1.6%, 8.4%)	14	8.6%	(6.1%, 14.8%)	12	8.7%	(7.2%, 15.3%)		
≥ 0.75	49	6.4%	(2.7%, 10.7%)	30	5.7%	(2.0%, 9.8%)	9	11%	(4.5%, 16.1%)	10	8.2%	(2.8%, 9.8%)		

* From use of a blinded CGM device for one week at baseline, missing for 6 subjects.

† Collected on randomization form, as assessed by clinic personnel over the last 7 days. Question was added to CRF after study initialization and data were missing for 29 subjects.

‡ The Hypoglycemia Fear Scale consists of 15 5-point Likert scale items, with scores scaled to a 0 to 100 range with higher scores indicating more fear of hypoglycemia; missing for one subject.