CGM Use with or without Remote Monitoring during Pregnancies Associated with Type 1 Diabetes (T1D)

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BACKGROUND

- Glucose levels should be tightly controlled throughout pregnancy in order to optimize maternal and fetal outcomes[1-4].

- Guidelines in Europe and the Unites States are inconsistent with recommendations for continuous glucose monitor (CGM) usage during gestation[5].

- An international, randomized controlled trial found that women with T1D using CGM throughout pregnancy had a significant increase in the sensor glucose time in range and improved fetal outcomes[6].

- Followers (family and friends) of pregnant women can view glucose trends and receive glucose alerts with remote monitoring using CGM Share (DexCom, San Diego, CA).

- This study evaluated CGM Share in pregnancy.

METHODS

- Single-center, prospective, 'open-label,' non-randomized, investigator-initiated pilot study.

- We stratified women in the 1st trimester of pregnancy to:
  1) CGM use with Share (CGM Share): women with iPhone, iPad, or iPod Touch and followers with devices compatible for data viewing,
  2) CGM use alone (CGM Alone): women without iPhone, iPad, or iPod Touch,
  3) no CGM use: women not using CGM (Figure 1).

Figure 1: Study Design
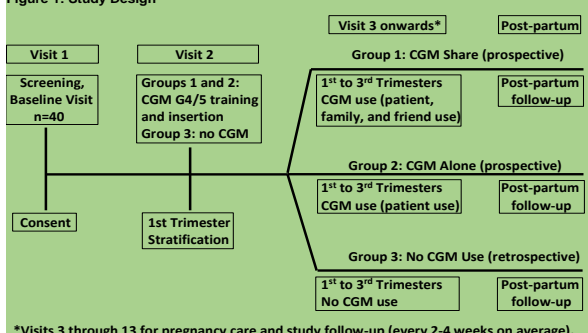
- There were 35 pregnant women with T1D (>18 yrs old, DM for >1 year) and 34 'followers' (one/pregnant woman) prospectively enrolled during pre-conception or within 13 weeks gestation. Seven pregnancies were excluded due to miscarriage or subject drop-out/withdrawal. Charts of 8 women not using CGM during a pregnancy within 3 years of the study were analyzed retrospectively as a control group.

- Pregnant subjects were trained to use the Dexcom G4 Platinum® CGM system with or without Share™ or allowed to use their own G5 systems.

- Questionnaires were administered at baseline, each trimester, and post-partum.

- Longitudinal mixed models were used for change in outcomes over time.

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RESULTS

Table 1: Baseline Characteristics

Baseline Characteristics	CGM Alone	CGM Share	No CGM
Number of subjects	13	15	8
Age (yr)[a]	24.4 (21.2, 30.3)	28.9 (26.7, 31.0)	27.6 (20.7, 29.5)
Diabetes duration (yr)[a]	11.6 (6.8, 17.0)	18.0 (10.0, 21.0)	9 (2.0, 15.5)
Body mass index (kg/m^2)	25.8 (24.6, 28.5)	24.7 (24.2, 31.4)	26.8 (22.6, 33.5)
Past cigarette use, n (%)[b]	8 (67)	3 (20)	2 (29)
Insulin delivery, n (%)[bc]			
Baseline MDI	7 (54)	2 (13)	4 (57)
Baseline Insulin pump	6 (46)	13 (87)	3 (43)
Follow-up MDI	4 (31)	0 (0)	2 (25)
Follow-up Insulin pump	9 (69)	15 (100)	6 (75)
Basal insulin (units)[a]	32.5 (20.0, 54.0)	23.1 (18.6, 30.0)	25.8 (20.8, 30)
Bolus insulin (units)[a]	24.1 (15.5, 31.9)	19.7 (14.3, 28.3)	20.6 (18.1, 25.5)
Preconception Hemoglobin A1C (%)[a]	8.1 (7.2, 9.0)	7.1 (6.3, 8.4)	7.2 (5.5, 8.4)

Abbreviations: yr, years; MDI, multiple daily injections
[a] Median (25th %ile, 75th %ile); [b] p-value<0.05 at baseline; [c] Three women on CGM Alone, 2 on CGM Share, and 3 on no CGM changed MDI to pump therapy during the pregnancy (p=0.07)

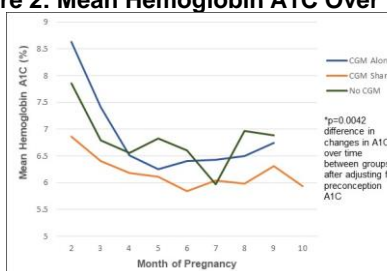### Figure 2: Mean Hemoglobin A1C Over Time

Table 2: Changes in Hypoglycemia Fear Survey[a] Scores Over Time

Score	CGM Alone	CGM Share
1st Trimester (n)	13	15
Behavior Score (mean ± SD)[b]	28.8 ± 5.8	27.9 ± 3.9
Worry Score (mean ± SD)[c,d]	45.1 ± 14.8	34.0 ± 7.2
2nd Trimester (n)	13	14
Behavior Score (mean ± SD)[b]	28.2 ± 6.9	28.9 ± 4.5
Worry Score (mean ± SD)[c,d]	37.5 ± 12.5	34.6 ± 9.7
3rd Trimester (n)	10	10
Behavior Score (mean ± SD)[b]	28.6 ± 6.6	28.2 ± 4.1
Worry Score (mean ± SD)[c,d]	43.4 ± 19	37.4 ± 7.8

[a] Data from the Hypoglycemia Fear Survey[7] with 27 questions (10 Behavior, 17 Worry). [b] p=0.48 over time; [c] p=0.03 over time; [d] p=0.04 for total (behavior and worry) over time.

Table 3: Maternal and Fetal Outcomes

Outcome	CGM Alone	CGM Share
Median CGM Ranges in Time:		
1st trimester <65 mg/dL (%)	7.5	7.3
1st trimester 65-140 mg/dL (%)[a]	52.8	59.3
1st trimester >140 mg/dL (%)	38.2	35.3
2nd trimester <65 mg/dL (%)	4.5	5.3
2nd trimester 65-140 mg/dL (%)[a]	50.7	56.6
2nd trimester >140 mg/dL (%)	46.1	37.2
3rd trimester <65 mg/dL (%)	3.8	4.5
3rd trimester 65-140 mg/dL (%)[a]	54.9	62.3
3rd trimester >140 mg/dL (%)	41.6	34.4
Gestational age (weeks)[bc]	36.7 (34.2, 37.2)	37.6 (36.6, 38.1)
Birth weight (grams)[c]	3,420 (2,538, 3,943)	3,610 (3,221, 3,988)
<37 weeks gestation, n (%)	7 (54)	4 (27)
Cesarean section, n (%)	8 (62)	13 (87)
Preeclampsia, n (%)	4 (31)	4 (27)
LGA, n (%)[c]	5 (39)	7 (47)
Macrosomia, n (%)[d]	0 (0)	3 (20)
Neonatal hypoglycemia, n (%)	7 (58)	11 (73)
Neonatal jaundice, n (%)	8 (67)	5 (33)
Neonatal hypoxemia, n (%)[b]	6 (46)	1 (7)
NICU admission, n (%)	5 (39)	7 (47)

Abbreviations: LGA, large-for-gestational age; NICU, neonatal intensive care unit
[a] p=0.058 over time; [b] p<0.05; [c] median (25th %ile, 75th %ile); [d] estimated fetal weight >90th percentile; [d] fetal weight >4 kilograms.

CONCLUSIONS

- CGM Share users had a significantly different trend in A1C over time compared with CGM Alone users and no CGM users (Figure 2).

- CGM Share users have less total fear and worry of hypoglycemia over time compared to CGM Alone users (Table 2).

- Percent time >140 mg/dL was lower in CGM Share users, but the groups were not significantly different (Table 3).

- Sensor glucose time in range (65-140 mg/dL) was larger in each trimester for CGM Share users with borderline significance (Table 2).

- Some neonatal outcomes were better in CGM Share users (Table 3).