

The Effects of Continuous Glucose Monitoring on the Management of Glucose in Patients with Type 2 Diabetes Mellitus

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Disclosure to Participants

- Notice of Requirements For Successful Completion
 - Please refer to learning goals and objectives
 - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours
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Problem statement

- Problem: Testing with finger-stick tells individuals what their current blood glucose is at this moment, but little else
- Testing A1C reflects the 2-3 month average
- Neither of these tools provide the individual with the continual feedback necessary to understand how many decisions each day effect glucose

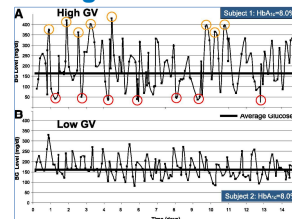


Objectives

- The learner will understand the effect that Continuous Glucose Monitoring has on glucose control in the patient with Type 2 Diabetes who are not taking insulin.
- The learner will be able to describe the process for carrying out a research project in a health care environment.



An A1C of 8.0 tells us little about glucose control



Kovatchev B, Cobelli C. Glucose variability: Timing, risk analysis, and relationship to hypoglycemia in diabetes. Diabetes Care. 2016 Apr; 39(4): 502-510



CGM vs Fingersticks

Day	Breakfast	Lunch	Dinner
11/9	117	123	145
11/11	106	123	145
11/6	121	131	120
11/5	120	119	141
11/9	127	134	130
11/7	124	125	130
11/9	122	126	130

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Literature Review

- Literature on use of CGM with patients with type 2 diabetes is sparse
 - Most included patients on insulin
 - More studies with patients with Type 1 diabetes
 - Some studies were meta-analysis
 - Pooling effects of a number of studies
 - Difficult to separate out Type 2 on no insulin

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Purpose of Our Study

- The purpose of the study was to find out how effective continuous glucose monitoring was in helping people with type 2 diabetes to manage their blood glucose
- The CGM used was the Dexcom G4

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IRB (Institutional Review Board) Process

- Any research study at our hospital has to be reviewed by the IRB
 - To determine if potential harm to patients
- Expedited review
 - No more than minimal risk to human subjects
 - Consent must still be obtained

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Continuous Glucose Monitor (CGM)

- CGM is a way to measure glucose levels in real-time throughout the day and night
- A tiny electrode called a glucose sensor is inserted under the skin to provide glucose information in tissue fluid
- It is connected to a transmitter that sends the information every 5 minutes via wireless radio frequency to a monitoring and display device

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Demographics

Beginning number of patients	30
Patients completing study	29
Men	19
Women	11
Median Age	58
Duration of Diabetes	1 month - 25 years
Taking medication for diabetes	26
Taking no medication for diabetes	4
Both English and Spanish Speaking	

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Study Participants

- 30 participants with Type 2 Diabetes (Only)
- 19 Men and 11 Non-Pregnant Females
- Median Age 58
- Diabetes managed by PCP not Endocrinologist
- Taking no medications, oral medications or non-insulin injectables
- English and Spanish speaking
- Insured and Non-insured



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Results



- Mean Dexcom glucose week 2 = **135.21**
- Mean Dexcom glucose week 8 = **134.1**
 - Paired t-test, 2-tailed significance p=.656
 - Not statistically significant

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12 Week Study Design

	Week 1 Visit 1	Week 2 Visit 2	Weeks 2-6	Week 7 Visit 3	Week 8 Visit 4	Week 12 Visit 5
Clinic Visit	1 hour	1 hour	No Visit	1 hour	1 hour	1hour
Sign Consent	X					
Hgb A1C / BMI	Done					Done
Emotional Health Questions	Fill out					Fill out
Dexcom G4	Applied	Removed		Applied	Removed	
Food / Activity Glucose Diary	Provided	Reviewed	Continue to Record	Reviewed	Reviewed	Reviewed
Demographic Questions	X					

Food and Exercise Data

- Data from Week 2 - 8 : Likert scales / used the Wilcoxon Signed Ranks test
- Exercise: significant difference p=.025
- Exercise: 24 ties (no changes made) and only 5 who exercised more
- Food: not significant difference p=.078
- Food: 18 ties, 9 who rated more positively and 2 who rated less

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Results

- Initial BMI mean **33.37** and Final BMI mean was **32.28**
 - Paired t-test, 2-tailed significance p=.000
- Initial A1C mean **7.5** and Final A1C mean **6.69**
 - Paired t-test, 2-tailed significance p=.000



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Food / Activity /Glucose Log (Participant #23)

DATE	MEAL / ATE	EXERCISE / ACTIVITY	HOW FEEL	WHAT I LEARNED
1/14/2017	1:05 PM handful of whole peanut			
3:25 PM	grilled pork chops	120 light house cleaning	fine	
10:00 PM	salad	111 resting	fine	
1/19/2017				
10:00am		110 dog walking	fine	I can see that I depend on blood sugar within mins of consumption
8:00am	omelet without bread 2 slices	110 30 mins treadmill	fine	
10:00am	fruit oat fiber 3 oz, banana, oatmeal	111 dog walking	fine	think that I never thought that an effect on blood sugar really do.
10:00am	fruit oat fiber 3oz	111 dog walking	fine	

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Results compared to other studies

- Ehrhardt, et al: (2011)
 - Population of Type 2 using oral meds or basal insulin
 - CGM vs SMBG (self-monitoring of blood glucose)
 - Randomized Controlled Trial, N=100, at 12 weeks
 - CGM group A1C decreased -1
 - SMBG decreased -0.5

Ehrhardt NM, Chellappa M, Walker MS, Fonda SJ, Vignirya RA. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. *Journal of Diabetes Science and Technology*. 2011;5(3):668-675.



Our results, to summarize

- Population of Type 2 not using insulin
 - Quasi-experimental, n=30, 12 week
 - Before intervention:
 - Mean A1C 7.5, Mean BMI 33.37
 - After intervention:
 - Mean A1C 6.69, reduction of -0.81, p=.000
 - Mean BMI 32.29, reduction of -1.09, p=.000



Results compared to other studies

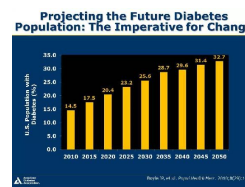
- DIAMOND trial: (2017)
 - Population of Type 2 using MDI insulin
 - CGM vs “Usual Care” (testing 4 x a day)
 - Randomized Controlled Trial, N=158, 24 weeks
 - CGM group A1C decreased -1
 - Usual care group A1C decreased -0.6

Beck RW, Riddlesworth TD, Ruedy K, et al: The DIAMOND Study Group. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections. *Ann Intern Med*. 2017;167(6):365-374.



Importance of Glucose Control in Diabetes

- If current trends continue, 1 of every 3 adults in the U.S. will have diabetes by 2050
- Diabetes is one of the leading causes of blindness, kidney failure and non-traumatic amputations of lower extremities in the US.
- The cost of medical care for a person with diabetes is approximately 2 x that of someone without diabetes
- Diabetes in adults in U.S. is not well-controlled



Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: American Diabetes Association; 2018. Standard of Medical Care in Diabetes—2018. *Diabetes Care* 2018;14(Suppl. 1):S105-S114.



Results compared to other studies

Journal	Name	Date	n	Population	Research Q	Weeks	Results	Notes
Journal of Diabetes Science and Technology (Ehrhart, Jigarsky)	(USA)	2011	100	T2 not on prandial insulin, but may be on basal insulin	CGM vs SMBG	12	Sig results CGM: A1C -1 SMBG: A1C -5	CGM worn 2 weeks on, 1 week off
Annals of Internal Medicine (Diamond)	(USA and Canada)	2017	158	T2 using MDI insulin	CGM vs Usual Care (test 4 times a day) (RCT)	24	Sig results CGM group A1C reduction -1	Usual care group A1C reduction -0.6
Diabetes Care (Morillo and Wickman)	(USA)	2017	30	T2 on oral meds or non-insulin injectables only	CGM before and after (Quasi-experimental)	12	Sig result, p=.000 Mean A1C at start of Study: 7.5 At end of study: 6.69 Reduction of -0.81	Sig result, p=.000 Mean BMI at start of Study: 33.37 At end of study: 32.29 Reduction of -1.09



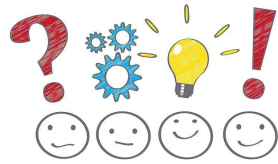
A New Strategy?

- With the rising number of people with diabetes and the rising cost of healthcare is there a strategy for people with type 2 diabetes to wear a CGM intermittently for optimal behavior modification and glucose control?
- If so, how many times / year would be optimum in order to see demonstrable changes in overall A1C ?



Thank you!

Questions?



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