

Brief History

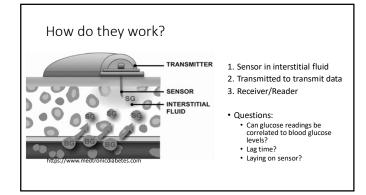
- History

 1925 Started checking urine sugars at home (insulin 1923)
 1964 First test strips for blood glucose
 1999 First continuous glucose monitor
 2016 First FDA-approved hybrid closed-loop system

Organization recommendations:

- 2010 AACE CGMS improve glycemic control and reduce hypoglycemia
 2015 AACE / ACE Clinical Practice Guidelines:

 CGM should be considered for patients with Type I and II diabetes on basal-bolus therapy
 2105 AADE CGM is appropriate for all patients with diabetes who are willing to wear one "regardless of age, diabetes type, or duration of diabetes"



Glucose in different areas



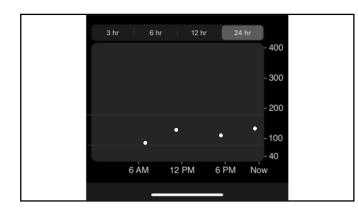
- Plasma glucose is 11% higher than whole blood glucose · If hematocrit is high, then
- Arterial glucose is 3-5% higher than venous glucose Capillary glucose is roughly the same as arterial
- Glucose diffuses from capillary to interstitial fluid based on a concentration gradient
 - Increased blood flow \rightarrow more glucose available to diffuse \rightarrow decreased lag time
 - Increase cellular uptake \rightarrow lower interstitial concentrations Lag time (2010 study says the lag time is between 4-27 minutes)

Benefits

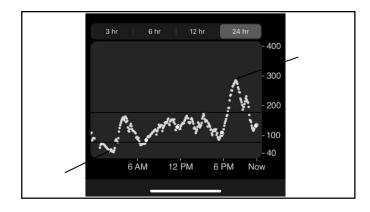
- Huge for diabetic patients with basal-bolus management!
- Also good studies for those on oral medication management
- See trends
 - Catch more highs and lows
 Nighttime highs and lows
- Immediate feedback
 More than a 3-month average with A1C on how they are doing
 See how different foods affect blood sugars
 Feedback on the accuracy of carb counting
 Feedback on how exercise affects blood sugars
 Biofeedback of hyperglycemia and hypoglycemia

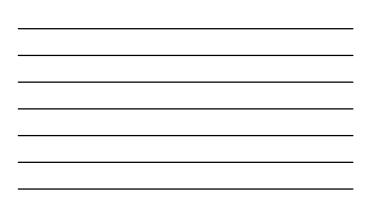












Limitations

- Interactions Vitamin C
- Salicylic acid
- Acetaminophen
- Uric acid • L-dopa
- Dehydration
- Potential for infection or allergic reaction
- Cost (insurance)

• Accuracy • Lag time for decision making

- Calibration needs?
- Calibration needs?
 MedtfroniC: "The system is intended to complement, not replace, information obtained complement, not replace, information obtained with the apy adjustments should be based on measurements obtained from standard blood glucose monitoring devices. All therapy adjustments should be based on measurements obtained using a home blood glucose meter and not on values provided by the system." (www.medtronicdiabetes.com)
- FreeStyle: "If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions" (<u>www.freestyle.abbott/us-en</u>)
- en) Eversense: "Fingersticks still required for calibration and when symptoms do not match sensor glucose readings." (https://global.eversensediabetes.com/) Dexcom "/ sourg lucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions." (Dexcom.com)

Impacts on Outcomes

• Randomized Clinical Trial published in 2017 and funded by Dexcom 158 adults with T2DM on daily injections of insulin (Hgb A_{1C} 7.5-10%)
 79 in CGM group / 79 in control group (mean Hgb A_{1c} 8.5% in both groups)

- Measured Hgb A_{1C} reduction at 24 weeks
- Results:

| | CGM Group | Control Group |
|--|-----------|---------------|
| Hgb A _{1C} | 7.5% | 7.9% |
| # (%) with Hgb A _{1C} <7.5 | 35 (45) | 22 (29) |
| # (%) with >10% reduction in Hgb $\rm A_{1C}$ | 44 (57) | 26 (35) |
| # (%) with Hgb A _{1C} reduction >1% | 40 (52) | 25 (33) |
| # (%) with Hgb A _{1C} reduction >0.5% | 61 (79) | 38 (51) |

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Impacts on Outcomes

• 2011 Study

- SUI1 Study
 100 people with T2 DM not on prandial insulin
 Being treated with oral medications (n=60), basal insulin (n=33), or diet/exercise alone (n=7)
 Hgb A_{1C} >7% <12%
 Randomized to CGM (n=50) or SMBG 4x daily (n=50)
 CGM Group mean Hgb A_{1C} & 4
 SMBG Group mean Hgb A_{1C} & 8.2
 Followed for 12 weeks
 Hgb A_{1C} exclusion (Acon (4.5 D)
- Followed for 12 weeks
 Hgb A_{1c} Reduction Mean (± SD)
 CGM group 1.0% (± 1.1%) ending mean of 7.4%
 SMBG group 0.5% (± 0.8%) ending mean of 7.7%
- Secondary outcomes
- No change in weight, BP, diabetes-related stress,

J Diabetes Sci Technol 2011;5(3):668-675

Abbot

- FreeStyle Libra 2
 Flash Glucose Monitor

 - Sensor changed every 14 days
 FDA approved in 2020 for patients 4+ years old
 - No fingerstick calibration Mean absolute relative difference (9.2%)
- FreeStyle Libra 3
 - Realtime CGM: 1-minute intervals
 - Sensor changed every 14 days
 FDA approved in 2022 for T1/T2 DM 4+ years old

 - No fingerstick calibration Mean absolute relative difference (7.9%)



Dexcom

 Dexcom G4 – 2012 Dexcom G5 - 2016

Dexcom G6

Realtime CGM: 5-minute interval
 Sensor changed every 10 days
 Transmitter lasts about 3 months

- Hardmitter Jasks adout 3 months
 No fingerstick calibration
 FDA approval in 2018 for diabetic patients 2+ years old
 Mean absolute relative difference (9.0%)
 Connects to T-slim X2 insulin pump and OmniPod 5
 semiclead loop system
 Urgent low sensor (predicts low up to 20 minutes in advance)
- Dexcom G7 not yet FDA approved

Medtronic

- Guardian Connect (Guarding 3 sensor)
 - Realtime CGM: 5-minute interval
 - Sensor changed every 7 days
 - Recharageable transmitter good for 1 year Fingerstick calibration 3-4/day

 - FDA approval in 2018 for patients 14-75 years old • Mean absolute relative difference (8.7%)

 - Connects into MiniMed 770G and 630G (semiclosed loop system)
 - Predictions for highs and lows up to 60 minutes in advance



Sensonics

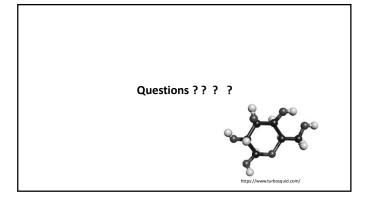
- Eversense CGM 2018

- Eversense CGM 2018
 Eversense E3

 Realtime CGM: 5-minute intervals
 Implanted sensor changed every 180 days
 Removeable transmitter (backing replaced every 24 hours), needs to be recharged daily
 No fingerstick calibration
 FDA approved Feb 2022 for patients 18+ years old
 Mean absolute relative difference (8.5%)







References

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