

MOVING THROUGH PREGNANCY WITH TECHNOLOGY
CLINICAL EXPERIENCE WITH PUMPS, CGMS AND THE HYBRID CLOSED LOOP

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CONFLICT OF INTEREST DISCLOSURE

- I have no conflicts of interest to disclose

OFF LABEL USE DISCLOSURE

- Dexcom® includes the following in their brief safety statement, "the GS is not approved for use in pregnant women."
- Medtronic includes the following in their important safety information, "the safety of the Minimed 670G system has not been studied in pregnant women."
- AACE/ACE 2014 consensus statement includes the following recommendations, "the literature does not provide clear evidence the CSII is necessary for optimal treatment of pregnant women with T1D."
- Humalog U200 insulin is not approved for use in insulin pumps

OBJECTIVES

- Review expert guidelines on blood glucose and HbA1c goals prior to conception and during pregnancy and why these numbers are important to fetal health.
- Explain general management theory as it pertains to the new pregnant patient. Decide when to change therapy regimen and when not to change therapy.
- Use an algorithm to determine settings for a new pump in pregnancy.
- Explain the role of CGMs in pregnancy and know when to start one.
- Define the role of pumps and CGMs during labor, delivery and postpartum.
- Use a steroid adjustment algorithm to offset glycemic effects of betamethasone.
- Determine appropriate patient populations for the hybrid closed loop system.

DIABETES GOALS BEFORE AND DURING PREGNANCY

FETAL OUTCOMES AND SUBOPTIMAL CONTROL

DIABETES GOALS PRE-GESTATIONAL DIABETES

	Fasting	Pre-meal	1 hour postprandial	2 hour post prandial	HbA1c
AACE/ACE	60-99mg/dL		PPG: 100-120mg/dL		≤6%
ADA	≤95	-----	≤140	≤120	<6-6.5%
ACOG	≤95	≤100	≤140	≤120	<6%
California Sweet Success/MFM	<90mg/dL	60-99mg/dL	<120mg/dL	-----	<6%

PRECONCEPTION COUNSELING

- Recommended for pre-gestational diabetes by all major associations
 - ACOG
 - ADA
 - AACE/ACE
- Women actively trying to get pregnancy (no contraception, reproductive endocrinologist)
 - Start aiming for pregnancy goals immediately
 - Optimize therapy immediately

FETAL OUTCOMES

- Uncontrolled diabetes in the 1st trimester – starts before patient even knows she is pregnant
 - Congenital anomalies
 - Heart defects
 - Musculoskeletal defects
 - Pregnancy loss
 - Pre-gestational diabetes at highest risk

FETAL FETAL OUTCOMES

- Uncontrolled diabetes in the 2nd and 3rd trimesters
 - Macrosomia
 - Jaundice
 - Hypoglycemia of the newborn
 - Preterm delivery
 - Neonatal RDS, polycythemia or hypothermia
 - Still birth
 - Lifelong struggles with obesity and diabetes
- All types of diabetes

ASSESSING THE NEWLY PREGNANT PATIENT

PATIENT CENTERED ASSESSMENT

- Assess current therapy
 - Long and/or short acting
 - Concentrated or not
 - Set dosing or insulin to carb ratio
 - Pumps and/or CGMs
- Assess level of diabetes education
 - AADE 7 – self behaviors
 - Proper timing of doses
 - Accurate carb counting
 - Advanced “pumper”

PATIENT CENTERED ASSESSMENT

- Assess whether blood glucose targets are being met
 - Is patient testing appropriately
 - HbA1c
- Develop plan with patient
 - AADE 7
 - “Getting back to basics”
 - Switch regimen? Or Continue current regimen?
 - Add pump? Or CGM?

"GETTING BACK TO BASICS"

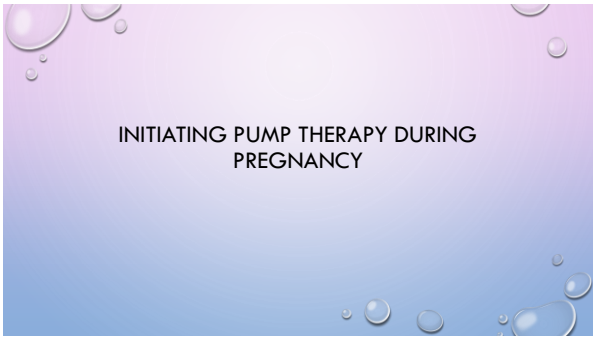
- What is included?
 - Carb counting
 - Pre-bolusing before meals
 - Pre-meal calculation of insulin to carb ratio (ICR) and correction ratio
- Why does it matter?
 - By the end of pregnancy, patient doses may quadruple
 - Must trust the math
 - Changes in pregnancy happen so quickly to continue to guess at doses

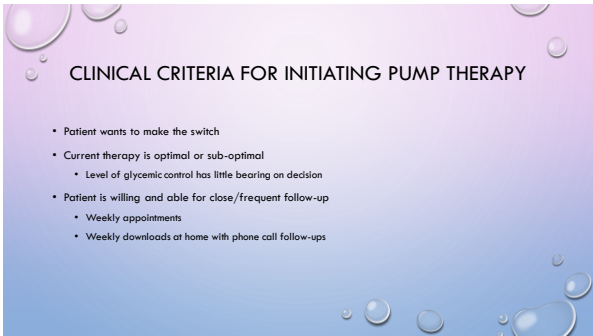
INSULIN OPTIONS IN PREGNANCY

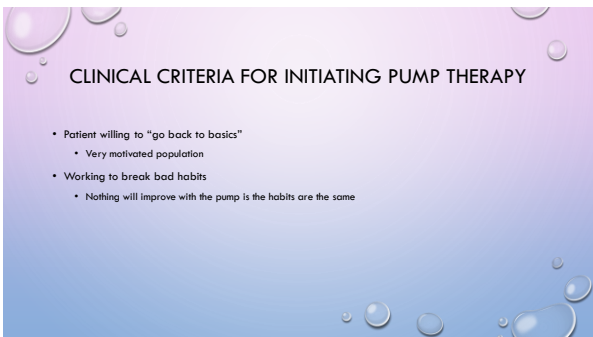
- Long acting
 - Insulin detemir (twice daily dosing)
 - Insulin glargine U100 (once daily)
 - Insulin glargine U300 (once daily)
- Short acting
 - Insulin lispro (U100 or U200)
 - Insulin aspart (U100)
 - Regular insulin (U100)
- Intermediate acting
 - NPH (twice daily)
 - Regular insulin (U500)
- New FDA approval – ultra rapid acting
 - Insulin aspart (Fiasp®)

INSULINS AVOIDED IN PREGNANCY AND PRE-PREGNANCY

- Inhaled insulin
 - Black Box warning for patients with asthma and COPD
 - Lung capacity is often diminished in late pregnancy
- Insulin degludec
 - Half life of 25 hours
 - Extreme lows in the post partum period
 - Recommend decreasing dose prior to delivery?
 - Can't always predict that
 - One of the most important times to have optimal control







PUMP START ALGORITHMS

- Endless options
 - Single basal rate
 - Rule of 1500, 1800, 500, 800
- [Perinatology pump start calculator](#)
 - Very successful
 - New pump settings
 - Re-doing pump settings
- Blood glucose Target
 - Patient driven – comfort level, current lows
 - 120 mg/dl – starting point
 - 110 mg/dl – increasing pump comfort
 - 100 mg/dl – have CGM
- Active insulin time
 - First trimester: 3.5 hours
 - Second trimester: 3 hours
 - Third trimester: 2.5 – 2 hours

PUMP START EXAMPLE

- LS is a 23 yo G1P0 at 18w3d. Her fasting average is 120 mg/dL, her pre-meal numbers average 140 mg/dL. She is ready for a pump start. Her ICR is 1:5 and her correction ratio is 1:20 with a target of 120. She is on insulin detemir 30 units twice daily. She logged all her mealtime insulin for 1 week and averaged 100 units daily. She weighs 135 lbs.
- [Perinatology pump start calculator](#)

PUMP START EXAMPLE

- New Pump settings
 - ICR 1:3
 - Correction 1:9 with a target of 120mg/dL

Second Trimester 12 AM to 4 AM hourly basal rate 4 AM to 10 AM hourly basal rate 10 AM to 6 PM hourly basal rate 6 PM to 12 AM hourly basal rate	0.5 units /hour 1.5 units /hour 1 units /hour 1 units /hour
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ADJUSTING PUMPS THROUGH PREGNANCY
THE NEVER-ENDING BATTLE

PREGNANCY FORCES AFFECTING INSULIN NEEDS

- First trimester
 - Unexplained hypoglycemia
 - Often first signs of pregnancy
 - Nausea and vomiting
- Second trimester
 - Shifts in hormones
 - Resistance starts

FORCES AFFECTING INSULIN NEEDS

- Beginning of third trimester
 - Resistance at a maximum
 - Needs can quadruple
 - Eating more / more hungry / cravings
- End of third trimester
 - Braxton Hicks contractions increase
 - Final shift in hormones
 - Placenta starting to deteriorate

ADDRESSING PATIENT NEEDS

- Frequent visits
 - Pump adjustments
 - Patient pep-talks/education
 - Longest between face to face visits: 4 weeks
- Office "bandwidth"
 - CDE incredibly important
 - Telehealth

THE UTILITY OF CONTINUOUS GLUCOSE MONITORS IN PREGNANCY

SHOULD WE BE CONCERNED?

CONTINUOUS GLUCOSE MONITORS

- Not approved in pregnancy (not tested)
- Concerns
 - Increased fluid associated with pregnancy
 - Increases chance of inaccuracy?
- Reality
 - Patients report no difference in blood glucose levels and CGM readings during different trimesters in pregnancy

ADVANTAGES OF CONTINUOUS GLUCOSE MONITORS

- Safety
 - Patients can push the boundaries of tight control
 - Detect changes in insulin needs faster
 - Patterns easier to detect
- Efficacy
 - Patients have better blood glucose numbers
- Phone calls and telehealth easier
 - More information for the provider

CLINICAL CRITERIA FOR INITIATING CGM THERAPY

- Patient wants to make the switch
- Current therapy is optimal or sub-optimal
 - Level of glycemic control has little bearing on decision
- Patient is willing and able for close/frequent follow-up

WHEN TO INITIATE CGM THERAPY

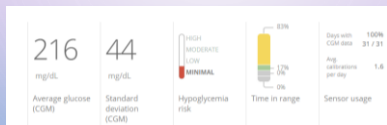
- Start therapy as soon as possible
- More valuable tool than pump?
 - Shows them more information
 - Deciding factor to get a pump
- Initiating pump and CGM therapy at the same time?
 - Requires lots of pre-work
 - Homework
 - Turn pump start and CGM start into teach back.

PATIENT CASE: UTILITY OF A CGM

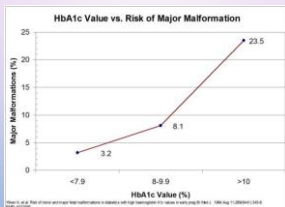
- AC is a 42 year old G5P3. She was with our diabetes team in a prior pregnancy when she was diagnosed with LADA. She was started on a pump and CGM during that pregnancy. She had a repeat cesarean section. Two months postpartum she was referred to Adult Endocrinology. She calls me after a positive home pregnancy test. Potentially gestation age of 5-6 weeks.
- Turn to neighbor:
 - How long to get patient in at your clinic?
 - What would you do?

PATIENT CASE : UTILITY OF A CGM

- Estimated HbA1c of 9.2

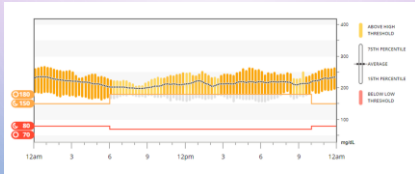


PATIENT CASE: UTILITY OF A CGM



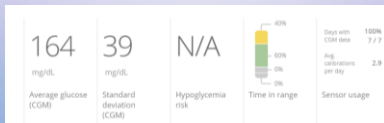
<http://perinatology.com/Reference/HemoglobinA1c%20and%20Malformation.htm>

PATIENT CASE: UTILITY OF A CGM

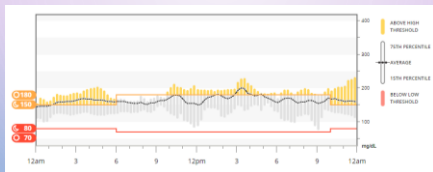


PATIENT CASE: UTILITY OF A CGM

- AADE 7
 - Not covering meals
 - not correcting hyperglycemia
- First adjustments over the phone and after 1 week:

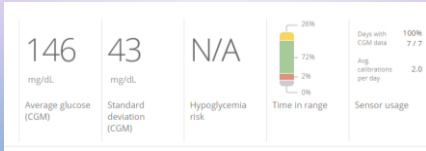


PATIENT CASE: UTILITY OF A CGM



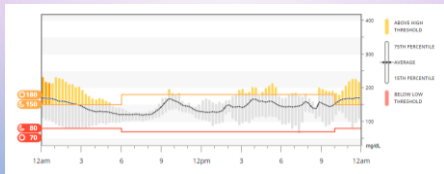
PATIENT CASE: UTILITY OF A CGM

- One more week of changes



7 / 7

PATIENT CASE: UTILITY OF A CGM



PATIENT CASE: UTILITY OF A CGM

- Lessons from this case
 - Done remotely with very little time spent on the phone
 - Download and assessment before phone call was made
 - Better for mom and baby
- Without a CGM
 - Two more weeks of high blood glucose
 - Hours on the phone with the patient recounting all blood glucose levels through the week to make changes to regimen

LABOR AND DELIVERY
IT IS TIME TO HAVE A BABY!

PUMP MANAGEMENT AND MODE OF DELIVERY

- Spontaneous Vaginal Delivery (SVD)
 - Not much choice in the matter
- Induction of Labor (IOL)
 - Usually allowed to eat
 - Do all insulin, as prescribed, until hospital check-in
 - Keep pump site and CGM away from abdominal area in case of emergent cesarean section

PUMP MANAGEMENT AND MODE OF DELIVERY

- Planned cesarean Section
 - Usually early in the morning
 - Do all insulin, as prescribed, until hospital check-in
 - If running too low, may decrease basal by -10-15%
 - Turn pump off and disconnect while rolling back to the operating room (OR)
 - CGM will not work in the OR due to the Bovie Pads
 - It will start working postpartum
 - Put pump site and CGM away from the abdominal area

PUMP AND CGM: LABOR

- Hospital policy
 - Patient managed pump
 - IV insulin drip
 - Subcutaneous insulin
- Obstetrician comfort level
 - IV insulin drip is easier and nurse driven
- Patient driven decision
 - Do not want to worry about their blood glucose while in labor

PUMP AND CGM: LABOR

- Patient managed pump
 - Completely driven by patient
 - Must use hospital meter to test and dose
 - May use CGM as a guide for testing
 - Pump settings are entered into the MAR
 - Patient must record all bolus activity and nursing staff must transcribe information
- Labor blood glucose goals 120-130 mg/dL

INSULIN NEEDS IN LABOR

- Pain makes blood sugar increase
 - Late epidural placement
 - May need more insulin
- Second stage of labor
 - Frequent and rhythmic contractions (5 min apart)
 - Insulin usually discontinued

PUMP AND CGM: POSTPARTUM

- Everything changes once the placenta is delivered
 - Honeymoon for 12 to 24 hours
 - Immediately go back to pre-pregnancy pump settings
 - Turn pump back on at 180mg/dL
- Breastfeeding
 - Can cause wide fluctuations in blood glucose
 - Adjust to more conservative targets
 - Immediately go back to non-pregnant blood glucose goals

BETAMETHASONE

- Common in patients with diabetes
- Uncontrolled diabetes
 - Higher risk for pre-eclampsia
 - Higher risk for pre-term labor

BETAMETHASONE

- Per ACOG guidelines we are administering up to 36w6d gestation if delivery imminent
 - Two IM doses 24 hours apart
- Steroid Algorithm
 - Adopted from California Sweet Success Program
 - Doses started at random times of the day
 - Risk of hypoglycemia is low
 - Successful use with all steroid use

BETAMETHASONE

Time Table	Notes	Change in insulin dose
0000	First betamethasone injection given	No change for 8-12 hours*
12 hours	Insulin resistance starts	+100% basal rates, ICR and correction ratio
24 hours	Second betamethasone injection given	
48 hours	Insulin resistance starts to wane	+50% basal rates, ICR and correction ration
72 hours	Insulin resistance undetectable	Original

* Patients entering the hospital with sub-optimal glucose control may start the increased dosing immediately

HYBRID CLOSED LOOP SYSTEM

IT'S PLACE IN DIABETES MANAGEMENT IN PREGNANCY

HYBRID CLOSED LOOP

- Potential issues
 - Not tested or approved
 - Target isn't appropriate for pregnancy
 - Algorithm takes too long to adapt
 - Can't correct highs at will

CLINICAL CRITERIA FOR HYBRID CLOSED LOOP

- Patient wants to make the switch
- Current therapy is sub-optimal
 - High pre-pregnancy HbA1c
 - Extreme fear of lows
 - Frequent hyperglycemia and subsequent hypoglycemia from over correcting
- Patient is able and willing to do close/frequent follow-up

INITIATING HYBRID CLOSED LOOP

- Rule of 500 for ICR
- Active insulin time
 - First trimester: 3.75 hours
 - Second trimester: 3.5 - 3 hours
 - Third trimester: 2.5 - 2 hours
- Pre-bolus before meals
- Well balanced meals

HYBRID CLOSED LOOP IN LABOR AND DELIVERY

- Patient managed pump
 - Use hospital meter to calibrate
- Disconnect in second stage of labor
- For cesarean section disconnect while in transit to the operating room

HYBRID CLOSED LOOP IN POSTPARTUM

- Postpartum hybrid closed loop
 - Reconnect once blood glucose is 180mg/dL
 - Set temp target to 180 mg/dl (for at least 1 week)
 - ICR back to pre-pregnancy value
 - Active insulin time: 3.75 - 4 hours
- Postpartum pump and CGM
 - Reset all settings to pre-pregnancy settings
 - Use without hybrid closed loop system for one week

MAJOR TAKE HOME POINTS

- Pregnancy is a diabetes sprint
- NPH and regular insulin are NOT the only options for pregnancy
- Pumps and CGMs should be considered at anytime in pregnancy
- "Going back to basics" is the single best thing a patient can do
- Hybrid closed loop system has a relevant place in therapy

QUESTIONS?

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