The Case for Status Quo: Diabetes Screening

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Disclosure / Conflict of Interest

- Career-long advocate for optimal patient care and avoidance of over-diagnosis & excessive intervention
- Not now, or ever have been, a member of the International Association of Diabetes and Pregnancy Study Group Consensus Panel
  - Nor with any organizations opposing IADPSGCP

Current Status

- Diabetes during pregnancy ≈6%
  - Greater if high-risk population
    - 80-90% "gestational"
  - 2010 FLR: 5.4% GDM, 0.9% type I & II
- Diagnosis: 50 gm glucola ➔ 100 gm 3-hr OGTT
  - NDDG (traditional, albeit not outcome-based)
    - 105 – 190 – 165 – 145
  - Carpenter-Coustan (diagnoses milder cases)
    - 95 – 180 – 155 – 140
  - "There are no data from clinical trials to determine which is superior." ACOG Practice Bulletin #30, 2001

Current Status

- Mild GDM associated with subtle increases in adverse perinatal outcome
  - CC criterion or one abnormal NDDG value
- Carpenter-Coustan criteria increases GDM diagnosis by 30-50%
  - More mild cases diagnosed
    - Little evidence that treatment of mildest GDM improves perinatal outcome
      - Labeling increases cesarean rate in some studies

Sermer, Diabetes Care, 1998
Cheng, Obstet Gynecol, 2009

Treatment of Mild GDM: Outcomes

- Crowther, NEJM, 2005: 1000 women "ACHOIS*"
  - Treatment reduced composite outcome (1 vs 4%, p=0.01), but no significant improvement in any individual outcome
    - Perinatal death (0 vs 1%), shoulder dystocia (1 vs 3%), fracture (0 vs <1%), nerve palsy (0 vs 1%)
      - Most composite effect was due to shoulder dystocia, not to death or permanent injury
  - More inductions (39 vs 29%, p<0.001) and NICU admissions (71 vs 61%, p=0.01) in treatment group

*Australian Carbohydrate Intolerance Study In Pregnant Women (ACISPW)

Treatment of Mild GDM: Outcomes

- Landon, NEJM, 2009: 958 women
  - No difference in composite outcome (32 vs 37%)
    - Fewer shoulder dystocias (1.5 vs 4%, p=0.02) but no reduction in trauma (0.6 vs 1.3%)
- Naylor, JAMA, 1996: 3800 women
  - A diagnosis of DM doubled the odds for cesarean, even when all other factors were equal (aOR 2.1)
    - "Recognition of GDM may lead to a lower threshold for surgical delivery that mitigates the potential benefits of treatment."

Despite 40 years of Study…

- Controversy continues about whether screening & treatment of GDM improves perinatal outcome

  - Recent US Preventive Services Task Force (2008) & Cochrane Reviews (2009&11): **INSUFFICIENT EVIDENCE**

  - ACOG Practice Bulletin #30, 2001: "…the evidence is **inconclusive** that treating GDM can prevent maternal and fetal complications…"

Hyperglycemia and Adverse Outcome in Pregnancy (HAPO) Study

- Observational: 23,000 women, 15 centers
- 75gm 2-hr OGTT at 24-32 wks
  - Blinded and no rx if FBS<105 and 2-hr <200
- Odds ratios based on nl BGs versus >1SD above mean for FBS, 1-hr, and/or 2-hr
  - Higher aORs for LGA (1.4), shoulder dystocia and preeclampsia (1.2), and primary CS and neonatal hypoglycemia (1.1)

HAPO, NEJM, 2008

HAPO Study

- All outcomes were continuums
  - No obvious thresholds
  - Consistent with several other studies

Epidemiologic—Not a randomized trial!

Was not a study of whether treatment improves outcomes

IADPSGCP Recommendations

- Any one abnormal BG on 75 gm 2-hr OGTT
- Test cut-points
  - FBS 92
  - 1-hr BG 180
  - 2-hr BG 153

16% of women would be labeled DM!

Plus pre-existing diabetics

IADPSGCP, Diabetes Care, 2010

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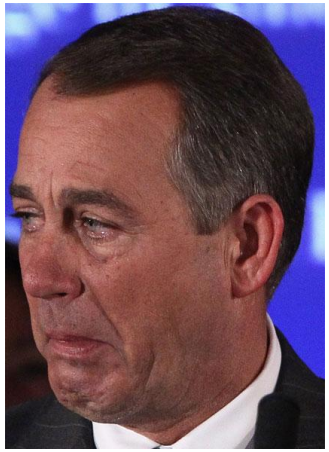
  - Labels and requires BG testing of 1-in-6 pregnant women

IADPSGCP Issues

- **Recommendations are untested**
  - Before adopting major change, should be sure of benefit!
    - OB seems woefully ignorant of this
      - Remember Electronic Fetal Monitoring, HSV Screening, and Aspirin & Antioxidants for Just About Everything?

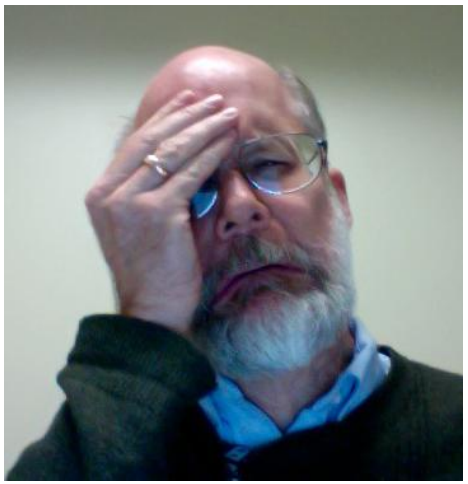
Costs

- Moss, BMC Preg/Childbirth, 2007
  - ACHOIS study of screening/treatment of mild GDM
  - Estimated additional $70,000 per 100 GDMs
    - In USA with 4 million births/year, assuming an additional 10-12/100 women labeled/year:
      - Adds $300,000,000/year to the cost of perinatal care



Costs

- Moss, BMC Preg/Childbirth, 2007
  - Increase induction rate by 9.7 % points
    - In USA, 2006 induction rate was 22.5%
      - Increase to >30% after HAPO?



Conclusions

- IADPSGCP recommendations *may* be plausible, but they are based on observational data
  - Expert opinion based on plausible epidemiologic/incomplete data often is wrong
- If we lack sufficient evidence that treatment of mild diabetes is beneficial, why accept the proposition that diagnosis and treatment of *even milder* diabetes will be worthwhile?

Conclusions

- Would triple the number of women with “diabetes”
  - Mostly mild “disease” at lowest likelihood of adverse outcome
  - Increase induction rate (cesarean too?)
  - High “number-need-to-treat” to prevent one adverse outcome

Conclusions

- Before adopting major changes in screening & diagnosis, need to have solid evidence that treatment will have desired benefit
  - Ideally, randomized controlled trials instead of "educated guesses"
- *Lacking this evidence, it is premature to adopt these recommendations*

Conclusions

Stick with current paradigms until you're convinced that the latest recommendations have been proven to work