DO WE NEED NEW CRITERIA FOR THE DIAGNOSIS OF GESTATIONAL DIABETES?

Donald R Coustan, MD
17 October 2015

OUTLINE

• CURRENT DIAGNOSTIC CRITERIA
• WHY THE NEED FOR NEW DIAGNOSTIC CRITERIA?
• HAPO STUDY
• IADPSG RECOMMENDATIONS
• WHY USE THE IADPSG RECOMMENDATIONS?
• WHY NOT USE THE IADPSG RECOMMENDATIONS?
• CURRENT STATUS

DIABETES SYMPOSIUM
BAPTISTHEALTH SOUTH FLORIDA

DIAGNOSING GESTATIONAL DIABETES

• MOST COMMON U.S. PARADIGM:
  • 2 STEP (SCREENING AND DIAGNOSTIC TESTING)
    • 50 GRAM, 1-HR SCREEN
    • 100 GRAM, 3-HR OGTT
    • NDDG
    • Carpenter/Coustan (BOTH BASED ON O’SULLIVAN/MAHAN CRITERIA)
• WORLD HEALTH ORGANIZATION
• OTHER
WHY DO WE NEED NEW CRITERIA?

• THIRD INTERNATIONAL WORKSHOP/CONFERENCE ON GDM (1991):
  – LACK OF INTERNATIONAL AGREEMENT ON TESTING: 50, 75 AND 100 GRAM CHALLENGES; IMPOSSIBLE TO COMPARE PREVALENCEs
  – 75 GRAM CHALLENGE WILL EVENTUALLY BECOME UNIVERSALLY EMPLOYED

METZGER ET AL: DIABETES 40(Suppl 2);197, 1991

WHAT IS THE EVIDENCE BEHIND THE NEW CRITERIA?

HYPERGLYCEMIA AND ADVERSE PREGNANCY OUTCOME (HAPO) STUDY

HAPO STUDY (HYPERGLYCEMIA AND ADVERSE PREGNANCY OUTCOMES)

RATIONALE:

• Overt diabetes clearly increases the risk of adverse pregnancy outcome.
• What level of glucose intolerance during pregnancy, short of diabetes, is associated with the risk of adverse outcome?
**HAPO STUDY**

- ~23,000+ NON-DIABETIC GRAVIDAS
- 15 CENTERS
- 9 DIFFERENT COUNTRIES
- BLINDED 75 GM OGTT 24-32 WEEKS
- EXCLUDED IF FBS >105 MG/DL, OR 2-HR >200 MG/DL


# Blinded Participants At Each Field Center

<table>
<thead>
<tr>
<th>Field Center</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bellflower</td>
<td>1903</td>
</tr>
<tr>
<td>Chicago</td>
<td>738</td>
</tr>
<tr>
<td>Providence</td>
<td>746</td>
</tr>
<tr>
<td>Cleveland</td>
<td>784</td>
</tr>
<tr>
<td>Toronto</td>
<td>1988</td>
</tr>
<tr>
<td>Belfast</td>
<td>1634</td>
</tr>
<tr>
<td>Manchester</td>
<td>2250</td>
</tr>
<tr>
<td>Barbados</td>
<td>2034</td>
</tr>
<tr>
<td>Petah-Tiqva</td>
<td>1798</td>
</tr>
<tr>
<td>Beersheba</td>
<td>1610</td>
</tr>
<tr>
<td>Bangkok</td>
<td>2426</td>
</tr>
<tr>
<td>Brisbane</td>
<td>1437</td>
</tr>
<tr>
<td>Newcastle</td>
<td>653</td>
</tr>
<tr>
<td>Singapore</td>
<td>1695</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>1620</td>
</tr>
</tbody>
</table>

**HAPO Protocol**

75 gm OGTT 24-32 weeks  
Fasting, 1 & 2 hr venous plasma  
25,505

Unblinded at Field Center if:
OGTT Fasting > 105 &/or 2 hr > 200  
or random glucose > 160 – 36 wks  
or < 45 mg/dl

746 (2.9%) unblinded for treatment  
1,443 (5.7%) incomplete

23,316

Standard care for Field Center  
Cord glucose & C-peptide  
Neonatal glucose: 1-2 hrs of age  
Anthropometrics by 72 hrs:  
Length, head circ, weight, skin folds x3

**HAPO STUDY**

RESULTS:

- CONTINUOUS RELATIONSHIP BETWEEN FBS, 1-HR AND 2-HR GLUCOSE ON 75 GM OGTT WITH:
  - BIRTHWEIGHT > 90TH PERCENTILE
  - CESAREAN SECTION
  - NEONATAL HYPOGLYCEMIA
  - CORD BLOOD C-PEPTIDE

- RELATIONSHIP HOLDS EVEN DOWN TO LOWER LEVELS OF GLUCOSE

**Associations: Glucose & 1° Outcomes**

- Birth Weight > 90th Percentile
- Primary C-Section
- Clinical Hypoglycemia
- Cord C-Peptide > 90th Percentile

**Impact of Potential Confounders**

- Adjustments for potential confounders including field center, ethnic group & BMI
  - Small to moderate attenuation of most unadjusted associations
- Associations did not differ among centers
- The results are applicable to all centers
- Results can be used globally to develop “outcome based” criteria for classifying glucose metabolism in pregnancy

**Secondary Outcomes**

- Each secondary outcome associated with measures of maternal glucose
  - Shoulder Dystocia/Birth Injury: infrequent but strong associations
  - Premature delivery (6.9%): relatively strong association with 1 & 2-hr glucose measures
  - Pre-eclampsia (4.8%): strong associations with each glucose measure (fully adjusted)
- Conclusion: continuous association of maternal glucose with multiple adverse perinatal outcomes.

**Summary of Secondary Outcomes**

- Each secondary outcome associated with measures of maternal glucose
  - Shoulder Dystocia/Birth Injury: infrequent but strong associations
  - Premature delivery (6.9%): relatively strong association with 1 & 2-hr glucose measures
  - Pre-eclampsia (4.8%): strong associations with each glucose measure (fully adjusted)
- Conclusion: continuous association of maternal glucose with multiple adverse perinatal outcomes.
HOW WERE THE NEW CRITERIA DEVELOPED?

• Why did HAPO research group make no specific recommendations?
  — No obvious inflection points
  — Need for international agreement

• Resolve issues: appoint a committee of “experts”
  — A task for the International Association of Diabetic Pregnancy Study Groups (IADPSG)

From Associations to Diagnostic Criteria: Role of IADPSG

• Affiliated Organizations
  - DPSG of EASD
  - JAPD (Japan)
  - ADIPS (Australasia)
  - West Coast USA DPSG
  - DPSI (India)
  - Canadian Special Interest Group for Diabetes and Pregnancy

• Associated Groups
  - European Association of Perinatal Medicine; Society of Maternal Fetal Medicine (USA); ADA Pregnancy Council; SAREDIA

Adjusted Odds Ratios: Maternal Glycemia as Continuous Variable & Primary Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Fasting</th>
<th>1-Hour</th>
<th>2-Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birthweight &gt;90%</td>
<td>1.38 (1.32-1.44)*</td>
<td>1.46 (1.39-1.53)</td>
<td>1.38 (1.32-1.44)</td>
</tr>
<tr>
<td>Primary C-section</td>
<td>1.11 (1.06-1.15)</td>
<td>1.10 (1.06-1.15)</td>
<td>1.08 (1.03-1.12)</td>
</tr>
<tr>
<td>Clinical Neo Hypo</td>
<td>1.08 (0.98-1.19)</td>
<td>1.13 (1.03-1.26)</td>
<td>1.10 (1.00-1.12)</td>
</tr>
<tr>
<td>Cord serum C-Peptide &gt;90%</td>
<td>1.55 (1.47-1.64)</td>
<td>1.46 (1.38-1.54)</td>
<td>1.37 (1.30-1.44)</td>
</tr>
</tbody>
</table>

*Odds ratios for glucose level ±1 SD (F=6.9; 1-hr=30.9; 2-hr=23.5 mg/dl)
### Adjusted Odds Ratios: Maternal Glycemia as Continuous Variable & Secondary Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Fasting</th>
<th>1-Hour</th>
<th>2-Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premature Delivery (&lt;37 wks)</td>
<td>1.05 (0.99-1.11)*</td>
<td>1.18 (1.12-1.25)</td>
<td>1.16 (1.10-1.23)</td>
</tr>
<tr>
<td>Shoulder Dystocia/Birth Injury</td>
<td>1.18 (1.04-1.33)</td>
<td>1.23 (1.09-1.38)</td>
<td>1.22 (1.09-1.37)</td>
</tr>
<tr>
<td>Intensive neonatal care</td>
<td>0.99 (0.94-1.05)</td>
<td>1.07 (1.02-1.13)</td>
<td>1.09 (1.03-1.14)</td>
</tr>
<tr>
<td>Hyperbilirubinemia</td>
<td>1.00 (0.95-1.05)</td>
<td>1.11 (1.05-1.17)</td>
<td>1.08 (1.02-1.13)</td>
</tr>
<tr>
<td>Preeclampsia</td>
<td>1.21 (1.13-1.29)</td>
<td>1.28 (1.20-1.37)</td>
<td>1.28 (1.20-1.37)</td>
</tr>
</tbody>
</table>

*Odds ratios for glucose level 1 SD (F=6.9; 1-hr=30.9; 2-hr=23.5 mg/dl)

### From Associations to Diagnostic Criteria: A Great Challenge

- Associations tend to be continuous and graded
- Choosing thresholds is arbitrary
- Are outcomes of equal importance?
- Is it important to measure FPG, 1-hr & 2-hr OGTT glucose concentrations?

### From Associations to Diagnostic Criteria: Taking the Challenge

- How much risk is too much risk?
  - Choose reference group
  - Apply both statistical models & outcome frequencies
- Should effectiveness of treatment be given consideration?
  - RCT results

### MEAN HAPO GLUCOSE VALUES

- Fasting 80.9 MG/DL
- 1-HR 134.1 MG/DL
- 2-HR 111.0 MG/DL

**Plasma Glucose Concentrations at Specified OR**

<table>
<thead>
<tr>
<th>Glucose</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/dl*</td>
<td></td>
</tr>
<tr>
<td>FPG</td>
<td>1.5</td>
</tr>
<tr>
<td>1-Hr PG</td>
<td>90</td>
</tr>
<tr>
<td>2-Hr PG</td>
<td>167</td>
</tr>
</tbody>
</table>

*Mean of threshold values for ↑ Fat, LGA, Cord Serum C-Peptide >90th%.

**IADPSG RECOMMENDATIONS**

- Cutoff values for GDM were based on odds ratio of 1.75 (compared to median glucose values):
  - Fasting: 92 mg/dl; 5.1 mmol/L
  - 1-hr post 75 gm: 180 mg/dl; 10.0 mmol/L
  - 2-hr post 75 gm: 153 mg/dl; 8.5 mmol/L
  - Any one or more elevation = GDM
- In HAPO population 16-18% would have GDM

IADPSG, Diabetes Care 2010:33:676-682.

**OUTCOMES (UNTREATED) WITH NEW CRITERIA (HAPO PARTICIPANTS)**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>% All Values &lt; Threshold</th>
<th>% Any &gt; 92/180/153</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birthweight &gt;90th percentile</td>
<td>8.3</td>
<td>16.2</td>
</tr>
<tr>
<td>Cord C-peptide &gt;90th percentile</td>
<td>6.7</td>
<td>17.5</td>
</tr>
<tr>
<td>% Body fat &gt;90th percentile</td>
<td>9.5</td>
<td>16.6</td>
</tr>
<tr>
<td>Preeclampsia</td>
<td>4.5</td>
<td>9.1</td>
</tr>
<tr>
<td>Preterm birth (&lt;37 weeks)</td>
<td>6.4</td>
<td>9.4</td>
</tr>
<tr>
<td>Shoulder dystocia/birth injury</td>
<td>1.3</td>
<td>1.8</td>
</tr>
<tr>
<td>Primary Cesarean section</td>
<td>16.8</td>
<td>24.4</td>
</tr>
</tbody>
</table>
DIAGNOSIS OF OVERT DIABETES IN EARLY PREGNANCY

ASSIGN DIAGNOSIS OF PRE-EXISTING DIABETES IF, AT FIRST VISIT, ANY OF THE FOLLOWING:
- FASTING PLASMA GLUCOSE ≥126 MG/DL
- HEMOGLOBIN A1C ≥6.5%
- RANDOM PLASMA GLUCOSE ≥200 MG/DL (CONFIRMED BY FPG OR HBA1C)

IADPSG RECOMMENDATION. DIABETES CARE 2010;33:676

WHY ADOPT IADPSG RECOMMENDATIONS FOR GDM DIAGNOSIS?
• 75 GRAM CHALLENGE
• MULTI-NATIONAL DATA; MULTINATIONAL CONSENSUS
• BASED ON PREGNANCY OUTCOMES
• SINGLE ABNORMAL VALUE

WHY NOT ADOPT IADPSG RECOMMENDATIONS FOR GDM DIAGNOSIS?

NIH CONSENSUS DEVELOPMENT CONFERENCE
4-6 MARCH 2013
NIH CONSENSUS DEVELOPMENT CONFERENCE

RECOMMENDATIONS

• Continue using 3-hr, 100 gm OGTT
• Continue 2-step process

NIH CONSENSUS DEVELOPMENT CONFERENCE

RATIONALE

1. Increased prevalence means additional burden for patients, providers, health care system
2. Uncertainties regarding benefits of identifying and treating so many additional GDMs, associated costs and interventions
3. Standardization would be desirable; reconsider if uncertainties are resolved

WHY NOT USE IADPSG RECOMMENDATIONS?

1. INCREASED PREVALENCE MEANS ADDITIONAL BURDEN FOR PATIENTS, PROVIDERS, HEALTH CARE SYSTEM.
   • IT DOESN'T SEEM REASONABLE TO RECOMMEND THRESHOLDS THAT IDENTIFY 16+% OF THE POPULATION.
   • CLOSER TO 18% WHEN WE INCLUDE THOSE UNBLINDED BECAUSE OF ELEVATED VALUES.

4. Fasting, waiting 2 hrs is an additional burden for patients
5. 2-hr GTT unstable; 1-step test likely to increase false positives
UNDIAGNOSED AND DIAGNOSED DIABETES, USA


PREDIABETES
IN 2009-2012
37% OF ADULTS;
26% AT AGE 18-44 YEARS


DIABETES (DIAGNOSED AND UNDIAGNOSED) AND PREDIABETES
• 12.3% DIABETES + 37% PREDIABETES = APPROXIMATELY 49% OF ADULT US POPULATION

• AMONG WOMEN AGES 18-44, 4.5% WITH DIABETES AND 26% WITH PREDIABETES = 30.5% (COWIE, NIDDK)

DIABETES (DIAGNOSED AND UNDIAGNOSED) AND PREDIABETES
• IS 17-18% GDM RATE SO OUTRAGEOUSLY HIGH?

• 30.5% PREDIABETES/DIABETES IS ALMOST TWICE AS HIGH!

• SHOULD WE MAKE CRITERIA FOR PREDIABETES AND DIABETES MORE STRINGENT IN ORDER TO LOWER THE BURDEN ON THE HEALTH CARE SYSTEM?
HEALTH CARE COSTS WILL INCREASE BECAUSE OF THE HIGH PREVALENCE OF GESTATIONAL DIABETES

True, just as the epidemic of diabetes and prediabetes is increasing health care costs in general...

HEALTH CARE COSTS WILL INCREASE

- CHALLENGE IS TO DEVELOP MORE EFFICIENT WAYS TO DELIVER CARE
  - GROUP SESSIONS
  - LESS FREQUENT GLUCOSE MONITORING
  - IS ANTEPARTUM FETAL TESTING NECESSARY FOR MILD GDMs?
  - DIET TREATMENT EFFECTIVE IN 80-92% OF MILD GDMs IN RANDOMIZED TRIALS

HEALTH CARE COSTS

- COST-BENEFIT ANALYSIS OF ACHOIS TRIAL:
  - COST PER SERIOUS PERINATAL OUTCOME PREVENTED: $27,503
  - COST PER PERINATAL DEATH PREVENTED: $60,506
  - COST PER ADDITIONAL LIFE-YEAR GAINED: $2,988


HEALTH CARE COSTS

- COMPARISON OF COST-EFFECTIVENESS OF ACOG 2-STEP APPROACH VS IADPSG 1-STEP APPROACH
  - ASSUMED RATE OF GDM INCREASED FROM 3.0% TO 16.2%
  - IADPSG APPROACH IS COST EFFECTIVE IF GDMs RECEIVE POST-DELIVERY INTENSIVE COUNSELING AND CARE TO PREVENT TYPE 2 DIABETES
  - IADPSG APPROACH NOT COST EFFECTIVE WITHOUT POST-DELIVERY CARE

  Werner et al. Diab Care 2012; 35: 529.
PREVENTION OF DIABETES

• 350 previous GDMS, FPG 95-125 mg/dl and 2-hr OGTT ≥140 mg/dl
• Randomized to metformin 850 mg BID vs intensive lifestyle intervention vs placebo
• Type 2 diabetes developed in:

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>ANNUAL INCIDENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLACEBO</td>
<td>15.2%</td>
</tr>
<tr>
<td>METFORMIN</td>
<td>7.8%</td>
</tr>
<tr>
<td>INTENSIVE LIFESTYLE</td>
<td>7.4%</td>
</tr>
</tbody>
</table>


PREVENTION OF DIABETES

• NNT TO PREVENT ONE CASE OF DIABETES OVER 3 YEARS:
  • METFORMIN 6.1
  • INTENSIVE LIFESTYLE 5.3


WHY NOT USE IADPSG RECOMMENDATIONS?

2. Uncertainties regarding benefits of identifying and treating so many additional GDMS, associated costs and interventions.

IS THERE EVIDENCE THAT TREATMENT PREVENTS ADVERSE OUTCOMES?

ACHOIS STUDY: Participants

• 16-30 weeks gestation, 18 centers (16 Australia, 2 U.K.)
• GDM risk factor OR abnormal glucose screen
• THEN BUNDEED 2-hour, 75-g OGTT
  • Fasting <140 mg/dL (7.8 mmol/L);
    (mean 86 ± 12 mg/dL)
  • 2-hour 140-198 mg/dL (7.8-11.0 mmol/L)
• Enrolled prior to OGTT, randomized after abnormal result
  • “Intervention” [N=490] vs “Routine Care” [N=510]

Crowther CA, et al. NEJM 352:2477-8, 2005
**Treatment of GDM Reduces Adverse Outcomes**

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>ROUTINE CARE (N = 524)</th>
<th>INTERVENTION (N = 506)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANY SERIOUS PERINATAL COMPLICATION</td>
<td>23 (4%)</td>
<td>7 (1%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Perinatal death</td>
<td>5</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Shoulder dystocia</td>
<td>16</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Bone fracture</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Nerve palsy</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*Crowther CA, et al. ACHOIS NEJM 352:2477-86, 2005*

**Birth Weight**
- ROUTINE CARE: 3482 ± 660
- INTERVENTION: 3335 ± 551
- P < .001

**LGA**
- ROUTINE CARE: 22%
- INTERVENTION: 13%
- P < .001

**Macrosomia (≥4 kg)**
- ROUTINE CARE: 21%
- INTERVENTION: 10%
- P < .001

**Preeclampsia**
- ROUTINE CARE: 18%
- INTERVENTION: 12%
- P = 0.02

**SGA**
- ROUTINE CARE: 7%
- INTERVENTION: 7%
- P = ns

**NICHD MFMU NETWORK STUDY**
- BLINDED 100 GRAM, 3-HR OGTT
- THRESHOLDS:
  - FASTING < 95 MG/DL
  - 1-HR ≥ 180 MG/DL
  - 2-HR ≥ 155 MG/DL
  - 3-HR ≥ 140 MG/DL
- “MILD GDM” = 2 ELEVATED VALUES BUT NORMAL FASTING
- RANDOMIZED TO TREATMENT (N=485) OR ROUTINE CARE (N=473)

*Landon MB et al. NEJM 361:1339-48, 2009*

**Treatment of GDM Reduces Adverse Outcomes**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>NICHID RCT</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>BW &gt;90th percentile</td>
<td>Not treated</td>
<td>14.5</td>
</tr>
<tr>
<td></td>
<td>Treated</td>
<td>7.1</td>
</tr>
<tr>
<td>P &lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-peptide &gt;85th percentile</td>
<td>Not treated</td>
<td>22.8</td>
</tr>
<tr>
<td></td>
<td>Treated</td>
<td>17.7</td>
</tr>
<tr>
<td>P = 0.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NICU admission</td>
<td>Not treated</td>
<td>11.6</td>
</tr>
<tr>
<td></td>
<td>Treated</td>
<td>9.0</td>
</tr>
<tr>
<td>P = 0.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder Dystocia</td>
<td>Not treated</td>
<td>4.0</td>
</tr>
<tr>
<td></td>
<td>Treated</td>
<td>1.5</td>
</tr>
<tr>
<td>P = 0.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preeclampsia</td>
<td>Not treated</td>
<td>5.5</td>
</tr>
<tr>
<td></td>
<td>Treated</td>
<td>2.5</td>
</tr>
<tr>
<td>P = 0.02</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Landon MB et al. NEJM 361:1339-48, 2009*
4. Fasting, waiting 2 hrs is an additional burden for patients

WITH 2-STEP APPROACH, 14-21% OF PATIENTS REQUIRE FASTING THEN WAITING 3 HOURS.

5. 2-hr GTT unstable; 1-step test likely to increase false positives:

- 1-STEP TEST IS A DIAGNOSTIC TEST, NOT A SCREENING TEST
- NO SUCH THING AS A FALSE POSITIVE WITH A DIAGNOSTIC TEST

IMPLICATIONS OF CHANGING

If IADPSG criteria are adopted, the biggest change is not the new thresholds; it is the transition from 2 elevated values to 1 elevated value:

- In HAPO data set, 64% of GDMs were diagnosed on the basis of a single elevated value

O’SULLIVAN & MAHAN (1964)

Rationale for requiring two abnormal values:
“It was considered expedient…to require two or more values to be met or exceeded. In this way misclassification due to a laboratory error, or occasional single high peaks resulting from unusually rapid absorption of glucose, could be avoided.”

AMERICAN DIABETES ASSOCIATION

- ENDORSED IADPSG RECOMMENDATIONS IN JANUARY 2011
- ENDORSED EITHER APPROACH IN JANUARY 2014
- EXPRESSED PREFERENCE FOR IADPSG APPROACH IN JANUARY 2015


WORLD HEALTH ORGANIZATION (W.H.O.)

Summer 2013
- Adopted IADPSG recommendations for GDM diagnosis
- Adopted recommendation for testing for pre-existing diabetes in early pregnancy

WHERE ARE WE NOW?

ACOG:
- NDDG or C&C 100 gram, 3-hr OGTT (2 elevated values)
- Universal 50-gram screen (two-step process)
WHO:
- IADPSG criteria (1 elevated value)
- One-step process
- Test high risk women at first visit for pre-existing diabetes
ADA: Either approach, favor IADPSG

Reference # WHO/NMH/MND/13.2

WHERE ARE WE NOW?

- Still no standard worldwide approach to screening/diagnostic testing
- W.H.O. recommendations
- FIGO about to recommend IADPSG
- Currently some form of IADPSG in:
  - China (variable)
  - India (controversy re fasting)
  - Italy (not universal testing)
  - Germany (2 step)
  - Australia (began 1 Jan 15)

WHERE ARE WE NOW?

- For U.S. to change, it will take more RCTs
- Will NIH fund these?
- Or must the data come from more enlightened countries?

RECENT DATA

- Madrid, Spain
- IADPSG criteria introduced in April 2012
- Compared C&C the year before to first year of IADPSG
- C&C year: 1,750 gravidas
- IADPSG year: 1,526 gravidas
- Treatment regimens the same

Duran A et al. Diab Care 2014;37:2442

MADRID DATA

<table>
<thead>
<tr>
<th></th>
<th>C&amp;C</th>
<th>IADPSG</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDM rate</td>
<td>10.6%</td>
<td>35.5%*</td>
</tr>
<tr>
<td>Hypertensive disorders</td>
<td>4.1%</td>
<td>3.5%*</td>
</tr>
<tr>
<td>Preterm birth</td>
<td>6.4%</td>
<td>5.7%*</td>
</tr>
<tr>
<td>C/S</td>
<td>25.4%</td>
<td>19.7%*</td>
</tr>
<tr>
<td>LGA</td>
<td>4.6%</td>
<td>3.7%*</td>
</tr>
<tr>
<td>SGA</td>
<td>7.7%</td>
<td>7.1%*</td>
</tr>
<tr>
<td>NICU admission</td>
<td>8.2%</td>
<td>6.2%*</td>
</tr>
</tbody>
</table>

*P<0.05

Cost savings 14,358 euros per 100 women

Duran A et al. Diab Care 2014;37:2442
RECENT DATA

- METROHEALTH MED CTR, CLEVELAND
- RETROSPECTIVE REVIEW
- 8,390 GRAVIDAS WHO HAD NL SCREEN OR 100 GM, 3-HR OGTT
- 338 MET C&C CRITERIA (TREATED AS GDMs)
- 281 MET IADPSG AND NOT C&C (NOT TREATED)
- 7,771 CONTROLS (NL OGTT)


CLEVELAND DATA

<table>
<thead>
<tr>
<th></th>
<th>C&amp;C GDM (treated)</th>
<th>IADPSG GDM (untreated)</th>
<th>NORMAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>338</td>
<td>281</td>
<td>7,771</td>
</tr>
<tr>
<td>MEAN BIRTH WEIGHT (GMS)</td>
<td>3,288</td>
<td>3,411*</td>
<td>3,240</td>
</tr>
<tr>
<td>LGA</td>
<td>16.0%</td>
<td>19.9%*</td>
<td>8.8%</td>
</tr>
<tr>
<td>C/S</td>
<td>35.8%</td>
<td>29.2%*</td>
<td>23.4%</td>
</tr>
<tr>
<td>MACROSOMIA</td>
<td>5.9%</td>
<td>9.6%*</td>
<td>5.0%</td>
</tr>
<tr>
<td>NICU ADMISSION</td>
<td>5.3%</td>
<td>8.5% (NS)</td>
<td>6.7%</td>
</tr>
</tbody>
</table>

*P<0.05 IADPSG GDM VS NORMAL


RECENT DATA (CHINA)

- RETROSPECTIVE REVIEW AT PEKING UNIVERSITY HOSPITAL #1 2005-2012
  - 2005-2011, 2-STEP WITH NDDG (75 GM) (N=18,836), GDM 8.4%
  - MAY 2011-31 DEC 2012, IADPSG (N=6,838), GDM 18.9%
- TREATMENT PROVIDED TO:
  - NDDG GDMs IN FIRST EPOCH (N=2,023)
  - IADPSG GDMs IN 2ND EPOCH (N=792)
- NO TREATMENT FOR:
  - IADPSG GDMs IN FIRST EPOCH (N=1,175)
  - NORMAL CONTROLS BOTH EPOCHS (N=21,629)

Yumei et al. Chinese Medical J 2014; 127(20): 3553-3356

RECENT DATA (PEKING STUDY)

<table>
<thead>
<tr>
<th></th>
<th>C/S</th>
<th>MACRO</th>
<th>PIH</th>
<th>NEO HYPO</th>
<th>PhIM</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORMAL</td>
<td>49%</td>
<td>7%</td>
<td>4%</td>
<td>1%</td>
<td>0.4%</td>
</tr>
<tr>
<td>NDDG Tx</td>
<td>58%*</td>
<td>8%</td>
<td>6%*</td>
<td>3%*</td>
<td>0.7%</td>
</tr>
<tr>
<td>IADPSG NO Tx</td>
<td>62%*</td>
<td>15%*</td>
<td>4%</td>
<td>3%*</td>
<td>0.5%</td>
</tr>
<tr>
<td>IADPSG Tx</td>
<td>51%</td>
<td>7%</td>
<td>5%</td>
<td>2%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

*P<0.01 compared to controls
**P<0.01 compared to treated groups

Yumei et al. Chinese Medical J 2014; 127(20): 3553-3356
RECENT DATA
(PEKING STUDY)

C/S MACRO PIH NEO HYPO
EPOCH 1 (NDDG Tx) N=18,836
52.5% 7.5% 6.7% 1.6%
EPOCH 2 (ADPSG Tx) N=6,838
46%* 6.3%* 7.0%+ 1.0%*

*p<0.01 compared to epoch 1
+p=0.04 compared to epoch 1

NICE RECOMMENDATIONS
(UK)

• SELECTIVE TESTING
• 75 GM, 2-HR OGTT
  – FASTING ≥101 MG/DL (5.6 MMOL/L)
  – NO 1-HR MEASUREMENT
  – 2-HRS ≥140 MG/DL (7.8 MMOL/L)

POPULATION DATA

REFERENCES


REFERENCES


Werner EF, Petkner CM, Zuckerwise L, Reel M, Funai EF, Henderson J, Thung SF. Screening for gestational diabetes mellitus: are the criteria proposed by the International Association of Diabetes and Pregnancy Study Groups cost-effective? *Diab Care* 2012;35:529-35.