Streamlining Time to Diagnosis and Treatment of Gestational Diabetes

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Background

• Gestational Diabetes Mellitus (GDM)
  – Glucose intolerance discovered during pregnancy
  – Affects ~ 240,000 (6-7%) pregnancies in the US annually
  – Increased risk for maternal adverse events and neonatal complications

(Moyer, 2014; Landon, 2009; Metzger, 2008)
Background

• Maternal adverse events
  – Hypertension
  – Preeclampsia
  – Polyhydramnios
  – Preterm delivery

• Neonatal complications
  – Macrosomia
  – Shoulder dystocia
  – Birth injuries
  – Hypoglycemia
  – Respiratory distress syndrome
  – Hyperbilirubinemia

• Increased risk for developing type 2 diabetes later in life

(Landon, 2009; Metzger, 2008; Moyer, 2014)
Background

• Lack of consensus on the best method to detect GDM

• Traditionally in the US, women are routinely screened between 24-28 weeks using a two-step procedure

• 1-hour oral glucose challenge test (GCT) and, if abnormal, followed by a fasting 3-hour glucose tolerance test (GTT) on a separate day

(Coustan & Jovanovic, 2015; ACOG, 2013)
Background

At our outpatient women’s center, we observe delayed diagnosis and treatment with two-step screening
Review of Literature: Key Findings

• Timely diagnosis and & treatment of GDM improves outcomes
• Two-step screening approach may lead to missed opportunities for follow-up care
• American Diabetes Association, International Association of Diabetes and Pregnancy Study Groups, and World Health Organization support a one-step screening approach
  – Fasting 2-hour 75gm oral GTT completed in 1 day

(Horvath, 2010; Moyer, 2014; Sievenpiper, 2012; ADA, 2015; Coustan & Jovanovic, 2015; IADPSG, 2010)
Review of Literature: Research supporting one-step GDM screening

Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study

- Published in NEJM 2008
- Purpose: To clarify risks of adverse perinatal outcomes associated with different degrees of maternal glucose intolerance less severe than criteria used to diagnose overt diabetes
- Observational/Correlational Study
- 15 centers in 9 countries
- 25,505 women @ 24-32 weeks gestation completed a 75g 2hr GTT

(IADPSG,2010; Metzger, 2008)
Results:

- Strong association between adverse perinatal outcomes and maternal glucose values below those typical of diagnosed diabetes
  
  • Birth weight > 90\textsuperscript{th} percentile
  • Cord-blood Serum C-peptide > 90\textsuperscript{th} percentile (fetal hyperinsulinemia)
  • Primary C-sec
  • Neonatal hypoglycemia
  • PTD
  • Shoulder dystocia/birth injury
  • NICU admission
  • Hyperbilirubinemia
  • Preeclampsia

- IADPSG developed one-step GDM diagnostic criteria based on findings (IADPSG, 2010; Metzger, 2008)
Review of Literature: Research supporting 1-step GDM screening

To evaluate the prevalence and clinical outcomes using a one-step method versus a two-step method to screen gestational diabetes mellitus

- Published in The Journal of Maternal-Fetal & Neonatal Medicine (2014)
- Randomized Clinical Trial
- Method
  - Group 1 (n=386)-1-step
  - Group 2 (n=400)-2-step
  - Classified into 3 subgroups: IADPSG-negative, GCT-negative, and C&C-negative

(Sevket et al., 2014)
Review of Literature: Research supporting one-step GDM screening

Results:

– Prevalence of GDM was 14.5% using 1-step vs 6% using 2-step

– Women with a normal one-step GTT by IADPSG criteria had better perinatal outcomes vs. women with normal glucose tolerance by the Carpenter-Coustan criteria used for the two-step process

– The incidence of preeclampsia and macrosomia were significantly lower in the IADPSG-negative group compared to the GCT-negative and C&C-negative groups

– Polyhydramnios, LGA, and greater infant birthweight were significantly lower in the IADPSG-negative group vs. the C&C-negative group

(Sevket et al., 2014)
PICO Question

In low-income pregnant women receiving care at a hospital-based outpatient women’s center, what is the effect on time to diagnosis and treatment of a one-step approach compared with the two-step procedure in diagnosing GDM?
Methodology

• An advanced practice nurse team assessed baseline two-step procedure data (n=319 charts) Oct 2014-January 2015
  – Mean time to diagnosis and treatment (diabetes education)
  – Gestational age (GA) at treatment

• We piloted a one-step fasting 2hr GTT GDM screening approach (n=100 women) for six weeks (March-April 2015)

• Post data was collected to identify
  – Average time to diagnosis and treatment
  – GA at treatment
Results: Two-step Procedure

1st Step:
One-hour 50 gram oral GCT
n=319 patients
(1 blood draw/patient)

GCT 140-199 mg/dL
n=59 patients

GCT ≥ 200 mg/dL
n=5 patients

2nd Step:
Fasting Three-hour 100 gram oral GTT
n=82 patients
(7 patients did not complete 2nd step)
(4 blood draws/patient)

GDM Diagnostic Criteria*
- Fasting ≥ 95 mg/dL
- 1 hour ≥ 180 mg/dL
- 2 hour ≥ 155 mg/dL
- 3 hour ≥ 140 mg/dL

GDM Diagnosis
n=22 patients (7%)
GDM diagnosed by GCT
n=5 patients (2%)
GDM diagnosed by 3hr GTT
n=17 patients (5%)

*Two or more values are required for diagnosis per Carpenter-Coxtan criteria
Results: One-step Procedure

Fasting Two-hour 75 gram oral GTT
n=100 patients
(3 blood draws/patient)

GDM Diagnostic Criteria**
Fasting ≥ 92 mg/dL
1 hour ≥ 180 mg/dL
2 hour ≥ 153 mg/dL

GDM Diagnosis
n=10 patients (10%)

**one or more values are required for diagnosis per the International Association of Diabetes and Pregnancy Study Groups criteria
Results

Reduction in Time to GDM Diagnosis and Treatment Comparing the Two-Step to the One-Step

<table>
<thead>
<tr>
<th>Time to Diagnosis</th>
<th>Number of Days (Mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Two-Step</td>
</tr>
<tr>
<td></td>
<td>One-Step</td>
</tr>
<tr>
<td>Range 0-1</td>
<td>0.1</td>
</tr>
<tr>
<td>n=10 patients</td>
<td></td>
</tr>
<tr>
<td>Range 1-44</td>
<td>15</td>
</tr>
<tr>
<td>n=52 patients</td>
<td></td>
</tr>
<tr>
<td>Range 5-16</td>
<td>10</td>
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<tr>
<td>n=9-16 patients</td>
<td></td>
</tr>
<tr>
<td>Range 7-42</td>
<td>29</td>
</tr>
<tr>
<td>n=16 patients</td>
<td></td>
</tr>
</tbody>
</table>
Results

• Mean GA at treatment
  – One-step = 29 weeks (range 26.6-32.1)
  – Two-step = 31 weeks (range 29.4-33.2)

• Compliance
  – 100/112 completed 1-step 2hr GTT (89%)
  – 52/59 completed fasting 3hr GTT (88%)
  – 1 GDM patient from each testing group and 1 GDM patient diagnosed by 1hr GCT failed to attend diabetes education/treatment
Results Summary: Two-step vs One-step

• GDM diagnosis
  – 17:319 patients (5%) vs. 10:100 (10%)
• Mean time to diagnosis
  – 15 days vs. 0.1 days
• Mean time from abnormal screen to treatment
  – 29 days vs 10 days
• Mean GA at treatment
  – 31 wks vs. 29 wks
Summary & Recommendations

• With the one-step approach
  – GDM is diagnosed on the same day
  – Diagnosed more frequently
  – Treatment is on average 19 days earlier than with the two-step approach

• One-step testing for GDM diagnosis is more convenient for the patient
  – Completed in one day
  – Fewer blood draws
Summary & Recommendations

• The results of this EBP project support using the one-step approach for prompt GDM diagnosis and treatment.
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Background

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- Affects ~ 240,000 (6-7%) pregnancies in the US annually (Moyer, 2014)
- Increased risk of maternal adverse events (hypertension, preeclampsia, polyhydramnios, and preterm delivery) and neonatal complications (macrosomia, shoulder dystocia, birth injuries, hyperglycemia, respiratory distress syndrome, and hyperbilirubinemia) (Landon, 2009; Metzger, 2008)
- Increased risk for developing type 2 diabetes later in life (Moyer, 2014)
- Different screening options exist, and there is lack of consensus among professional organizations on the best method to detect GDM (Costas & Jovanovic, 2015)
- Traditionally in the US, women without known diabetes have been screened between 24-28 weeks gestation using a two-step procedure (ACOG, 2013) (Figure 1)
- At our outpatient women’s center, we observe delayed diagnosis and treatment with two-step screening

Review of Literature

Key Findings:
- Timely diagnosis and treatment of GDM improves outcomes (Horvath, 2010; Moyer, 2014)
- Two-step screening approach may lead to missed opportunities for follow-up care due to suboptimal adherence to second step (Stevenpiper, 2012)
- American Diabetes Association, International Association of Diabetes and Pregnancy Study Groups (IADPSG), and World Health Organization support a one-step screening approach (ADA, 2015; Costas & Jovanovic, 2015; IADPSG, 2010) (Figure 1)
- IADPSG developed one-step diagnostic criteria based on the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study findings: strong association between adverse perinatal outcomes and maternal glucose values below those typical of diagnosed diabetes (IADPSG, 2010; Metzger, 2008)
- Women with a normal one-step GTT by IADPSG criteria had better perinatal outcomes compared to women with normal glucose tolerance by the Carpenter-Costas criteria used for the two-step process (Siev, 2014)

PICO Question

In low-income pregnant women receiving care at a hospital-based outpatient women’s center, what is the effect on time to diagnosis and treatment of a one-step approach compared with the two-step procedure in diagnosing GDM?

Methodology

- A team of advanced practice nurses assessed charts (n=339) for baseline two-step procedure data: time to diagnosis and treatment (diabetes education) and gestational age (GA) at treatment (October 2014 - January 2015)
- We piloted a one-step fasting two-hour GTT GDM screening approach (n=100 women) for six weeks (March - April 2015) and collected post data to identify average time to diagnosis and treatment and GA at treatment for patients diagnosed with GDM

Results: Two-step vs One-step Gestational Diabetes Mellitus (GDM) Diagnosis

Two-step procedure completed over 2 weeks:
- One-hour 50 gram oral GTT:
  - 1 hour 140-199 mg/dl
  - 2 hour 140-199 mg/dl
  - Positive greater than 199 mg/dl
- Follow-up 3-hour 100 gram glucose tolerance test (GTT) on a separate day

One-step procedure completed in 1 day:
- Fasting two-hour 100 gram oral GTT:
  - Normal < 140 mg/dl
  - Borderline 140-189 mg/dl
- GTT: positive greater than 189 mg/dl

GDM Diagnostic Criteria:
- Fasting one-hour 140-199 mg/dl
- Two or more values on sequential measurements

GDM diagnosis in 100 patients (100%)

Results: Reduction in Time to GDM Diagnosis & Treatment Comparing the Two-step to the One-step

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<td>15</td>
</tr>
<tr>
<td>Time to Treatment</td>
<td>Range 0-1 n=32 patients</td>
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Results Continued

- Mean GA at treatment using one-step = 29 weeks (range 26.6-32.1)
- Mean GA at treatment using two-step = 31 weeks (range 29.4-33.2)
- 1 GDM patient from each testing group and 1 GDM patient diagnosed by 1 hr GCT failed to attend diabetes education/treatment

Summary & Recommendations

- With the one-step approach, GDM is diagnosed on the same day, more frequently, and treatment is on average 19 days earlier than with the two-step approach
- One-step testing for GDM diagnosis is more convenient for the patient as test is completed in one day with fewer blood draws
- The results of this evidence-based practice project support using the one-step approach for prompt GDM diagnosis and treatment

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Challenges

• One-step procedure not currently part of ACOG guidelines

• Space in our office lab and lobby to hold patient

• Difference in laboratory costs/100 screens w/ 20% needing 2\textsuperscript{nd} step: $964.80
  – 1-step: 2hr GTT=$24.12
  – 2-step: 1hr GCT=$8.04 +3hr GTT=$32.16=$40.20

• Difference in patient charges/100 screens w/ 20% needing 2\textsuperscript{nd} step: $15,220
  – 1-step: 2hr GTT=$444.00
  – 2-step: 1hr GCT=$174.25 + 3hr GTT=$592.75= $762
Future Directions

• We now complete 2\textsuperscript{nd} step of two-step procedure in our office
  – 2 out of 4 readings are usually back before patient leaves our office
  – Diabetes Ed is scheduled sooner
  – QI project

• Plan to share results within our physician group, maternal fetal medicine, diabetes education, THR, and at regional and national conferences.
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- Shae Martinez, Texas Health Dallas Medical Librarian
- Texas Health Dallas Women’s Health Center Staff
Change

If you want to make enemies, try to change something.
-Woodrow Wilson

Change is the law of life. And those who look only to the past or present are certain to miss the future.
-John F. Kennedy
Questions
References

References

