Pregestational Diabetes Mellitus Pilot Study with Diabetes Self Management Program (DSMP) and Wireless Enabled Meter

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PRISMA HEALTH™
I have no meaningful conflicts of interest to declare.
Background
Background

• 14.9 million women have diabetes

• Type I or II complicates 1-2% of pregnancies

• Higher incidence in African Americans & Hispanics compared to Caucasians

• Obesity
Background

• Uncontrolled DM leads to:
  • SAB
  • Fetal anomalies
  • Preeclampsia
  • IUFD
  • Macrosomia
  • Neonatal hypoglycemia
  • Neonatal hyperbilirubinemia
## Background

<table>
<thead>
<tr>
<th>Insulin resistance increases with trimester</th>
<th>More frequent monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medication adjustments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ACOG recommends targeted therapy for DM</th>
<th>Diet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exercise</td>
</tr>
<tr>
<td></td>
<td>Nutrition counseling</td>
</tr>
</tbody>
</table>

| OB/GYN Center: 2775 patients/year      | 16% have history of or overt diabetes |

| May 2016 Diabetes Self-Management program began | 15-30 minute diabetes education sessions |


Purpose

The purpose of this study is to provide improved management of diabetes during pregnancy using remote patient monitoring and improve patient understanding of diabetes and diabetes self-management.
Methods
Methods

• **Pilot study:** Prospective and retrospective

• **Inclusion criteria:**
  • Patients with pre-gestational Type I or II diabetes
  • 18 years or older
  • Care at OB/GYN Center

• **Exclusion criteria:**
  • Patients with gestational diabetes
Methods

Recruitment

• Patient presented for prenatal care
• Assessment
• Referred to DSMP via EMR
• CDE performed initial education visit
# Methods

## Retrospective group
- June 2016 - January 2017
- 25 patients
- Standard of care
  - *CGM

## Intervention group
- February 2017 - January 2018
- 25 patients
- Standard of care with enhanced model
  - Wireless meter
  - *CGM
Methods

**Patient Care Team**
- Co-management for treatment decisions
  - 15-30 minute CDE session
  - Face-to-face contact with OB
  - Referral as needed
Methods

Data Collection

- Between visits: Remote review, contacted patient via text/phone/email/meter message
- EMR documentation
- Chart review
- RedCap database
- PHQ-8 at study start and end
- Diabetes Assessment Pre/post-questionnaire
Methods

Outcomes

Primary:
• Increased adherence rate of DM monitoring
• Increased medication utilization

Secondary:
• Improved patient understanding
• Improved self-management
• Decreased hyper/hypoglycemic events
• Time to achieve euglycemia
• Less pre-delivery admissions
• Less maternal-fetal complications
Statistical Analysis

R statistical software

Student’s t-test or Wilcoxon rank-sum

Chi-squared or Fisher’s exact test

P-values < 0.05 were statistically significant
Results
Results

Demographics

• Only one baseline difference noted

Intervention group started study at 10.8 weeks

Standard group started study at 15.4 weeks

($p = 0.02$)
# Results

<table>
<thead>
<tr>
<th>Table 1: Demographics</th>
<th>Type of Participant</th>
<th>Intervention</th>
<th>Standard Diabetes Care</th>
<th>P-value</th>
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<tbody>
<tr>
<td><strong>N</strong></td>
<td>25</td>
<td>25</td>
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<td></td>
</tr>
<tr>
<td><strong>Age, Mean ± SD</strong></td>
<td>29.2 ± 6.16</td>
<td>31.6 ± 6.39</td>
<td></td>
<td>0.174</td>
</tr>
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<td><strong>Pregestational Diabetic Type, N(%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.529</td>
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<tr>
<td>Type 1</td>
<td>8 (32)</td>
<td>6 (24)</td>
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<tr>
<td>Type 2</td>
<td>17 (68)</td>
<td>19 (76)</td>
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<td><strong>Gestational Age at Enrollment, Mean ± SD</strong></td>
<td>16.2 ± 7.18</td>
<td>NA</td>
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<tr>
<td><strong>Gestational Age at Start of Study, Mean ± SD</strong></td>
<td>10.8 ± 4.82</td>
<td>15.4 ± 7.93</td>
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<td><strong>On Medication at Study Start, N(%)</strong></td>
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<td>Yes</td>
<td>17 (68)</td>
<td>18 (72)</td>
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<tr>
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<td>8 (32)</td>
<td>7 (28)</td>
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<td><strong>Number of Medications at Study Start, N(%)</strong></td>
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<td>2</td>
<td>8 (32)</td>
<td>12 (48)</td>
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</tr>
<tr>
<td>3</td>
<td>1 (4)</td>
<td>2 (8)</td>
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<tr>
<td>4</td>
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<tr>
<td>5</td>
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<td>&gt;5</td>
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<td>7 (28)</td>
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<td><strong>Type of Medication, N(%)</strong></td>
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<td>Metformin</td>
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<td>Glyburide</td>
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<tr>
<td>SGLT2</td>
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<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td>12 (48)</td>
<td>17 (68)</td>
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<td></td>
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<tr>
<td><strong>Patient Provided Glucose Log at Study Start, N(%)</strong></td>
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<td></td>
<td></td>
<td>0.208</td>
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<tr>
<td>Yes</td>
<td>23 (92)</td>
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<td></td>
</tr>
<tr>
<td>No</td>
<td>2 (8)</td>
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<td>NA</td>
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</tr>
</tbody>
</table>
Results

Tracking Visits

• No differences noted in type and number of visits
  • Prenatal care visits
  • Hospital admissions
  • Emergency Department
  • OB Triage
  • LOS
Results

Contact via Text
- Intervention: N of 13
- Standard: N of 4

Contact via Phone
- Intervention: mean 9.65
- Standard: mean 5.27

Contact via Office
- Intervention: mean 12.8
- Standard: mean 8.72

$p = 0.007$

$p = 0.011$

$p = 0.017$
Results

• Intervention group spent more time in education vs. standard care group
  • 4.44 hours vs. 2.89 hours
  • $p = 0.03$
Results

Pregnancy Outcomes

• No differences in:
  • Medication adjustments
  • Timing/amount of hyper/hypoglycemic events
  • Mode of delivery
  • Infant anomalies
  • Infant delivery weight
  • Delivery gestational age
  • APGARs
  • Delivery complications
## Results

### Pregnancy Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 25)</th>
<th>Control (n = 25)</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Hypoglycemic events</td>
<td>12.7 ± 22.7</td>
<td>5.6 ± 9.02</td>
<td>0.180</td>
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<tr>
<td>Hyperglycemic events</td>
<td>20.5 ± 29.1</td>
<td>9.32 ± 19.7</td>
<td>0.141</td>
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<tr>
<td>Use of continuous glucose</td>
<td>15 (60)</td>
<td>6 (24)</td>
<td>0.010</td>
</tr>
<tr>
<td>monitor, n (%)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Gestational age at delivery,</td>
<td>34.8 ± 4</td>
<td>36 ± 2.45</td>
<td>0.213</td>
</tr>
<tr>
<td>weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonatal hypoglycemia, n (%)</td>
<td>3 (12)</td>
<td>9 (26)</td>
<td>0.047</td>
</tr>
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<td></td>
<td></td>
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</tr>
</tbody>
</table>
Results

Postpartum Outcomes

- 22 patients (88%) completed study
- 22 patients (88%) completed postpartum visit
- 22 patients (88%) had a documented PCP or were referred to PCP
Results

Questionnaires

• PHQ-8:
  • Pre-test – 22 patients, mean score 13.8
  • Post-test – 5 patients, mean score 5
  • Score ≥ 10 indicates major depression

• Diabetes Assessment:
  • No differences noted pre-test to post-test
Discussion
Discussion

Increased phone contacts, office visits and text messaging noted for intervention group

Overall increased time in education

More use of CGM along with wireless meter

Accurate, real-time data

Log comparison

Better informed treatment decisions

Earlier delivery

Decreased neonatal hypoglycemia
Discussion

• 88% of intervention group:
  • Completed the study
  • Postpartum visit
  • Long-term follow up with PCP

• Postpartum
  • Lost to follow up
  • Insurance coverage ends with pregnancy
  • End of access to care

• Technology improves biofeedback and ownership of disease process
Discussion

• Telehealth impact on obstetrics
  • 2010 Patient Protection and Affordable Care Act

• Mixed data on outcomes
  • 2017 Cochrane review
  • CONCEPPT trial

• Continuous glucose monitor (CGM)
<table>
<thead>
<tr>
<th>Date</th>
<th>Fasting</th>
<th>2 hrs Brk</th>
<th>2 hrs Lwn</th>
<th>2 hrs Din</th>
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<td>120</td>
<td>127</td>
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<td><strong>9/25</strong></td>
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<td>98</td>
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<td>122</td>
<td>131</td>
<td>136</td>
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Telcare System

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<tr>
<th>Date</th>
<th>Active Date</th>
<th>Tests</th>
<th>Prescribed</th>
<th>Adherence</th>
<th>Last Reading</th>
<th>Low Readings (24h)</th>
<th>High Readings (24h)</th>
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<tr>
<td>2017-04-27</td>
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<tr>
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</tbody>
</table>
CGM Download

**Statistics**
- Average Glucose: 147 mg/dL
- Sensor Usage: 7 of 7 Days
- Calibrations / day: 3.7
- Standard Deviation: ± 63 mg/dL

**Target Range**: 60 - 120 mg/dL
**Nighttime**: 10:00 PM - 0:00 AM

**Interpretation**

**Daily Patterns** (with Ambulatory Glucose Profile)
10 August 2017 - 17 August 2017 (8 days)

**Estimated A1c**: 9.4%, or 79 mmol/mol
Discussion

• Study limitations
  • Sample size
  • Patient buy-in
    • Glucose testing 1-2X/day
    • Recommended 4X/day

• Convenience of testing

• Social barriers to healthcare
  • Remote data review and treatment adjustments

• Improved communication

• Results clinically significant
Conclusion

• Remote glucose monitoring with wireless technology in diabetes for pregnant mothers is an enhanced care model

• More time is spent in education

• Treatment decisions are more obvious

• Leads to improved patient engagement
Future Implications

- Studies to include a larger patient population and patients with gestational diabetes.
- The standard of care
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References


- Graphics: