The STORCC Initiative: Standardized Outcomes in Reproductive Cardiovascular Care

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Disclosures

The STORCC initiative is supported by the Brigham and Women’s Hospital Watkins Discovery Award, the Barton and Weinberg Family Fund, the Connors Center for Women and the Boston Adult Congenital Heart Disease Program Dunlevie Fund and Sarah Marie Liamos Fund for Adult Congenital Heart Disease Research

The PICCALO initiative is supported by the Brigham and Women’s Heart Center Linda J. Pollin Innovation Award
Case: The Harrowing Narrowing

- 29-year-old, G2P1 nurse with a bicuspid aortic valve
- Six years ago: 25-mm Perimount pericardial tissue AVR
- Three years ago: Uneventful pregnancy and delivery
- Two years ago: Asymptomatic, Aortic valve peak 30 mmHg and mean 20 mmHg, mild AR, normal LV size & function

Current presentation
- 24 weeks gestation: dyspnea and a presyncopal event
- 32 weeks gestation: 2nd presyncopal event

Severe Prosthetic Valve AS
Next Steps

- Multidisciplinary team meeting with maternal fetal medicine, cardiology, interventional cardiology and cardiac surgery

- Management options:
  - Valve-in-valve transcatheter Ao valve replacement (TAVR)
  - Surgical aortic valve intervention
  - Admit for observation and monitoring
  - Early Cesarean delivery

How do we make these decisions?
Objectives

- To recognize the risk factors for adverse maternal outcomes in pregnant women with cardiovascular disease
- To describe the development of the Pregnancy and Cardiovascular Disease Program at the Brigham & Women’s Hospital
- To discuss the STORCC initiative’s initial findings

Hemodynamics of Pregnancy

- Plasma volume
- Stroke volume
- Heart rate
- Cardiac output
- SVR

Duration of pregnancy (weeks)
Pre-Pregnancy Risk Assessment

- Maternal cardiac issues
- Obstetrical issues
- Neonatal issues

Correspondence

Pregnancy and Contraception in Congenital Heart Disease: What Women Are Not Told

- 37% of women denied having been told they were at increased risk of complications
- Only 50% had received contraceptive counseling

Kovacs A. *J Am Coll Cardiol* 2008

Maternal Cardiac Risk Stratification

<table>
<thead>
<tr>
<th>CARPREG</th>
<th>ZAHARA (weighted)</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior CVD event</td>
<td></td>
<td>Class I: Low risk: PS, PDA, MVP, repaired ASD</td>
</tr>
<tr>
<td>NYHA Class &gt;II or cyanosis</td>
<td>HVOTO peak &gt;50 mmHg or AVA &lt;1 cm² (2.5)</td>
<td>Class II: Moderate risk: repaired TOF, unrepaired ASD, ASD</td>
</tr>
<tr>
<td>LVOT peak &gt;30 mmHg; MVA &lt;2.0 cm²; AVA &lt;1.5 cm²</td>
<td>Hx of arrhythmia (1.5)</td>
<td>Class III: High risk*</td>
</tr>
<tr>
<td>Systemic ventricular EF &lt;40%</td>
<td>Cardiac Meds (1.5)</td>
<td>Class IV: Contraindicated*</td>
</tr>
<tr>
<td>Cyanotic HD (1.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NYHA &gt; II (.75)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVVR ≥ moderate (.75)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Siu S et al *Circulation* 2001; Drenthen W et al *Eur Heart J* 2010; Regitz-Zagrosek V et al *Eur Heart J* 2011
### WHO Classification: Maternal Cardiac Risk

**European Society of Cardiology Guidelines**

<table>
<thead>
<tr>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyanotic heart disease</td>
<td>Pulmonary hypertension</td>
</tr>
<tr>
<td>Mechanical valve</td>
<td>Severe systemic ventricular dysfunction (ejection fraction &lt;30%, NYHA III-IV)</td>
</tr>
<tr>
<td>Systemic right ventricle</td>
<td>Severe symptomatic aortic stenosis</td>
</tr>
<tr>
<td>Fontan</td>
<td>Native severe coarctation</td>
</tr>
<tr>
<td>Marfan syndrome: aorta 40-45 mm</td>
<td>Marfan syndrome: aorta &gt;45 mm</td>
</tr>
<tr>
<td>Bicuspid aortic valve: aorta 45-50 mm</td>
<td>Bicuspid aortic valve: aorta &gt;50 mm</td>
</tr>
</tbody>
</table>

**Significantly increased risk of severe maternal morbidity and mortality**

Regitz-Zagrosek V. et al. *Eur Heart J* 2011

### Long-term Risk of Vascular Events

![Graph showing the risk of cardiac events over time](Image)

- **Adverse Maternal Cardiac Events During Pregnancy**: 27±9%
- **No Adverse Maternal Cardiac Events During Pregnancy**: 13±3%

Balint OH et al. *Heart* 2010
Registry on Pregnancy and Cardiac Disease (ROPAC)

- 60 hospitals, 28 countries (86% developed countries)
- 1321 pregnant women from 2007-2011
- 66% had congenital heart disease
- 15% hospitalized for cardiac reason: heart failure
- Majority of women deliver safely if:
  - Adequate pre-pregnancy evaluation
  - Specialized high-quality care during pregnancy and delivery
- Since initial publication, multiple others manuscripts on specific cardiac conditions and outcomes during pregnancy

Roos-Hesselink JW et al. *Eur Heart J* 2012

Back to Our Case

29-year-old nurse with severe prosthetic aortic valve dysfunction at 32 weeks gestation

"Timing is everything"
Pregnancy Risk: Aortic Stenosis

- 96 women with aortic stenosis
  - 62: moderate AS (peak gradient 36 – 63 mmHg)
  - 34: severe AS (peak gradient ≥64 mmHg)
- 21% hospitalized during pregnancy: no deaths
  - More common in severe AS (25% vs. 13%, p=0.02)
  - Highest in **symptomatic** severe AS
- 35% of patients with severe AS had LBW infants


AS: Predictors of Adverse Maternal Outcome

BWH Pregnancy & Cardiovascular Disease Program

• Multidisciplinary program
• Available: 24/7, 365 days/year
• Inpatient consultations to women of childbearing age requiring valve interventions
• Weekly outpatient clinic
  – Pregnant women with heart & vascular disease
  – Pre-pregnancy & contraception consultations
  – Consultations for pregnant women with concerning symptomatology
  – Coordinated management of women with hypertension with follow-up after pregnancy

BWH Pregnancy & Cardiovascular Disease Program

• Monthly meeting to review pregnancy events & delivery plans
  – Obstetrics, OB anesthesia, Nursing, Cardiology
  – Neonatology and CT surgery when needed
• Individualized care plan clearly defining management and potential complications is developed and placed in record
• Congenital heart disease anatomy diagram in EPIC
• Nurses are cross-trained in OB and cardiology
The Team

Monthly Multidisciplinary Meeting

A STORCC color code is assigned to each woman as a visual adjunct to clinical classification of perceived low, intermediate and high risk for adverse outcomes for each subspecialty care category based on level of the multidisciplinary team’s consensus.
Patient Name

- Echo, Date (BCH): Mild MR (sub-pulm), LV (sub pulm) HTN (80-85). Mod conduit obstruction. Mild (systemic) TS (grad 6-8)/TR. No (systemic) RVOTO. Mild AR. Mild RV dysfunction.
- Cath, Date: CI 3L/min/m², PAp 15-18, RVp 98-10, RVEDP 8-12. LVOT gradient 20-25
- Holter, Date: Rare PVCs, V-couplets
- Exercise test: Deferred
- Fetal echo, Date: Normal
- NT-proBNP
  - Date 502 pg/ml
  - Date 829 pg/ml

Developing a Delivery Plan

- Timing – what is the optimal gestational age?
- Who is on the team?
  - Nursing, Cardiology, Anesthesiology, MFM, Neonatology, Social Work
- How to deliver?
  - Vaginal delivery, Cesarean delivery, Assisted second stage
- Where to deliver and what type of monitoring?
  - Labor and delivery unit, Operating room, Cardiac floor or intensive care unit
Our Case Continues

Admitted to the hospital
Cardiac evaluation:
- CMR for TAVR planning:
  - Asc Ao = 5.4 cm
- Right heart catheterization:
  - RA 1 mmHg
  - PA 17/6 mmHg
  - PCWP 7 mmHg
  - CI 3.2 L/min/m²

Where and When to Deliver?

- At 36 weeks, an assisted second stage delivery scheduled
- Moved to the CCU
- Obstetric planning:
  - Cervical ripening
  - Epidural placed with some hypotension
- Moved to hybrid OR for delivery
  - 4F femoral line placed
  - Vacuum-assisted vaginal delivery (6 lb 14 oz girl)

Everyone in the OR had a specific role
The frequency at which women with CVD should be clinically evaluated during pregnancy is not established.

The AHA published a scientific statement on the management of pregnancy in women with complex congenital heart disease emphasizing the need for multidisciplinary meeting, however, the utility of these meetings has not been demonstrated.

**Clinical Program with Research Focus**

**AHA SCIENTIFIC STATEMENT**

**Management of Pregnancy in Patients With Complex Congenital Heart Disease**

A Scientific Statement for Healthcare Professionals From the American Heart Association

Recommendation:

“From a practical point of view, inductions should be initiated so that delivery will likely occur during regular hours when the adult CHD teams are readily available.”
STORCC Initiative

- Standardized Outcomes in Reproductive Cardiovascular Care
- Funded by the BWH Watkins Discovery Award
- Objectives: To establish, assess and validate a prospective standardized protocol for the clinical evaluation of pregnant women with CVD

STORCC Study Design

- Prospectively enrolled pregnant women with heart disease, including congenital or acquired cardiac lesions or those with arrhythmias
- Inclusion criteria:
  ✓ Age ≥18 years
  ✓ Care at the Brigham & Women’s Hospital
- Exclusion criteria:
  ✓ Failure to provide informed consent
- Institutional Review Board approval
STORCC Cardiac High-Risk

Presence of one of more of these risk factors:
- Prior adverse cardiac event
- New York Heart Association (NYHA) Class >II
- Oxygen saturation ≤90%
- Systemic ventricular ejection fraction (EF) <40%
- LVOT peak gradient >30 mmHg
- Connective tissue disorder

STORCC Standardized Protocol

Valente AM et al. Manuscript in preparation
STORCC Initial Results

- Analysis: September 2011 through November 2016
- 214 pregnant women w/ CVD -> 257 pregnancies
- 7 women excluded due to early miscarriage
- 250 pregnancies
  - 136 standardized protocol
  - 114 routine care

Baseline Maternal Characteristics

<table>
<thead>
<tr>
<th>Total (n=250)</th>
<th>Routine Care (n=114)</th>
<th>Standardized Care (n=136)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age at enrollment (years)</td>
<td>32 (19 - 42)</td>
<td>32 (19 - 42)</td>
<td>31 (20 - 40)</td>
</tr>
<tr>
<td>Parity</td>
<td>1 (0 - 4)</td>
<td>1 (0 - 3)</td>
<td>1 (0 - 4)</td>
</tr>
<tr>
<td>Multiple gestation</td>
<td>7 (3%)</td>
<td>3 (3%)</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Type of heart disease</td>
<td>192 (77%)</td>
<td>70 (61%)</td>
<td>122 (90%)</td>
</tr>
<tr>
<td>Congenital heart disease</td>
<td>28 (11%)</td>
<td>19 (17%)</td>
<td>9 (7%)</td>
</tr>
<tr>
<td>Connective tissue disorders</td>
<td>22 (9%)</td>
<td>21 (18%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Valvular</td>
<td>4 (2%)</td>
<td>3 (3%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Vascular</td>
<td>4 (2%)</td>
<td>1 (1%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Anatomical disease complexity</td>
<td>76 (30%)</td>
<td>37 (32%)</td>
<td>39 (29%)</td>
</tr>
<tr>
<td>Simple</td>
<td>76 (30%)</td>
<td>20 (18%)</td>
<td>56 (41%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>98 (40%)</td>
<td>57 (50%)</td>
<td>41 (30%)</td>
</tr>
<tr>
<td>Complex</td>
<td>30 (12%)</td>
<td>19 (17%)</td>
<td>11 (8%)</td>
</tr>
<tr>
<td>Prior adverse cardiovascular event</td>
<td>5 (2%)</td>
<td>3 (3%)</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>Pre-existing diabetes</td>
<td>31 (12%)</td>
<td>16 (14%)</td>
<td>15 (11%)</td>
</tr>
</tbody>
</table>

Median (range), or frequency (percent)
### Maternal Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Total (n=250)</th>
<th>Routine Care (n=114)</th>
<th>Standardized Care (n=136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-blocker use pre-pregnancy</td>
<td>59 (20%)</td>
<td>20 (25%)</td>
<td>21 (15%)</td>
</tr>
<tr>
<td>Anxiety or depression</td>
<td>82 (33%)</td>
<td>42 (37%)</td>
<td>40 (29%)</td>
</tr>
<tr>
<td>Assisted reproductive technology</td>
<td>28 (11%)</td>
<td>13 (11%)</td>
<td>15 (11%)</td>
</tr>
</tbody>
</table>

### Diagnostic Testing Results

- **Exercise testing (68%)**
  - Peak oxygen consumption = 20 ml/kg/min
  - 69% predicted peak VO2
  - Chronotropic index = 0.70
- **Holter monitoring (82%)**
  - 13% non-sustained SVT
  - 8% non-sustained VT
- **Echocardiography (100%)**
  - 94% normal systemic ventricular function
  - 14% LVOT gradient >30 mmHg
Serial Echocardiograms

- 14 women (10%) had significant changes by echo:
  - decrease in systemic ventricular function (4)
  - decrease in pulmonary ventricular function (1)
  - accelerated increase in valvular gradient (4)
  - pericardial effusion (3)
  - valvular vegetation (1)
  - aortic dissection (1)

- This resulted in change of management in 4 women:
  - percutaneous Ao valve placement during the 2nd trimester
  - admission to the cardiac intensive care unit
  - change in location of delivery (2)

Compliance

- Patient compliance with standardized protocol visits:
  - 252/272 completed visits (93%) in the 2nd and 3rd trimesters
  - 104/136 (76%) completed postpartum visits

- Patient compliance with echocardiography:
  - Higher in the low-risk group (90%) vs. high-risk (74%)
  - 24 women did not complete a postpartum echo
  - 33 women had an additional echo outside of protocol
    - None of the results changed management
### BNP

<table>
<thead>
<tr>
<th>Cardiac Outcome</th>
<th>Total (n=184)</th>
<th>BNP &gt;450 pg/ml (n=13)</th>
<th>BNP &lt;450 pg/ml (n=171)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 (10%)</td>
<td>5 (38%)</td>
<td>13 (8%)</td>
<td>0.004</td>
<td></td>
</tr>
</tbody>
</table>

*Elevated BNP in pregnancy or the postpartum period was associated with greater chance of adverse cardiac outcomes*

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### Back to our Case

- Three days post-partum: significant heart failure requiring aggressive diuresis
- NT-pro BNP elevated at 2958 pg/ml
- Five days post-partum: mechanical AVR, replacement of ascending aorta

Her question: Is it safe for me to have more children?
Anticoagulation: Mechanical Valves Pregnancy

Nishimura R et al. *Circulation* 2014

STORCC Outcomes

<table>
<thead>
<tr>
<th>Total (n=250)</th>
<th>Routine Care (n=114)</th>
<th>Standardized Care (n=136)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any cardiac outcome</td>
<td>25 (10%)</td>
<td>13 (11%)</td>
<td>12 (9%)</td>
</tr>
<tr>
<td>Any obstetric outcome</td>
<td>110 (44%)</td>
<td>46 (40%)</td>
<td>64 (47%)</td>
</tr>
<tr>
<td>Any neonatal outcome</td>
<td>80 (32%)</td>
<td>32 (28%)</td>
<td>48 (35%)</td>
</tr>
</tbody>
</table>

- Cardiac: HF 5%, Sustained arrhythmia 2%, Cardiac intervention 2%
- Obstetric: Preterm delivery 12%, Postpartum Hemorrhage 9%
- Neonatal: NICU admission 26%, SGA 8%, Fetal CHD 6%
**STORCC: Limitations**

- Women often presented for care beyond 20 weeks gestation
- Protocol deviations occurred
- Classification of all connective tissue patients as high-risk
- STORCC color codes are subjective
### STORCC: Patient Surveys

<table>
<thead>
<tr>
<th>Response</th>
<th>Total (n = 236,204)</th>
<th>Routine Care (n=108,88)</th>
<th>Standardized Protocol (n=128,116)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referred by HCP</td>
<td>172 (73%)</td>
<td>85 (79%)</td>
<td>87 (68%)</td>
</tr>
<tr>
<td>Referred by friend</td>
<td>17 (7%)</td>
<td>10 (9%)</td>
<td>7 (5%)</td>
</tr>
<tr>
<td>Referred by ACHA</td>
<td>32 (14%)</td>
<td>7 (6%)</td>
<td>25 (20%)</td>
</tr>
<tr>
<td>Counseled to avoid pregnancy</td>
<td>41 (17%)</td>
<td>19 (18%)</td>
<td>22 (17%)</td>
</tr>
<tr>
<td>Right amount of testing</td>
<td>178 (87%)</td>
<td>81 (92%)</td>
<td>97 (84%)</td>
</tr>
</tbody>
</table>

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### STORCC: Summary

- The STORCC protocol for prospective diagnostic testing and follow of pregnant women with CVD was successfully established and compliance was high.
- The strength of standardized testing and care protocols as well as detailed classification of labor and delivery characteristics allows for robust analyses into specific questions regarding mode and timing of delivery.

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Mode of Delivery

• Consensus guidelines typically reserve Cesarean delivery for obstetric indications with specific exceptions for high-risk CVD

• However, there is a reported 33% rate of primary Cesarean delivery for cardiac indications

• Hypothesis: Planned vaginal birth confers no increased risk of obstetric or cardiovascular morbidity compared to planned Cesarean delivery in women with CVD

Maternal Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Planned Vaginal Birth (n=210)</th>
<th>Planned Cesarean Delivery (n=66)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal Age</td>
<td>33 (29-35)</td>
<td>34 (29-38)</td>
<td>0.06</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>111 (52.9)</td>
<td>19 (28.8)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Preterm</td>
<td>25 (11.9)</td>
<td>19 (28.8)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>OB Comorbidity Index</td>
<td>4 (3-5)</td>
<td>5 (3-6)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>High-Risk Cardiac Disease</td>
<td>73 (34.8)</td>
<td>25 (37.9)</td>
<td>0.64</td>
</tr>
<tr>
<td>Adverse Cardiac Event in Pregnancy</td>
<td>8 (3.8)</td>
<td>7 (10.6)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

Key Definitions: High-Risk Cardiac Disease defined as prior adverse event, NYHA Class > II, oxygen saturation <90%, systemic EF <40%, LVOT peak gradient > 50 mmHg, or aortopathy associated with connective tissue disease. Adverse Cardiac Event refers to any component of the composite cardiac outcome unrelated to delivery.
Actual Mode of Delivery According to Planned Mode of Delivery

- 210 Attempted Vaginal Birth (76.1%)
- 161 Spontaneous Vaginal Delivery (76.7%)
- 20 Operative Vaginal Delivery (9.5%)
- 15 Obstetric Indication (7.1%)
- 29 Cesarean Delivery (13.8%)
- 5 Cardiac Indication (2.4%)
- 27 Ineligible for Vaginal Birth (40.9%)
- 39 Eligible but Declined (59.1%)
- 66 Planned Cesarean Delivery (23.9%)

Note: One patient presenting with an acute aortic dissection was deemed ineligible for vaginal birth and delivered by cesarean delivery.

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Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Planned Vaginal Birth (n=210)</th>
<th>Planned Cesarean Delivery (n=66)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite Cardiac</td>
<td>9 (4.3)</td>
<td>2 (3.0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Sustained Arrhythmia</td>
<td>1 (0.48)</td>
<td>0 (0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>7 (3.3)</td>
<td>2 (3.0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Composite Obstetric</td>
<td>21 (10.0)</td>
<td>11 (16.7)</td>
<td>0.08</td>
</tr>
<tr>
<td>Postpartum Hemorrhage</td>
<td>4 (1.9)</td>
<td>7 (10.6)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Infection</td>
<td>19 (9.0)</td>
<td>5 (7.6)</td>
<td>0.81</td>
</tr>
<tr>
<td>Venous Thromboembolism</td>
<td>0 (0)</td>
<td>3 (4.5)</td>
<td>0.01</td>
</tr>
<tr>
<td>Severe Maternal Morbidity</td>
<td>9 (4.3)</td>
<td>8 (12.1)</td>
<td>0.04</td>
</tr>
<tr>
<td>Maternal ICU Admission</td>
<td>1 (0.48)</td>
<td>2 (3.0)</td>
<td>0.14</td>
</tr>
<tr>
<td>Neonatal ICU Admission</td>
<td>4 (1.9)</td>
<td>1 (1.5)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Sensitivity Analysis: No difference in the primary cardiac outcome or the secondary adverse obstetric outcome in the subset of women with high-risk cardiac disease or those with obstetric comorbidity indices ≥ 7.

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Timing of Delivery

- The American College of Obstetrics and Gynecology recommends against early term delivery in the absence of a medical indication
- “Early term”: 37 weeks through 38 weeks 6 days
- “Term”: 39 weeks and beyond
- Hypothesis: To examine maternal outcomes in women with CVD who delivered in the early term period compared with those who delivered later

Rouse CE et al. Manuscript in preparation

Maternal Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Early term (n=83)</th>
<th>Term (n=142)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal Age</td>
<td>32 (29-35)</td>
<td>32 (29-35)</td>
<td>0.77</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>31 (37.3)</td>
<td>72 (50.7)</td>
<td>0.17</td>
</tr>
<tr>
<td>Prior Cesarean</td>
<td>23 (27.7)</td>
<td>20 (14.1)</td>
<td>0.12</td>
</tr>
<tr>
<td>Hypertension</td>
<td>15 (18.1)</td>
<td>10 (7.0)</td>
<td>0.01</td>
</tr>
<tr>
<td>High-Risk Cardiac Disease</td>
<td>13 (15.7)</td>
<td>19 (13.4)</td>
<td>0.64</td>
</tr>
<tr>
<td>Adverse Cardiac Event in Pregnancy</td>
<td>5 (6.0)</td>
<td>4 (2.8)</td>
<td>0.14</td>
</tr>
</tbody>
</table>

Key Definitions: High-Risk Cardiac Disease defined as prior adverse event, NYHA Class > II, oxygen saturation <90%, systemic EF <40%, LVOT peak gradient > 30 mmHg, or aortopathy associated with connective tissue disease. Adverse Cardiac Event refers to any component of the composite cardiac outcome unrelated to delivery.

Rouse CE et al. Manuscript in preparation
## Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Early Term (n=83)</th>
<th>Term (n=142)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cesarean Delivery</td>
<td>36 (43.4)</td>
<td>35 (24.6)</td>
<td>0.004</td>
</tr>
<tr>
<td>Composite Cardiac</td>
<td>4 (4.8)</td>
<td>5 (3.5)</td>
<td>0.24</td>
</tr>
<tr>
<td>Sustained Arrhythmia</td>
<td>1 (1.2)</td>
<td>0</td>
<td>0.44</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>3 (3.6)</td>
<td>5 (3.5)</td>
<td>0.44</td>
</tr>
<tr>
<td>Composite Obstetric</td>
<td>7 (8.4)</td>
<td>14 (9.9)</td>
<td>0.72</td>
</tr>
<tr>
<td>Postpartum Hemorrhage</td>
<td>2 (2.4)</td>
<td>4 (2.8)</td>
<td>0.33</td>
</tr>
<tr>
<td>Infection</td>
<td>6 (7.2)</td>
<td>10 (7.0)</td>
<td>0.96</td>
</tr>
<tr>
<td>Venous Thromboembolism</td>
<td>1 (1.2)</td>
<td>2 (1.4)</td>
<td>0.44</td>
</tr>
<tr>
<td>Severe Maternal Morbidity</td>
<td>3 (3.6)</td>
<td>7 (4.9)</td>
<td>0.24</td>
</tr>
<tr>
<td>Maternal ICU Admission</td>
<td>1 (1.2)</td>
<td>0</td>
<td>0.37</td>
</tr>
<tr>
<td>Neonatal ICU Admission</td>
<td>1 (1.2)</td>
<td>4 (2.8)</td>
<td>0.64</td>
</tr>
</tbody>
</table>

Rouse CE et al. Manuscript in preparation

## Indications for Non-spontaneous Delivery

Rouse CE et al. Manuscript in preparation
Newest Initiative: PICCALO

- **Pregnancy: Influencing Cardiac Care to Affect Lifelong Outcomes**
- Funded by the BWH Linda J. Pollin Award
- The American College of Obstetrics and Gynecology recommends that healthy pregnant women exercise at moderate intensity for at least 30 minutes most days of the week
- Despite the increase in numbers of women with CVD that are experiencing pregnancy, the safety and potential benefits of exercise in this group are not known
- Hypothesis: *Moderate intensity exercise in pregnant women with CVD does not reduce placental blood flow*

**Practice ACOG. Obstetrics & Gynecology. 2002**

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**PICCALO: Methods**

**Inclusions**
- Women 18 years of age
- Intrauterine pregnancy confirmed by fetal heart tones and early ultrasound assessment
- Enrolled prior to 20 weeks gestation

**Exclusions**
- Failure to provide informed consent
- Spontaneous abortions or ectopic pregnancies
- Specific CVD Diagnosis:
  - Pulmonary Hypertension
  - Severe Valvar Disease
  - Left Ventricular EF <40%
  - NYHA Class >II
  - Cyanosis
  - Pacer Dependent Patients

* Based on the 2014 AHA/ACC Vascular Heart Disease Guidelines and the 2008 AHA/ACC Guidelines for Adults with Congenital Heart Disease; EF, ejection fraction; NYHA, New York Heart Association

**Economy KE. Unpublished Data**
**PICCALO: Study Design**

- **Study Involvement and Assessment**
  - Study enrollment
  - Assignment of study group
    - No CVD
    - M/CVD
    - Mild-severe CVD
  - Assignment of randomization device
  - Exercise education assessment
  - NYHA Functional Class assessment
  - Body weight measurement
  - TK/TK+ PK/PT
  - C-reactive protein drawn #1

- **End Point Assessment - Primary Endpoint**
  - Medical history/Doppler measurement

- **Study Completion**
  - Second Institutional End point
    - Post-Partum
  - Maternal body weight

**Participant Screening**

- <20 weeks GA
- 20-32 weeks GA
- 32-34 weeks GA
- 35+ weeks GA
- Delivery
- 6-12 weeks post-partum

**Internal Safety / Clinical Assessment**

- Maternal weight
- Maternal blood pressure
- Fetal heart rate
- Standardized by bedside data (twice weekly)
- Fetal weekly activity logs

**Blood Data #2**

- C-reactive protein

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**PICCALO: Primary Outcome**

- **Gated Study**
  - WDW: 45 Hz
  - Bv: 0.08 m/s
  - Depth: 68.8 mm
  - PRF: 4.4 kHz

- **Unpublished Data**

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Economy KE. Unpublished Data
Exercise Ability by Disease Severity

Percent Increase in HR from 1 Hour Prior to Exercise to Peak During Exercise

Economy KE. Unpublished Data
The management of pregnant women with heart disease should be individualized and involves partnership with maternal fetal medicine, cardiology, anesthesia and neonatology.

Thank you