Modifying Maternal Sleep Position
Back to the drawing board
- June 22, 2017 -
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Dalhousie Medical School
Halifax, Canada
@AllanKember

Conflict of Interest & Disclosures
• co-inventor of the PrenaBelt
• volunteer at GIRHL
• medical student at Dalhousie Medical School

Outline
Stillbirth, Low Birth Weight, & Maternal Sleep Position
Positional Therapy & Interventional Trials
Back to the drawing board…
(Global) Stillbirth

2.6 million

www.stillbirthalliance.org #EndStillbirths

True or false?

Most stillbirths are unavoidable.

False!
Most stillbirths are preventable >50% during labor

www.stillbirthalliance.org #EndStillbirths

Most stillbirths are preventable

150 years


Stillbirth not mentioned in the UN Sustainable Development Goals

...but were included in the WHO Global Strategy for Women, Newborns, and Children 2016-2030
Low Birth Weight

20 million

20X

Major contributor to stillbirth
Maternal Sleep

- 155 cases, 310 controls
- Supine sleep position on the previous night (before stillbirth or interview) associated with late SB compared with left side (aOR 2.54; 95% CI: 1.04-6.18; p=0.005).
- Recall bias?


- 220 postpartum Ghanaian women
- Supine sleep during pregnancy an independent predictor of:
  - LBW (aOR 5.0; 95% CI: 1.2-20.2; p=0.025)
  - SB (aOR 8.0; 95% CI: 1.5-43.2; p=0.016)
- LBW found to mediate relationship between supine sleep and SB.
- Minimal recall bias

• 103 cases, 192 controls
• Supine sleeping in pregnancy over last month associated w/ SB (aOR = 6.26, with a 95% CI: 1.2-34)
• Supine sleep may be additional risk for late SB in already-compromised fetus


• 100 cases, 200 controls
• Non-left-sided sleep position during pregnancy associated with SB (aOR = 2.9; 95% CI: 1.5-5.8; p=0.002)

Supine position

Inferior vena cava compression by gravid uterus

venous return

↑ cardiac output

↓ placental perfusion

↑ Fetal Risk

Exacerbation of snoring/OSA?

Cyclic maternal hypoxia, oxidative stress...


Outline

Stillbirth, Low Birth Weight, & Maternal Sleep Position

Positional Therapy & Interventional Trials

Back to the drawing board…
Positional Therapy

PrenaBelt

PrenaBelt

=
PrenaBelt Trials

<table>
<thead>
<tr>
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<td>2nd Outcomes</td>
<td>Sleep quality &amp; quantity, user feedback, reps, BPS validation</td>
<td>fetal HR, sleep quality, sleep quantity, reps, BPS validation</td>
<td>Compliance, body position, user feedback, pregnancy outcomes</td>
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Eligibility Criteria

**Inclusion:**
- ≥18 years old
- Low-risk singleton pregnancy
- 26-30 wks @ screening

**Exclusion:**
- BMI > 35 at booking
- Pregnancy complicated by obstetric conditions
- Sleep complicated by medical conditions
- Multiple pregnancy
- Known fetal abnormality

*Australia: 32-38 weeks

---

Canada – Demographics

<table>
<thead>
<tr>
<th>(n=20)</th>
<th>Mean [SD]</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>30.9 (5.0)</td>
<td>22 – 39</td>
</tr>
<tr>
<td>Gestational age (weeks)</td>
<td>30.1 (2.8)</td>
<td>28.0 – 36.0</td>
</tr>
<tr>
<td>Current BMI</td>
<td>30.4 (3.6)</td>
<td>25.0 – 37.8</td>
</tr>
<tr>
<td>Pre-pregnancy BMI</td>
<td>26.6 (3.3)</td>
<td>22.4 – 35.0</td>
</tr>
</tbody>
</table>

| Self-reported sleep duration (hours) | 7.6 (1.1) | 4.0 – 10.0 |

<table>
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<tr>
<th>Fell asleep:</th>
<th>Last week</th>
<th>When not pregnant</th>
</tr>
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<tbody>
<tr>
<td>Supine Left</td>
<td>5 (25%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>Right</td>
<td>11 (55%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>Prone</td>
<td>0</td>
<td>11 (55%)</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Woke up:</th>
<th>Last week</th>
<th>When not pregnant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supine Left</td>
<td>8 (40%)</td>
<td>11 (55%)</td>
</tr>
<tr>
<td>Right</td>
<td>12 (60%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>Prone</td>
<td>11 (55%)</td>
<td>9 (45%)</td>
</tr>
</tbody>
</table>

---

Canada – Primary Outcome

<table>
<thead>
<tr>
<th>n=20 in each group (crossover)</th>
<th>Treatment Mean [SD] Median Range</th>
<th>Sham Mean [SD] Median Range</th>
<th>Difference [95% CI]</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep time supine (minutes)</td>
<td>44.6 (27.4) 20.7 0 – 291</td>
<td>75.5 (48.7) 76.3 0 – 304</td>
<td>27.9* [4.0 – 56.2]</td>
<td>p 0.03</td>
</tr>
<tr>
<td>Sleep time left (minutes)</td>
<td>241 (108) 229 30 – 460</td>
<td>224 (110) 227 0 – 382</td>
<td>-18.5 [56.5 – 19.5]</td>
<td>p 0.32</td>
</tr>
<tr>
<td>Sleep time right (minutes)</td>
<td>132 (119) 118 0 – 421</td>
<td>125 (109) 136 0 – 361</td>
<td>-7.1 [40.7 – 26.6]</td>
<td>p 0.67</td>
</tr>
</tbody>
</table>

*2-sided Paired Wilcoxon (signed rank)
Canada – Primary Outcome

Minutes Supine vs. Intervention

- Difference in means: 27.9, p = 0.03

Canada – Secondary Outcomes

- Sleep
- Respiration
- Body position sensor

Canada – User Feedback

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<tr>
<td>Self report % supine</td>
<td>7.5 (2.1)</td>
<td>8.5 (1.9)</td>
<td>4.1 [7.5 – 9.0]</td>
<td>0.50</td>
</tr>
<tr>
<td>0 – 90</td>
<td>0 – 80</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction (out of 10)</td>
<td>7.1 (2.1)</td>
<td>7.5 (1.9)</td>
<td>0.28 [0.5 – 1.0]</td>
<td>0.46</td>
</tr>
<tr>
<td>1 – 10</td>
<td>5 – 10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfort (out of 10)</td>
<td>7.8 (2.3)</td>
<td>8.6 (1.5)</td>
<td>0.80 [0.0 – 2.8]</td>
<td>0.06</td>
</tr>
<tr>
<td>1 – 10</td>
<td>8 – 10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intention to use (out of 10)</td>
<td>7.0 (2.3)</td>
<td>7.1 (2.4)</td>
<td>0.1 [0.8 – 1.0]</td>
<td>0.81</td>
</tr>
<tr>
<td>1 – 10</td>
<td>1 – 10</td>
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Limitations...

Qualitative: softer balls, "snooze" feature, more breathable fabric...

#1 reason for changing position from lateral to supine?...
PrenaBelt Trials

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<td>fetal HR, SA sleep quality, sleep quantity, resps, BPS validation</td>
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Australia - Summary

- No difference in sleep quantity or self-reported sleep quality.

Australia - Case-Study

#20 Without PrenaBelt
Maternal AHI = 7.8
Maternal O₂ desaturation count = 7

#20 With PrenaBelt
Maternal AHI = 0.8
Maternal O₂ desaturation count = 1
Australia – Maternal + Fetal ECG

- Linear mixed-effects model
- Supine (when compared w/ Left):
  - SS ↑ mHR and ↓ fHR
  - SS ↓ mHRV and ↑ fHRV
  ↑ mHR + ↓ mHRV
  ?autonomic perturbation? (Sympathetic > Parasympathetic)
  ↓ fHR + ↑ fHRV
  ... in the setting of fHR decels...
  ?indicative of acute hypoxia?

PrenaBelt Trials

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<td>4 EX</td>
<td>19 DO/LTFU + 19 EX + 18</td>
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<td>1° Outcome</td>
<td>Body position</td>
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<td>Birth weight</td>
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<td>2° Outcomes</td>
<td>Sleep quality &amp; quantity, user feedback, resps, BPS validation</td>
<td>Fetal HR, 38 sleep quality, sleep quantity, resps, BPS validation</td>
<td>Compliance, body position, user feedback, pregnancy outcomes</td>
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Ghana - Demographics

| Age (years) | 29.0 (3.6) | 26 – 35 |
| Gestational age at trial entry (weeks) | 28.0 (1.38) | 26 – 30 |
| Current BMI | 28.7 (4.3) | 18 – 42 |
| Pre-pregnancy BMI | 26.0 (5.2) | 16 – 36 |
| Self-reported sleep duration (hours) | 8.1 (1.3) | 4 – 13 |
Ghana – Sleep Habits

<table>
<thead>
<tr>
<th></th>
<th>Last week</th>
<th>When not pregnant</th>
</tr>
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<tr>
<td><strong>Fell asleep:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supine</td>
<td>21 (12%)</td>
<td>57 (31%)</td>
</tr>
<tr>
<td>Left</td>
<td>100 (55%)</td>
<td>19 (10%)</td>
</tr>
<tr>
<td>Right</td>
<td>67 (37%)</td>
<td>19 (10%)</td>
</tr>
<tr>
<td>Prone</td>
<td>2 (13%)</td>
<td>88 (49%)</td>
</tr>
<tr>
<td><strong>Woke up:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supine</td>
<td>44 (24%)</td>
<td>60 (33%)</td>
</tr>
<tr>
<td>Left</td>
<td>67 (37%)</td>
<td>16 (14%)</td>
</tr>
<tr>
<td>Right</td>
<td>67 (37%)</td>
<td>34 (19%)</td>
</tr>
<tr>
<td>Prone</td>
<td>6 (3%)</td>
<td>63 (35%)</td>
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Ghana – Compliance

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<thead>
<tr>
<th>Compliance Rate</th>
<th>Treatment Mean (SD)</th>
<th>Sham Mean (SD)</th>
<th>Difference [95%CI]</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>Per Sleep Diary (%)</td>
<td>55 (27)</td>
<td>58 (26)</td>
<td>-3 [-11 to 5.9]</td>
<td>0.57</td>
</tr>
</tbody>
</table>

Average: 56%

*Overestimated Sleep Diary by 10%

Average objective compliance: 30%

Ghana – Body Position

<table>
<thead>
<tr>
<th>% of night in position:</th>
<th>Treatment n=12 Mean (SD)</th>
<th>Sham n=9 Mean (SD)</th>
<th>Difference [95%CI]</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Left side (%)</td>
<td>25 (14)</td>
<td>33 (6)</td>
<td>-18 to 0.6</td>
<td>0.06</td>
</tr>
<tr>
<td>Right side (%)</td>
<td>35 (16)</td>
<td>31 (14)</td>
<td>-10 to 17</td>
<td>0.57</td>
</tr>
<tr>
<td>Supine (%)</td>
<td>46 (20)</td>
<td>37 (14)</td>
<td>-6 to 24</td>
<td>0.22</td>
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</table>
Ghana – Primary Outcome

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<th>Outcome</th>
<th>Treatment</th>
<th>Sham</th>
<th>Difference</th>
</tr>
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<tbody>
<tr>
<td>Birth weight (g)</td>
<td>3186 (484)</td>
<td>3079 (493)</td>
<td>107 [ -44.5 to 258.8]</td>
</tr>
<tr>
<td>BW centile* (%)</td>
<td>44.9 (30.7)</td>
<td>38.9 (29.8)</td>
<td>6.05 [-2.97 to 15.43]</td>
</tr>
</tbody>
</table>

*adjusted for maternal height & weight, parity, ethnicity, sex, gestational age at delivery

Ghana – Secondary Outcomes

- No difference between treatment vs. sham for:
  - Gestational age
  - Small-for-gestational-age rate
  - Low birth weight rate
  - Pre-term delivery rate
  - Stillbirth rate
  - Mode of delivery

Ghana – Limitations

- Accuracy of self-reporting (Sleep Diary)
- Blinding
- Confounding?
  - Informal education by recruiters (midwives) about supine sleep during informed consent process
  - Is the “Sleep-On-Side” (SOS) message common knowledge in Ghana?
**PrenaBelt Trials**

- **Location**: Accra, Ghana
- **Design**: Double-blind, sham-controlled, randomized
- **Intervention**: PrenaBelt, sham-PrenaBelt
- **Duration**: 12 weeks
- **Setting**: Home
- **Sample size**: 200
- **Discontinue**: 162
- **Outcome**: Birth weight

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<th>Outcome</th>
<th>GPT Treatment n=82 Mean (SD)</th>
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<th>HBWS n=162 Mean (SD)</th>
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<td>3033 (514)</td>
<td>p 0.03</td>
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<td>38.9 (29.8)</td>
<td>46.0 (30.5)</td>
<td>p 0.58</td>
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**Difference**: 153g

*Bonferroni correction = 0.05/3 = 0.017*

---

**SOS message is common!**

- **N=1551 assessed for eligibility**
- **#1 reason for exclusion?**
- **n=707 (46%) heard the SOS message in connection with SB and LBW!**
- **Who did they hear it from?**

<table>
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<th>Source</th>
<th>Number (%)</th>
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<tr>
<td>Doctor</td>
<td>75 (11%)</td>
</tr>
<tr>
<td>Internet</td>
<td>79 (11%)</td>
</tr>
<tr>
<td>Midwives</td>
<td>453 (64%)</td>
</tr>
<tr>
<td>Relatives and friends</td>
<td>96 (14%)</td>
</tr>
<tr>
<td>Television</td>
<td>4 (0.6%)</td>
</tr>
</tbody>
</table>

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**GPT vs. HBWS – Primary Outcome**

- **Outcome**: Birth weight

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**Difference**: 153g

*95%CI: 21 – 286 p 0.02**

---

*but had never heard that supine sleep could be a risk factor for stillbirth and low-birth weight

---

**“Health Birth Weight Study” (HBWS)**

- **Location**: Accra, Ghana
- **Design**: Cross-sectional (non-interventional control)
- **Intervention**: None
- **Duration**: N/A
- **Setting**: Home
- **Sample size**: 163
- **Discontinue**: 19 DO/LTFU + 19 EX = 38
- **Outcome**: Birth weight
- **2° Outcomes**: Compliance, body position, user feedback, pregnancy outcomes
- **Eligibility**: Same

---

*Ghana PrenaBelt Trial*
### Take-Home Points

**Canada**
- PrenaBelt reduces supine time during 3T sleep (lab)

**Australia**
- PrenaBelt reduces supine time during 3T sleep (home)
- PrenaBelt improves maternal breathing & reduces fetal HR decels
- HR and HR variation patterns in the supine position, compared to left, may reflect increased maternal sympathetic tone and concomitant adaptive response in the fetus

**Ghana**
- Despite low compliance (45-55%) and high % of time spent supine (~42%), PrenaBelt (and back sleep education?) increases birth weight cp. to non-intervention
- Some interesting secondary outcomes: reduced preterm delivery
- SOS message is common (46%)

### Outline

- Stillbirth, Low Birth Weight, & Maternal Sleep Position
- Positional Therapy & Interventional Trials
- Back to the drawing board…
Future Work

- Supine sleep and pregnancy risk
  - If there's a "high-risk supine sleeper", how to identify?
- Compliance
  - If it's important, how to increase it?
- Body position and pregnancy outcomes:
  - A dose-response relationship?
- Preterm delivery

Ideas

- Keep it simple?

Tennis ball!
Ideas

- Discouragement versus Inhibition
- Balls (pressure points) versus Wedge (stop)

Back view:

Top view:

Ideas

- PrenaBelt + Sensor

Ideas

- PrenaBelt + Sensor + Vibration Mechanism
Ideas

• Build an app?!

http://www.proximalbox.com/somnopose/

Outline

Stillbirth, Low Birth Weight, & Maternal Sleep Position

Positional Therapy & Interventional Trials

Back to the drawing board...

Acknowledgements

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Dr. Jerry Coleman
Josephine, Joyce, Jemima, Rose
Prof. Joseph Seffah
Maxfield Okere
Australia
Dr. Jane Warland
Prof. Janina Morrison
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Dr. Jillian Dorrian
USA
Dr. Ali Borazani
Dr. Louise O’Brien
Kevin Li
Beth Sterrett
Dr. John McArthur

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Grands Défis Canada

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  Dr. H.B. Atlee Endowment Award
Dalhousie Medical Research Foundation
  Lalia B. Chase Summer Research Studentship
Dalhousie Medical School
  Faculty of Medicine Summer Studentship
Dr. Richard J. Currie, OC

Canada – Body Position Sensor

N=40  Spearman’s rank correlation rho  Rating

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<th>Position</th>
<th>Correlation</th>
<th>Rating</th>
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<td>Supine</td>
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<td>Fair</td>
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<td>Lateral</td>
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Questions?