Sonographic Cervical Length for the Prediction of Preterm Birth: Standardization of the Technique and Pitfalls

Sonia S. Hassan, M.D.
Edgar Hernandez Andrade, M.D.
Wayne State University
Perinatology Research Branch, NICHD/NIH/DHHS

Learning Objectives

After completing the presentation, learners will be able to discuss:
1. The definition of a sonographic short cervix
2. The gestational age at which a cervix should be examined
3. Additional ultrasound parameters to assess the risk of preterm birth
   - Cervical Funnel
   - Dynamic Change
   - Amniotic Fluid Sludge
4. The correct technique for the measurement of cervical length in pregnancy
5. Amniotic Fluid sludge
6. Treatments for a sonographic short cervix
7. Future methods to assess the cervix in pregnancy

Preterm Birth is the Leading Cause of Infant Mortality

- Respiratory distress syndrome
- Chronic lung disease
- Bowel injury/inflammation
- Long-term mental disabilities
- Cerebral palsy

Disclosures

Presenter Name: Sonia S. Hassan, M.D.

Relevant Financial Relationships: None

Lecture Outline

- The definition of a sonographic short cervix
- Gestational age at which a cervix should be examined
- Additional ultrasound parameters to assess the risk of preterm birth
  - Cervical Funnel
  - Dynamic Change
  - Amniotic Fluid Sludge
- The correct technique and pitfalls for the measurement of cervical length in pregnancy
- Interventions to prevent preterm birth in women with a sonographic short cervix
- Future methods to assess the cervix in pregnancy

Preterm Birth Results in…


Hassan, Hernandez, Romero
**Magnitude of the Problem**

- ~ 13 million preterm births worldwide
- 500,000 in the United States
- Highest rates: Africa and North America

**Preterm Birth Rate in the US 1990-2008**

- Preterm (<37 weeks)
- Late preterm (34-36 weeks)
- Early preterm (<34 weeks)

**The Annual Societal Economic Burden Associated with Preterm Birth in the United States**

In excess of $26.2 billion in 2005

**Sonographic Cervical Length**

![Cervical glands](image)

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**A Short Cervix is the Most Powerful Predictor of Spontaneous Preterm Birth**

![Cervical length 11mm](image)

**What is a Short Cervix?**

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**Definition of a Short Cervix**

50% Risk for Spontaneous Preterm Delivery < 32 - 33 weeks

<table>
<thead>
<tr>
<th>Low risk</th>
<th>15 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior preterm birth</td>
<td>25 mm</td>
</tr>
<tr>
<td>Twins</td>
<td>25 mm</td>
</tr>
<tr>
<td>Triplets</td>
<td>25 mm</td>
</tr>
</tbody>
</table>

---

**Cervical Length 11 mm**

![Cervical length](image)
Definition of Short Cervix
50% Risk for Spontaneous Preterm Delivery
< 32 - 33 weeks

<table>
<thead>
<tr>
<th>Low risk</th>
<th>15 mm</th>
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<td>25 mm</td>
</tr>
<tr>
<td>Triplets</td>
<td>25 mm</td>
</tr>
</tbody>
</table>

Hassan, Hernandez, Romero

Cervical Length 22 mm

Hassan, Hernandez, Romero

Short Cervix

Congenital (DES exposure)
Surgical (conization)
Infection
Acute Cervical insufficiency
Extracellular matrix changes
Progesterone deficiency


Frequency of Intra-amniotic Inflammation and Intra-amniotic Infection in Patients with a Short Cervix

Intra-amniotic inflammation 22%
Intra-amniotic infection 9%


What Gestational Age Should the Cervix be Examined?

Hassan, Hernandez, Romero
First Trimester Assessment of the Uterine Cervix

**Isthmus**

Cervix

Hassan, Hernandez, Romero

Perinatology Research Branch, NICHD/NIH, Wayne State University

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First Trimester Assessment of the Uterine Cervix

**Isthmus**

Cervix

Hassan, Hernandez, Romero

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First Trimester Assessment of the Uterine Cervix

**Cervical length (mm)**

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Are There Additional Parameters to Assess the Risk of Preterm Birth During Transvaginal Sonography?

- Cervical funnel
- Dynamic change
- Amniotic fluid sludge

Hassan, Hernandez, Romero

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Funneling and Dynamic Change Have no Independent Predictive Value for Preterm Delivery After Cervical Length is Considered

Funnel

Dynamic Change

How Should the Cervix be Examined? Techniques and Pitfalls

Normal Cervical Anatomy
Cervical Length is the Most Important Measurement

Methods of Sonographic Examination of the Uterine Cervix in Pregnancy

- Transabdominal
- Transperineal
- Transvaginal

Transabdominal versus Transvaginal Sonographic Evaluation of the Cervix

- Transabdominal examination requires a full bladder
- Transabdominal cervical length is longer than transvaginal cervical length in the same patient
- Mean difference 5.2 mm (+/-14.3, p<0.001)
Transperineal versus Transvaginal Sonographic Evaluation of the Cervix

- Developed before transvaginal transducers were available
- Should avoid pelvic examination before the scan
- Allows visualization of the cervix, but it is more difficult to interpret

Transperineal Sonographic Evaluation of the Cervix

- Strong correlation with transvaginal measurements
- Failure to obtain a clear image
  - 30% of mid-trimester pregnancies
  - 19% of third-trimester cases
- Landmarks can be obscured by bowel gas

Measurement of Sonographic Cervical Length

- Transvaginal ultrasound
- Empty bladder
- Sagittal view identified
**Recommendations for Standardization of Cervical Examination with Ultrasound**

1) Flat internal os or isosceles triangle
2) Observe entire length of canal
3) Symmetric image of external os
4) Equal size and density of the anterior and posterior lips of the cervix

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**Measurement of Sonographic Cervical Length**

- Three measurements – shortest length recorded
- Examine for three minutes at minimum
- Recognition of sludge

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**Avoid the Presence of a Full Bladder**

- **Full bladder**
  - Cervical length 35 mm
- **Empty bladder**
  - Cervical length 17 mm

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**Avoid Unequal Distance and Density of Anterior and Posterior Cervical Lips**

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**Avoid Poor Visualization of the Endocervical Canal**
Measure the Portion of the Endocervical Canal that is Closed

Non-Measurable Cervix/Dilated Canal

Bulging Amniotic Sac
Presence of dense aggregates of particulate matter in close proximity to the internal cervical os

- 17% positive AF cultures vs. 0% (no sludge)
- 63% Histological chorioamnionitis
- 15% Clinical chorioamnionitis vs. 5%
- 60% spontaneous PTB (<32 wks) vs. 15%
- 37% neonates admitted to NICU vs. 16%

Amniotic Fluid "Sludge" Increases the predictive value for preterm delivery
What is Sludge?
**Amniotic Fluid “sludge” Sample**

- Mycoplasma hominis, Streptococcus mutans, Aspergillus flavus

**Scanning Electron Microscopy**

- Biofilm: Bacterial Cells and Exopolymeric Matrix Material

**Prediction**

- ?
- Prevention

**Interventions to Prevent Preterm Birth in Women with a short cervix**

- Progesterone
- Cerclage
- Pessary

**Treatments for a Sonographic Short Cervix**

- Hassan, Hernandez, Romero

**Prediction**

- Hassan, Hernandez, Romero

**Interventions to Prevent Preterm Birth in Women with a short cervix**

- Hassan, Hernandez, Romero
Vaginal progestrone reduces the rate of preterm birth in women with a sonographic short cervix: a multicenter, randomized, double-blind, placebo-controlled trial


Fonseca EB et al. NEJM 2007;357:462-9


Effect of Vaginal Progesterone on the Rate of Preterm Birth

Hassan, Hernandez, Romero

Results of a meta-analysis including data from the OPPTIMUM study


Study | Relative risk (95% CI) | Vaginal Progesterone | Placebo | Weight (g) | Relative risk (95% CI) |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Fonseca 2007</td>
<td>28/16</td>
<td>38/112</td>
<td>29.3</td>
<td>0.60 (0.30-0.84)</td>
<td>27/16</td>
<td>38/112</td>
</tr>
<tr>
<td>O'Brien 2007</td>
<td>4/16</td>
<td>6/19</td>
<td>3.5</td>
<td>1.06 (0.37-2.98)</td>
<td>4/16</td>
<td>6/19</td>
</tr>
<tr>
<td>Hassan 2010</td>
<td>20/355</td>
<td>46/233</td>
<td>33.5</td>
<td>0.59 (0.38-0.93)</td>
<td>20/355</td>
<td>46/233</td>
</tr>
<tr>
<td>Cetingoz 2011</td>
<td>5.1</td>
<td>2.9</td>
<td>1.5</td>
<td>0.37 (0.04-2.93)</td>
<td>5.1</td>
<td>2.9</td>
</tr>
<tr>
<td>OPPTIMUM 2016</td>
<td>29/133</td>
<td>38/118</td>
<td>32.2</td>
<td>0.57 (0.20-1.56)</td>
<td>29/133</td>
<td>38/118</td>
</tr>
</tbody>
</table>

Combined

Summary

Relative risk (95% CI) 0.62 (0.40-0.95)

Implied NNT 10 (3-28)

Hassan, Hernandez, Romero


Effect of Vaginal Progesterone on Neonatal Outcomes

Hassan, Hernandez, Romero

Reports of Major Impact

Vaginal progestrone in women with an asymptomatic sonographic short cervix in the midtrimester decreases preterm delivery and neonatal morbidity: a systematic review and metaanalysis of individual patient data


The Next Step:
A Meta-analysis of Individual Patient Data


Hassan, Hernandez, Romero
Type 1 error rate (95\% CI) 0.000 0.000
Relative risk (95\% CI) 0.92 (0.81-1.02) 0.93 (0.83-1.05)

Combined

Participants randomly assigned to vaginal progesterone 100 mg/day or placebo from 18 gestation and a cervical length ≤25 mm, or spontaneous preterm delivery, whichever occurred first 118 participants, 62 in the placebo group and 56 in the vaginal progesterone group

Objective

10000 10000

Vaginal progesterone 100 mg/day or 200 mg/day or placebo from 18 gestation and a cervical length ≤15 mm, or spontaneous preterm delivery, whichever occurred first 75 participants, 38 in the placebo group and 37 in the vaginal progesterone group

Pregnancy outcome

Delivery before 36 weeks

0.80 (0.67 to 0.97) 0.80 (0.67 to 0.97)

Delivery before 34 weeks

0.85 (0.51 to 0.83) 0.85 (0.51 to 0.83)

Delivery before 28 weeks

0.87 (0.45 to 0.99) 0.87 (0.45 to 0.99)

Any maternal adverse event

1.21 (0.87 to 1.69) 1.21 (0.87 to 1.69)

Prenatal outcome

? ?

Respiratory distress syndrome

0.47 (0.27 to 0.81) 0.47 (0.27 to 0.81)

Composite maternal morbidity/mortality

0.59 (0.38 to 0.91) 0.59 (0.38 to 0.91)

Outcome IPD Meta-analysis

Effect of vaginal progesterone on preterm birth before 33 weeks’ gestation

Placebo Group

Vaginal progesterone

Placebo Group

Relative risk (95\% CI)

0.80 (0.67 to 0.97)

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### Outcome IPD Meta-analysis

<table>
<thead>
<tr>
<th>Outcome</th>
<th>RR or mean difference (95% CI)</th>
<th>Vaginal Progesterone Group</th>
<th>Placebo Group</th>
<th>p value</th>
<th>NNT (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy outcome</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Delivery before 36 weeks</td>
<td>0.80 (0.67 to 0.97)</td>
<td>28%</td>
<td>35%</td>
<td>0.02</td>
<td>14 (9-56)</td>
<td></td>
</tr>
<tr>
<td>Delivery before 34 weeks</td>
<td>0.65 (0.51 to 0.80)</td>
<td>17%</td>
<td>26%</td>
<td>0.000</td>
<td>8 (6-10)</td>
<td></td>
</tr>
<tr>
<td>Delivery before 28 weeks</td>
<td>0.67 (0.45 to 0.99)</td>
<td>8%</td>
<td>11%</td>
<td>0.04</td>
<td>27 (16-69)</td>
<td></td>
</tr>
<tr>
<td>Any maternal adverse event</td>
<td>1.21 (0.87 to 1.64)</td>
<td>12%</td>
<td>11%</td>
<td>0.26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perinatal outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>0.47 (0.27 to 0.81)</td>
<td>5%</td>
<td>10%</td>
<td>0.007</td>
<td>18 (13-51)</td>
<td></td>
</tr>
<tr>
<td>Composite neonatal morbidity/mortality†</td>
<td>0.59 (0.38 to 0.91)</td>
<td>8%</td>
<td>14%</td>
<td>0.02</td>
<td>18 (12-81)</td>
<td></td>
</tr>
<tr>
<td>Neonatal death</td>
<td>0.44 (0.18 to 0.97)</td>
<td>1%</td>
<td>3%</td>
<td>0.07</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes: *any of the following events: respiratory distress syndrome, intraventricular hemorrhage, necrotizing enterocolitis, proven neonatal sepsis, or neonatal death; CI = confidence interval; NNT = number needed to treat; p = p value*

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### What is the totality of the data?

Vaginal progesterone reduces the risk of preterm birth and improves perinatal outcome in women with a short cervix

Vaginal progesterone is safe for use in pregnancy

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### Prior Preterm Birth and a Short Cervix: Cerclage or Vaginal Progesterone?

Hassan, Hernandez, Romero

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### Interventions to Prevent Preterm Birth in Women with a Short Cervix

Hassan, Hernandez, Romero

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### Reports of Major Impact

Vaginal progesterone vs cervical cerclage for the prevention of preterm birth in women with a sonographic short cervix, previous preterm birth, and singleton gestation: a systematic review and indirect comparison metaanalysis


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### Prior preterm birth and a Short Cervix: Cerclage or Vaginal Progesterone?

1) Vaginal progesterone:
   - significant 53% reduction in the risk of preterm birth at <32 weeks
   - 57% decrease in the risk of composite perinatal morbidity and mortality
2) Cervical cerclage:
   - significant 34% reduction in the risk of preterm birth at <32 weeks
   - 36% decrease in the risk of composite perinatal morbidity and mortality
3) Vaginal progesterone and cervical cerclage both effective
4) Surgery vs. medical

Hassan, Hernandez, Romero
Interventions to Prevent Preterm Birth in Women with a Short Cervix

Evidence for the use of a pessary to reduce preterm birth in women with a short cervix is not conclusive

Hassan, Hernandez, Romero

Twins

Hassan, Hernandez, Romero
Vaginal progesterone decreases preterm birth and neonatal morbidity and mortality in women with a twin gestation and a short cervix: an updated meta-analysis of individual patient data

Effect of Vaginal Progesterone on the Risk of TWINS

<table>
<thead>
<tr>
<th>Study</th>
<th>Weight (%)</th>
<th>Relative risk (fixed) (95% CI)</th>
<th>Pooled RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fornaca 2007</td>
<td>9/15</td>
<td>0.95 (0.50-1.81)</td>
<td>0.90 (0.45-1.81)</td>
</tr>
<tr>
<td>Rojas 2007</td>
<td>1/1</td>
<td>0.78 (0.27-2.22)</td>
<td>0.78 (0.27-2.22)</td>
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<tr>
<td>Cetingoz 2011</td>
<td>3/5</td>
<td>3.50 (0.70-17.44)</td>
<td>3.50 (0.70-17.44)</td>
</tr>
<tr>
<td>Serres 2013</td>
<td>3/11</td>
<td>9.90 (0.56-0.93)</td>
<td>9.90 (0.56-0.93)</td>
</tr>
<tr>
<td>Rode 2007</td>
<td>50/159</td>
<td>0.69 (0.51-0.93)</td>
<td>0.69 (0.51-0.93)</td>
</tr>
<tr>
<td>Combined</td>
<td>9/36</td>
<td>2.22 (0.04-3.74)</td>
<td>2.22 (0.04-3.74)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Study</th>
<th>Vaginal progesterone</th>
<th>Placebo/no treatment</th>
<th>Adjusting for non-independence between twins</th>
<th>NNT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RDS</td>
<td>R. Romero</td>
<td>102/311</td>
<td>131/280</td>
<td>0.67 (0.55-0.82)</td>
<td>8 (4-16)</td>
</tr>
<tr>
<td>Perinatal death</td>
<td>Hassan, Hernandez, Romero</td>
<td>34/319</td>
<td>62/286</td>
<td>0.70 (0.50-0.89)</td>
<td>25 (3-156)</td>
</tr>
<tr>
<td>Neonatal death</td>
<td>Hassan, Hernandez, Romero</td>
<td>6/34/318</td>
<td>62/286</td>
<td>0.49 (0.34-0.71)</td>
<td>2 (5-50)</td>
</tr>
<tr>
<td>Birth weight &lt;1500 grams</td>
<td>Hassan, Hernandez, Romero</td>
<td>49/311</td>
<td>76/280</td>
<td>0.52 (0.37-0.71)</td>
<td>17 (5-17)</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>Hassan, Hernandez, Romero</td>
<td>49/311</td>
<td>76/280</td>
<td>0.52 (0.37-0.71)</td>
<td>17 (5-17)</td>
</tr>
</tbody>
</table>

Effect of Vaginal Progesterone on the Risk of Adverse Perinatal Outcomes

Should all Women be Screened with Transvaginal Ultrasound for Cervical Length?

Practical Consideration
How Difficult and Time-Consuming is it to Perform a Transvaginal Ultrasound?

Pain Score Indicated in the Third-trimester Group for the Different Methods of Examining the Cervix: Transvaginal Ultrasound, Transperineal Ultrasound, and Digital Examination

<table>
<thead>
<tr>
<th>Score 5 (Extremely Painful)</th>
<th>Score 4 (Severely Painful)</th>
<th>Score 3 (Moderately Painful)</th>
<th>Score 2 (Mildly Painful)</th>
<th>Score 1 (Mildly Painful)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Percent</th>
<th>0</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
</tr>
</thead>
</table>

Transvaginal ultrasound
Transperineal ultrasound
Digital examination

World Health Organization
Ten Principles for Good Screening Test

1. Condition = Important Health Problem
2. Available Treatment
3. Facilities Available for Diagnosis
4. Recognizable Latent Phase
5. Suitable Test or Examination
6. Test Acceptable to Population
7. Natural History of Disease Adequately Understood
8. Policy for Treatment
9. Cost of Case-Finding Economically Balanced with Care
10. Case-Finding Should be Continuing Process

Comparison of Strategies used for Screening in Medicine

<table>
<thead>
<tr>
<th>Test</th>
<th>Number needed to screen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pap Smear for Cervical Cancer</td>
<td>1140</td>
</tr>
<tr>
<td>Mammography more than 55 years</td>
<td>543</td>
</tr>
<tr>
<td>Mammography between 40 and 45 years</td>
<td>3125</td>
</tr>
<tr>
<td>Prostate-specific Antigen for Prostate Cancer</td>
<td>1254</td>
</tr>
<tr>
<td>Ultrasound cervical length to prevent one case of PTB &lt;35 weeks (&lt;25 mm)</td>
<td>357</td>
</tr>
<tr>
<td>Ultrasound cervical length to prevent one case of neonatal morbidity/mortality (&lt;25 mm)</td>
<td>218</td>
</tr>
</tbody>
</table>

Future Sonographic Methods to Evaluate the Uterine Cervix for the Prediction of Preterm Birth?

- Hassan, Hernandez, Romero

Vaginal progesterone for asymptomatic cervical shortening and the case for universal screening of cervical length

C. Andrew Coombs, MHS, PhD
Cervical Elastography and the Prediction of Preterm Birth

Hassan, Hernandez, Romero

- Tissue displacement (strain) or velocity of propagation of a mechanic stimulus within the cervix as a "shear wave" can provide information on the softness/stiffness of the cervix
- Changes in "elasticity" are displayed in a color elastogram

Elastogram
Region of Interest
Averaged oscillatory displacement
Applied to the entire elastogram
Strain or percentage of deformation
Within the ROI
Strain
Color elastogram
Stiffness color bar
Region of Interest
Elastogram

Cervical Shear Wave Elastography

- Sagittal view of the cervix showing in red slow shear wave velocity (soft tissue) and in blue high shear wave velocity (stiff tissue)
- Transverse view of the internal os showing in blue high shear wave velocity (stiff tissue)
- Transverse view of the internal os showing in red slow shear wave velocity (soft tissue)
- Soft areas are displayed in red/orange
- Stiff areas are displayed in blue


Color elastogram

In Normal Pregnanies the Internal Cervical os Becomes Softer (Increased Strain) as Gestation Progresses

Conclusions (I)

- Sonographic cervical length is the most powerful predictor of preterm birth
- The definition of a short cervix varies by obstetrical history
- In patients with a short cervix in the midtrimester:
  - 22 have intra-amniotic inflammation and 9% have intra-amniotic infection
- The optimal time to examine the cervix is 19-24 weeks gestation
- Correct technique for cervical length examination is critical
- The cervix should be measured
  - With an empty bladder by transvaginal ultrasound, in a sagittal view

Key References


Conclusions (II)

- Amniotic fluid sludge increases the predictive value for preterm delivery
- In women with a sonographic short cervix:
  - Vaginal progesterone decreases preterm birth and neonatal morbidity in women with a short cervix (singleton and twins)
  - Cerclage reduces preterm birth (prior history of preterm birth and a short cervix)
  - Pessary has not been definitively proven to decrease preterm birth
  - It is of benefit for pregnant women to undergo a sonographic cervical length measurement in the midtrimester to assess her risk for preterm birth

Thank You