Cervical Ripening using Dilapan-S at term: UTMB Experience

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PRAGUE 2018
Introduction

- Four million women give birth each year in the United States.
- More than 20% undergo induction of labor.
- Induction is one of the most common procedures performed during pregnancy.
- Both mechanical and pharmacologic agents are used for induction of labor.

Figure 1. Induction of labor, by gestational age: United States, 1990–2012

NOTES: Singleton only. Early preterm is less than 34 weeks of gestation; late preterm is 34–36 weeks; early term is 37–38 weeks; full term is 39–40 weeks; late term is 41 weeks; postterm is 42 weeks or more. Access data table for Figure 1 at: http://www.cdc.gov/nchs/data/databriefs/db185_table.pdf.

Maternal Fetal Medicine Research Network
The Assessment of Perinatal EXcellence (APEX) study

- Columbia
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- Duke
- Northwestern
- Ohio State
- Stanford
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- U Colorado
- U North Carolina
- U Texas-Houston
- U Texas SW-Dallas
- U Utah
- UTMB Galveston
- Women and Infants
Maternal Fetal Medicine Research Network
The Assessment of Perinatal EXcellence (APEX) study

- Rigorous review of deliveries.
- Of 100,927 term singletons, 29134 (29%) were induced.
- Of the 29134 induced, 12012 (41%) had cervical ripening.
- Of the 12012 that had cervical ripening:
  - 5658 (47%) had **Foley balloon**.
  - 7414 (62%) had **Prostaglandin gel, cervidil or misoprostol**.
  - 69 (0.6%) had **Laminaria**.
Induction of labor rate is increasing.

Choosing Induction methods that are safe and efficient in achieving a vaginal delivery becomes more important.

Induction of labor in the setting of an unfavorable cervix may lead to longer lengths of stay, increased hospital costs, and/or increased maternal or neonatal morbidities.

Cervical ripening prior to induction with oxytocin in women with an unfavorable Bishop score increases the likelihood of a vaginal delivery.
Introduction

- Overall, the data shows mechanical methods to be comparable with pharmaceutical methods in terms of delivery outcomes, with less risk of uterine hyperstimulation when mechanical methods are used alone.
Mechanical Dilators: Balloon Catheters

- Foley catheter is commonly used.
- Transcervical placement of the catheter is followed by inflation of the balloon tip with varying amounts of saline, typically between 30 and 60 mL.
- Traction can be applied to the free end of the catheter.
- The Foley balloon is usually expelled when the cervix is 3 to 4 cm dilated, depending on the amount of saline used for inflation.
Mechanical Dilators: Double Balloon Catheters

- RCT by Salim and colleagues showed no differences in time to delivery between catheter types.
- Statistically significant increase in the number of operative deliveries (defined in their study as vacuum or cesarean delivery) and composite adverse fetal outcomes.
- Pennell and colleagues compared the single-balloon catheter, double-balloon catheter, and prostaglandin gel for labor induction of nulliparous women with unfavorable cervices.
  - No differences were found between the 3 groups with regard to cesarean delivery rates, but patients reported lower pain scores when the single-balloon device was used (P<0.001).
Mechanical Dilators: Osmotic Dilators

- Laminaria tents and Dilapan-S devices achieve cervical ripening through absorption of water from surrounding tissues, without the aid of exogenous pharmaceutical agents.

- Both are commonly used for induced abortion in the late first and early second trimesters, as well as a means to overcome cervical stenosis in nonpregnant women before gynecological procedures.

- Increasing trend to use it as cervical ripening agent for term inductions after FDA approval.
Gilson and colleagues compared Dilapan-S to oxytocin alone for induction of labor assessing change in Bishop score, length of labor, mode of delivery, and maternal and neonatal outcomes between the groups. Dilapan-S group had a statistically significant increase in Bishop score after treatment. No differences in the overall length of labor or cesarean delivery rate. Ramanauskas compared Dilapan-S to laminaria for prelabor cervical ripening and found no statistically significant differences in cesarean delivery rates between the 2 groups or in comparison with a control group. There are no recent or large-scale studies investigating hygroscopic dilators for labor induction at term.
At UTMB:

- Using the intracervical Foley catheter for over 10 years at our large, academic medical center in the majority of our cervical ripening patients.

- We believe that mechanical dilators should be the first choice for cervical ripening in women who require induction of labor and ripening and is a primary candidate for outpatient cervical ripening.
<table>
<thead>
<tr>
<th>Patient Demographics</th>
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<tbody>
<tr>
<td>No. of Subjects</td>
</tr>
<tr>
<td>Age [Range]</td>
</tr>
<tr>
<td>Nulliparous Rate (%)</td>
</tr>
<tr>
<td>Gestational Age [Range]</td>
</tr>
</tbody>
</table>
## UTMB Experience: Dilapan-S Registry

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median increase of Bishop score (range)</td>
<td>3 [0-8]</td>
</tr>
<tr>
<td>CD Rate (%)</td>
<td>17.9</td>
</tr>
<tr>
<td>Device to delivery time (hrs) [Range]</td>
<td>25.7 [12.8 - 45.0]</td>
</tr>
<tr>
<td>VD Rate within 24 hrs (%)</td>
<td>46.1</td>
</tr>
<tr>
<td>VD Rate within 36 hrs (%)</td>
<td>71.8</td>
</tr>
<tr>
<td>VD Rate within 48 hrs (%)</td>
<td>82.1</td>
</tr>
<tr>
<td>VD Rate within (hrs) [Range]</td>
<td>12.3 (8.7-13.3)</td>
</tr>
<tr>
<td>Time of Dilapan in Cervix (hrs) [Range]</td>
<td></td>
</tr>
<tr>
<td># of Dilapan Rods [Range]</td>
<td>5 (3-6)</td>
</tr>
<tr>
<td>Amniotomy (%)</td>
<td>74.4</td>
</tr>
<tr>
<td>Oxytocin (%)</td>
<td>87.2</td>
</tr>
</tbody>
</table>
Maternal and Neonatal Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>During cervical ripening, n %</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tachysystole</td>
<td>1</td>
<td>(0.2)</td>
</tr>
<tr>
<td>NRFHT</td>
<td>1</td>
<td>(0.2)</td>
</tr>
<tr>
<td>Cervical laceration</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>10</td>
<td>(2.3)</td>
</tr>
<tr>
<td>Dilator entrapment</td>
<td>0</td>
<td>(0)</td>
</tr>
<tr>
<td>Dilator fragmentation</td>
<td>0</td>
<td>(0)</td>
</tr>
</tbody>
</table>
## Maternal and Neonatal Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious complications, n %</td>
<td>14</td>
<td>3.2</td>
</tr>
<tr>
<td>Composite neonatal complications, n %</td>
<td>17</td>
<td>5.3</td>
</tr>
<tr>
<td>5 min Apgar score &lt; 7</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>Cord PH &lt; 7.1</td>
<td>8</td>
<td>3.3</td>
</tr>
<tr>
<td>NICU admission</td>
<td>6</td>
<td>1.3</td>
</tr>
</tbody>
</table>
Predictors for Vaginal Delivery

Vaginal delivery rates were significantly correlated with Bishop scores of pre and post Dilapan-S and difference.

After adjusting for age, BMI, number of dilators, cervical ripening time, and gestational age, both prior vaginal delivery and post-Dilapan-S Bishop scores were strong predictors of vaginal delivery (estimate coefficient: 0.1275 ± 0.03 P = .0002; 0.049 ± 0.01 P = .0001; respectively).
Predictors for Vaginal Delivery

Aggregate ROC
Predictors for Vaginal Delivery
Dilapan-S: Potential Pro’s

- Cervidil and Dilapan-S are the only FDA approved methods.

- Cervidil disadvantages:
  - Tachysystole.
  - Continuous fetal heart tracing.
  - Expensive.
  - Cannot be used jointly with oxytocin.

- Compared to Balloon mechanical dilator:
  - Dilapan-S is FDA approved.
  - Nothing hangs out of the perineum, hence easier for outpatient usage.
Dilapan-S: Con’s

- Need for learning curve for use.
- Need for a speculum.
- Grand multiparous: difficulty in (exposure for placement).
- Nulliparous: higher chances for Round 2 of Dilapan-S or for further cervical ripening methods.
RCT: Dilapan-S Vs Balloon Catheter

- **Objective:**
  - To determine the efficacy of Dilapan-S compared with Foley balloon for cervical ripening and induction of labor in pregnant women greater than 37 weeks.
UTMB Experience: RCT Dilapan-S Vs Balloon Catheter

- Primary Outcome
  - Rate of vaginal delivery.

- Secondary Outcomes
  - Vaginal delivery rate within 24 and 36 hours post insertion.
  - Time to reach active stage of labor defined as ≥ 6 cm.
  - Change in Bishop score.
  - Rate of spontaneous and operative vaginal delivery.
  - Rate of cesarean sections.
  - Patient satisfaction.
RCT: Results

- SOON TO COME....
Future Directions

- Applying as an outpatient setting?
- VBAC.
- Blunt application instead of using a speculum?
- Based on the RCT results:
  - Alternative to Foley Balloon.
  - More comfortable? Better patient satisfaction?
  - Simultaneous use with oxytocin.


