International observational E-registry on the use of Dilapan-S® for cervical ripening prior to labor induction

International study from 7 countries (11 study sites), monitoring clinical outcomes of the use of synthetic osmotic dilator Dilapan-S® for cervical ripening prior to induction of labor.

Study
Chief investigator: Prof. Janesh Gupta, MSC, MD, FRCOG, Birmingham Women’s Hospital, Birmingham, UK

Mean number of dilators used
3.8 pieces

Main Focus on
• Duration of cervical ripening
• Overall duration of induced labor procedure
• Vaginal delivery rate

543 subjects enrolled / 444 eligible for analysis

Mean Age
29.3 years

Mean Gestational Age
39.4 weeks

65.1% Nulliparas
26% Multiparas
8.9% Previous C. Section

45% of indications represented relative contraindications for usage of prostaglandines

Major indications for labor inductions
1. Post-term pregnancy 31%
2. IUGR 12%
3. Pre-eclampsia 11%
4. Gestational Diabetes Mellitus 10%
5. Previous C-Section 6%
**Efficacy**

Mean gain of Bishop score +3.6

Cervical Ripening achieved in 94.4%

Rate of vaginal delivery 70%

*Vaginal delivery rate varied between 51-83%, depending on study center*

**Patient Satisfaction**

• Mild discomfort 3.4%
• Mild uterine contractions 25%
• Fully acceptable insertion 95%

**Safety**

• Infectious complications of mother or baby related to usage of dilators: 0%
• Suspected fetal pathology based on CTG: 0.2%
• Apgar score (5 min) <7: 0.7%

**Significantly better outcomes when Dilapan-S® left in situ up to 12 hours**

<table>
<thead>
<tr>
<th></th>
<th>&lt; 12 hrs</th>
<th>&gt; 12 hrs</th>
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</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>188</td>
<td>256</td>
</tr>
<tr>
<td>Mean number of dilators</td>
<td>4</td>
<td>3.6</td>
</tr>
<tr>
<td>Mean vaginal delivery rate</td>
<td>76.6%</td>
<td>64.8%</td>
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<td>Mean vaginal delivery within 36 hrs</td>
<td>66%</td>
<td>48.4%</td>
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<tr>
<td>Mean insertion - delivery time</td>
<td>24.3 hrs</td>
<td>39.1 hrs</td>
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**Conclusion**

• The use of Dilapan-S® leads to high vaginal delivery rate.
• Significantly better outcomes when Dilapan-S® left in situ up to 12 hours versus longer duration.
• Use of Dilapan-S® does not lead to serious maternal or neonatal adverse effects.

**References:**