Prospective clinical study comparing Dilapan-S® with PGE₂ gel and Estradiol gel

Material and methods:
- 247 patients were randomized to one of the following preinduction protocols:
  - four hygroscopic dilators (Dilapan-S®) applied intracervically (n = 82) for 14 hours
  - 0.5 mg of Prostaglandin E2 gel (Prepidil gel) administered intracervically (n = 83)
  - 150 mg of Estradiol gel administered intravaginally (n = 82)
- Including criteria: patient informed consent, singleton pregnancy of more than 36 weeks, cephalic presentation, Bishop score < 5 points, reactive non-stress test.
- Cervical ripening was evaluated as successful, if Bishop Score increased to ≥5 (measured on the 10 points scale) and/or by at least 2 points in a time period of 14 hours.

Results:
- Average Bishop score increase (measured on the 10 point scale).
  - Dilapan-S®: 3.9
  - PGE₂ gel: 3.7
  - Estradiol gel: 2.8

  - Vaginal delivery rate in Dilapan-S® group: 80.5%.

<table>
<thead>
<tr>
<th></th>
<th>Successful preinduction rate</th>
<th>Labor induced by preinduction alone</th>
<th>Induction to delivery interval</th>
<th>Caesarean section rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilapan-S®</td>
<td>89%</td>
<td>20.7%</td>
<td>7 hrs 49 m</td>
<td>19.5%</td>
</tr>
<tr>
<td>PGE₂ gel</td>
<td>85%</td>
<td>31.3%</td>
<td>7 hrs 27 m</td>
<td>24.4%</td>
</tr>
<tr>
<td>Estradiol gel</td>
<td>76.8%</td>
<td>17.1%</td>
<td>9 hrs 15 m</td>
<td>24.4%</td>
</tr>
</tbody>
</table>

- Neither serious side effects nor negative neonatal outcome were noted in either group, incl. infectious complications.
Conclusion:

- Dilapan-S® rods and PGE$_2$ gel proved as similarly efficient in cervical ripening and with higher efficacy in comparison with Estradiol gel.
- Induction to delivery interval was shorter in the PGE$_2$ gel and the Dilapan-S® groups.
- The Dilapan-S® group had the lowest Caesarean section rate.
- All cervical ripening methods were evaluated as safe.
- The labor and delivery should preferably take place during the daytime for high-risk patients. From this point of view, Dilapan-S® seems more appropriate for preinduction of high-risk pregnancies.
- Safety profile of Dilapan-S® suggests the product might be appropriate for out-patient cervical ripening for low-risk patients.