Clinical Evidence

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

Material and Methods

- 247 patients were randomized to one of the following pre-induction 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)

- Included 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 > (measured on the 10 point 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 pre-induction rate</th>
<th>Labor induced by pre-induction 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>

Conclusion

- Dilapan-S* rods and PGE₂ gel proved similarly efficient in cervical ripening and with higher efficacy in comparison with Estradiol gel.

- Induction to delivery interval was shorter in the PGE₂ 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 that the product might be appropriate for outpatient cervical ripening for low-risk patients.