A Randomized Controlled Trial of Dilapan–S® versus Foley Balloon for Pre-induction Cervical Ripening (DILAFOL Trial)

**Study design:** A single center, randomized, open-label trial. 419 women were randomized from November 2016 to February 2018.

**Principal investigator:** Antonio F. Saad, MD, University of Texas Medical Branch, Galveston, Texas, USA

**Objective:** Confirm Dilapan–S® non-inferiority to the Foley balloon for pre-induction cervical ripening at term.

**Main focus on:**
- Vaginal delivery rate
- Safety profile
- Patient satisfaction survey

**Methods:**
- Pregnant women > 37 weeks with unfavorable cervix (≤ 3 cm dilated and ≤ 60% effaced).
- Foley balloon (inflated with 60 cc saline) or Dilapan–S® (as many rods as possible; mean number of rods used was 5) inserted for 12 hours cervical ripening.
- If the cervix remained unfavorable, then one more round of the assigned dilator was used.
- Management following ripening was left up to the clinical providers.

**Patient population:**

<table>
<thead>
<tr>
<th></th>
<th>Dilapan–S® (N=210)</th>
<th>Foley balloon (N=209)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age (median, weeks)</td>
<td>39.0</td>
<td>39.0</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>41.9 %</td>
<td>46.9 %</td>
</tr>
<tr>
<td>Multiparous</td>
<td>58.9 %</td>
<td>53.1 %</td>
</tr>
<tr>
<td>BMI (median)</td>
<td>30.67</td>
<td>30.8</td>
</tr>
<tr>
<td>Modified Bishop score at randomization (median)</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>
Efficacy

Cervical ripening success rate with 1st round of dilator

Both products reached excellent rate of successful ripening. % of women needed another intervention for ripening was only 1.5% in Dilapan-S® group and 0.5% in Foley group, resp.

Vaginal delivery rate

Dilapan-S® vaginal delivery rate was non-inferior to Foley balloon.

Caesarean section rate

Device placement to delivery (median, hours)

Device placement

Delivery

p = 0.0881
Patient satisfaction

All women were completing a satisfaction survey. Answers were chosen on a predefined 5-point scale.* Following graphical representation indicates frequency of positive rating — cumulated proportion of answers “ALWAYS” and “OFTEN” on scale.*

Ability to perform daily activities (walking, dressing, hygiene, shower, …)

Ability to get some relaxing time

Ability to get some sleeping time

Dilapan–S® was superior to Foley balloon in patient satisfaction during cervical ripening.

Safety

<table>
<thead>
<tr>
<th></th>
<th>Dilapan–S® (N=196)</th>
<th>Foley balloon (N=214)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal bleeding*</td>
<td>3.1 %</td>
<td>0.9 %</td>
</tr>
<tr>
<td>Rupture of membranes*</td>
<td>0.9 %</td>
<td>0.9 %</td>
</tr>
<tr>
<td>Tachysystole*</td>
<td>0 %</td>
<td>0 %</td>
</tr>
<tr>
<td>Non-reassuring fetal status*</td>
<td>0.5 %</td>
<td>1.4 %</td>
</tr>
<tr>
<td>5 min Apgar &lt; 7</td>
<td>0.5 %</td>
<td>0.5 %</td>
</tr>
<tr>
<td>Maternal infectious co-morbidity**</td>
<td>0 %</td>
<td>0 %</td>
</tr>
</tbody>
</table>

* During cervical ripening interval. ** Related to device used.
Conclusion:

- The study represents level 1 evidence, that Dilapan–S® is non-inferior to Foley balloon in terms of achieving vaginal delivery.
- Difference was not large enough to show Dilapan–S® superiority, however Dilapan–S® vaginal delivery rate was higher by 5.2% (81.3%).
- Low occurrence of adverse events confirms Dilapan–S® favorable safety profile.
- Patients were more satisfied with Dilapan–S® compared with Foley balloon.
- Significant advantages of Dilapan–S® over Foley balloon include FDA approval, more comfortable wearing (no protrusion from the introitus and no need to keep under tension) and overall higher patient satisfaction.

References:
2. Data on file, MEDICEM Technology s. r. o., Czech Republic, 2019