Clinical Evidence

Dilapan-S®
HYGROSCOPIC CERVICAL DILATOR

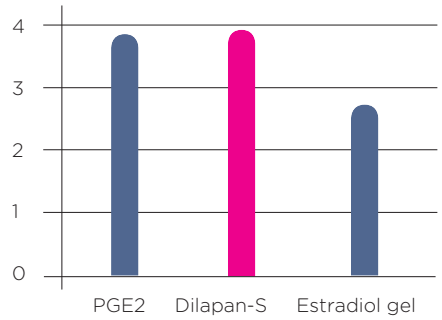
Prospective clinical study comparing Dilapan-S with PGE_2 gel and Estradiol gel

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
  - PGE_2 gel: 3.7
  - Estradiol gel: 2.8
- Vaginal delivery rate in Dilapan-S® group: 80.5%



	Successful pre-induction rate	Labor induced by pre-induction alone	Induction to delivery interval	Caesarean section rate
Dilapan-S	89%	20.7%	7 hrs 49 m	19.5%
PGE2 gel	85%	31.3%	7 hrs 27 m	24.4%
Estradiol gel	76.8%	17.1%	9 hrs 15 m	24.4%

Conclusion

- Dilapan-S® rods and PGE_2 gel proved 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 that the product might be appropriate for outpatient cervical ripening for low-risk patients.

Reference: *Roztocil A et al.: A comparison of three preinductioncervical priming methods: Prostaglandines E2 gel, Dilapan-S rods and Estradiol gel. CZ Gynecol. 63, 1998, c.1, str. 3-9*