Dilapan-S vs standard methods for cervical ripening in term pregnancies:

An individual patient data meta-analysis

Saad AF, Pedroza C, Gavara R, Gupta J, Wapner RJ, Saade GR. AJOG MFM, Dec 2024

DOI: <u>10.1016/j.ajogmf.2024.101583</u>

Objective:

 To compare the cesarean delivery rate of DILAPAN-S to alternatives, evaluating its effectiveness, safety, and patient satisfaction against traditional cervical ripening methods, with subgroup analyses based on patient characteristics such as parity and body mass index.

Materials and methods:

- The meta-analysis used individual patient data (IPD) from four randomized controlled trials (RCTs) involving 1,731 women (1,036 allocated to DILAPAN-S, 695 to alternative cervical ripening methods).
- The involved trials compared DILAPAN-S with other cervical ripening methods, including the Foley balloon (DILAFOL trial), oral misoprostol (COMRED trial), and dinoprostone vaginal inserts (SOLVE trial). The fourth trial used was HOMECARE trial, comparing DILAPAN-S in-patient vs out-patient use.
- Bayesian statistics was used to calculate probabilities of noninferiority and superiority of the effectiveness of DILAPAN-S compared to other methods.

Results:

- Overall cesarean delivery rates: No significant difference was observed between DILAPAN-S (28%) and other methods (30%).
- Subgroup benefit for multiparous women: Subgroup analysis demonstrated significant interaction with parity with a 99% probability of lowering risk of cesarean rates among multiparous women induced with Dilapan-S.
- **Safety profile:** Maternal and neonatal outcomes were similar between DILAPAN-S and other methods, except a significantly lower rate of complications during ripening (19% vs 47%) in DILAPAN-S group.
- **Patient satisfaction**: DILAPAN-S group showed significantly higher patient satisfaction during cervical ripening (able to walk, eat, shower, rest, relax, sleep) and less pain while the drug/device was in place.

Key take away messages / comments:

- This is the first comprehensive meta-analysis using individual participant data to compare DILAPAN-S with other methods, highlighting its effectiveness, reduced cesarean section rates in specific populations, and enhanced patient satisfaction.
- DILAPAN-S is as effective as other methods, with reduced risk of cesarean delivery in multiparous women.
- The use of DILAPAN-S is associated with a significantly lower rate of complications during the ripening period.
- DILAPAN-S provides a more comfortable cervical ripening process with significantly reduced pain levels and improved patient satisfaction.
- DILAPAN-S can be confidently used as an effective, safe, and patient-friendly option for cervical ripening in both inpatient and outpatient settings. The findings support the use of DILAPAN-S as a preferred cervical ripening agent.