EXECUTIVE SUMMARY

Cervical Ripening Efficacy of Synthetic Osmotic Cervical Dilator Compared With Oral Misoprostol at Term: A Randomized Controlled Trial. (COMRED trial)

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Objective:

- To compare the efficacy of DILAPAN-S to oral misoprostol in cervical ripening prior to induction of labor.

Materials and methods:

- Prospective, multi-center randomized non-inferiority clinical trial ran from 2018 to 2021.
- **Primary outcome** was vaginal delivery within 36 hours.
- **Secondary outcomes** included overall rate of vaginal delivery / cesarean delivery, induction to delivery interval, total length of hospital stay, maternal and fetal safety, and maternal satisfaction.
- 307 women were randomized (all with ≥37 weeks of gestation and initial Bishop score <6) with 4 withdrawals. The final analysis included 151 women in DILAPAN-S group and 152 in misoprostol group.
- 3 to 5 DILAPAN-S dilators were inserted and left in situ for 12 hours, whereas the misoprostol group received up to 6 doses of 25 mcg orally every 2 hours.
- After 12 hours of cervical ripening, oxytocin was initiated with an early artificial rupture of membranes in both groups.
- While women in the DILAPAN-S group were allowed to ambulate, women in the misoprostol group had to undergo continuous CTG monitoring.

Results:

- Nulliparous represented 53.6 % of the sample size in DILAPAN-S group and 53.3 % in misoprostol group.
- **Vaginal delivery within 36 hours:** 61.6 % in DILAPAN-S group vs. 59.2 % in misoprostol group.
- **Overall rate of vaginal delivery:** 72.8 % in DILAPAN-S group vs. 72.4 % in misoprostol group.
- **Vaginal delivery within 24 hours:** 41.1 % in DILAPAN-S group vs. 38.2 % in misoprostol group.
- **Uterine tachysystole with non-reassuring fetal heart tracing (NRFHT)**: 2.6 % in DILAPAN-S group vs. 7.3 % in misoprostol group.
- **5 minutes Apgar score <7:** none in DILAPAN-S group vs. 1 case in misoprostol group.
- **Cord arterial blood pH <7.1**: none in DILAPAN-S group vs. 4 cases in misoprostol group.
- **Pain scores during cervical ripening ≥5 points (0–10 point scale):** 36.8 % of women in the DILAPAN-S group vs. 51.1 % in misoprostol group (p=0.02).
- **Unpleasant abdominal sensations (strong agreement):** 24.2 % of women in the DILAPAN-S group vs. 37.3 % in misoprostol group (p=0.03).
- **Ability to sleep and rest (strong agreement):** 66 % of women in the DILAPAN-S group vs. 47 % in misoprostol group (p=0.02).
- 58.2 % of women in the misoprostol group didn´t receive all 6 planned doses of misoprostol due to different complications during the cervical ripening period.

Key take away messages:

- **DILAPAN-S is fully comparable to low-dose oral misoprostol in vaginal delivery rates (VD, VD24, VD36) while offering a better safety profile and superior maternal satisfaction.**
- **Vaginal delivery rate within 24 hours was fully comparable; this outcome confirms that "speed of action" is related to IOL clinical protocol rather than to the method of cervical ripening. DILAPAN-S offers the same "speed of action" to complete vaginal birth as low-dose oral misoprostol.**
- **Uterine tachysystole with NRFHT during cervical ripening was lower in DILAPAN-S group.**
- **Unlike misoprostol, no newborn with 5 minutes Apgar score <7 and Cord arterial pH <7.1 occurred in DILAPAN-S cohort, which confirms DILAPAN-S safety benefits.**
- **Unlike DILAPAN-S, almost 60 % of women in the misoprostol group didn´t receive the planned dosage of the agent due to complications associated with its use. Cervical ripening with DILAPAN-S is more predictable and therefore allows enhanced IOL scheduling.**
- **Mothers induced by DILAPAN-S reported significantly lower pain when compared to oral misoprostol.**
- **While women in DILAPAN-S group were allowed to ambulate, women in the misoprostol group underwent continuous CTG monitoring.**