EXECUTIVE SUMMARY

Efficacy of Dilapan-S compared to Foley balloon in preinduction cervical ripening - a noninferiority trial

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Objective:

- To compare the efficacy of Dilapan-S and Foley balloons for pre-induction cervical ripening.

Materials and methods:

- A single center, randomized, non-inferiority trial.
- A total of 296 women (148 in each group) with a Bishop score between 0-2 in term pregnancy were included.
- Depending on initial cervical dilatation, 1 - 3 DILAPAN-S were inserted. Foley balloon volume not reported.
- Cervical ripening progress was assessed after 12 hours of insertion.
- Women with unfavourable cervix were further provided by PGE_1 or PGE_2 for further augmentation of induction.
- Primary outcomes included Bishop score improvement, mode of delivery, number of contractions, induction to delivery interval and augmentation method.

Results:

- Nulliparous represented 91.2% in DS group and 93.2.% in FB group (p=NS)
- In the DS group, there were significantly more women with gestational diabetes mellitus and fetal growth restriction.
- **Initial Bishop score 0:** 70.9% in DS group and 81.1% in FB group (p=NS)
- **Bishop score improvement:** significantly higher in FB group ($p<0.001$)
- Lower need for augmentation using PGE_1 ($p=0.01$) or PGE_2 ($p<0.001$) in FB group
- **Normal vaginal delivery rate:** 63.5% in DS group vs 65.5% in FB group (p=NS)
- **Induction to delivery interval:** significantly longer in DS group
- **Uterine contractions during cervical ripening:** 24.3% in DS group vs 79.7% in Foley group ($p<0.01$)
- **Maternal and neonatal complications:** No significant differencies were identified between groups, however there were two cases of umbilical cord presentation in FB group, necessitating emergency Caesarean section.

Key take away messages / comments:

- **DILAPAN-S is a safe, effective alternative to Foley balloon, demonstrating non-inferiority.**
- **DILAPAN-S confirmed its favorable safety and efficacy profile for various patient conditions, including those with gestational diabetes mellitus or fetal growth restriction, without increasing adverse outcomes.**
- **Maternal and neonatal outcomes were comparable between the groups; however, two cases of cord prolapse in the FB group indicate its assosiated health risks. This led the authors to conclude that „DILAPAN-S can be prescribed as safer alternative to Foley balloon".**
- **The significantly lower frequency and intensity of contractions in the DILAPAN-S group underscore its gentler approach, contributing to enhanced maternal comfort.**
- **The majority of induced women were nulliparas with highly unripe cervices, which likely resulted in a lower number of DILAPAN-S dilators being inserted. Considering the mode of action of DILAPAN-S, it is generally understood that inserting only 1–3 dilators may not be sufficient to increase the Bishop score from 0 to 6 in a single round, leading to a higher rate of additional PGE augmentation.**