EXECUTIVE SUMMARY

Randomized control trial comparing hygroscopic cervical dilators to cervical ripening balloon for outpatient cervical ripening

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Objective:

- To demonstrate equivalent efficacy between synthetic hygroscopic dilators and the single balloon catheter for outpatient cervical ripening.

Materials and methods:

- A prospective randomised controlled equivalence trial.
- The primary outcome was time from admission to delivery, secondary objectives included further efficacy, safety parameters, and patient outcomes.
- A total of 174 women [87 DILAPAN-S (DS), 87 Foley balloon (FB)] with a Bishop score <6 and cervical dilation <2cm near term were included and completed the trial.
- In DS group, up to 3 dilators were placed. In FB group, the balloon was inflated with 30 ml sterile saline.
- Patients were discharged home and were scheduled for labour induction within 24 hours.

Results:

- Nulliparous represented 73.6% in DS group and 81.6% in FB group (p=NS)
- **Mean change in Bishop score:** +2 points for both groups (p=NS)
- **Mean change in cervical dilatation:** +2 cm for both groups (p=NS)
- **Treatment failure (no cervical change):** 4.5% in DS group vs 2.3% in FB group (p=NS)
- **Time from admission to delivery:** 18.01 hours in DS group vs 17.55 hours in FB group (p=NS)
- **Return before scheduled induction:** 0% in DS group vs 9.2% in FB group **(p=0.007)**
- **Device expulsion before admission:** 0% in DS group vs 9.2% in FB group **(p=0.007)**
- **Vaginal delivery rate**
    - **Primiparous:** 67.2% in DS group vs 69.0% in FB group (p=NS)
    - **Multiparous:** 95.7% in DS group vs 100.0% in FB group (p=NS)
- **Maternal and neonatal complications:** No significant safety issues were identified in either group
- **Pain score at insertion (VAS 0-10):** 3.0 in both groups (P=NS)
- **Maternal satisfaction with at home ripening:** 92.8% in DS group vs 96.2% in FB group (p=NS)

Key take away messages / comments:

- **Good efficacy outcomes, low rate of complications and high patient satisfaction demonstrate a suitability of DILAPAN-S for outpatient use.**
- **Both groups achieved significant progress in Bishop score and cervical dilatation despite the use of a limited number of DILAPAN-S dilators (up to three) or low balloon inflation volumes (30 ml). This approach aimed to minimise patient discomfort and unplanned early admissions.**
- **Unlike the Foley balloon, DILAPAN-S was not associated with patients complaints such as restricted movement, difficulty using the bathroom, discomfort from tape, or tape failure.**
- **DILAPAN-S was associated with significantly fewer early admissions and spontaneous expulsions.**

- **In the context of outpatient procedures, the onset of labour before scheduled admission was considered as unfavorable event. All patients who experienced this were from the Foley balloon group.**
- **The study notes that the placement of DILAPAN-S is feasible in a provider's office, similar to intrauterine device placement, potentially reducing costs and simplifying logistics.**