EXECUTIVE SUMMARY

Evaluation of an outpatient cervical ripening program using osmotic dilators and Foley balloon catheters

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Objective:

- To describe characteristics, satisfaction, and outcomes for patients undergoing outpatient cervical ripening.

Materials and methods:

- A retrospective observational study accompanied by a prospective patient satisfaction survey was conducted at two hospitals within the same health system.
- A total of 120 women [80 DILAPAN-S (DS), 40 Foley balloon (FB)] with a Bishop score <6 and cervical dilation <2cm near term were included.
- Device choice varried by hospital, with DILAPAN-S represented in 95% at hospital A and 55% at hospital B.
- Simplified Bishop score (SBS) was used to measure ripening effectiveness (0-9 points).
- All patients were scheduled for induction of labour no later than 24 hours following device insertion.
- Due to the significant baseline differencies between groups, a weighted results methodology was employed to eliminate potential bias in the outcomes.

Results:

- Nulliparous represented 71% in DS group and 62.5% in FB group (p=NS)
- **Mean change in Bishop score:** +1.9 points for DS vs 1.6 points for FB (p=NS)
- **Mean change in cervical dilatation:** +1.8 cm for DS vs +2.0 cm for FB (p=NS)
- **Need for additional ripening agent:** 54.6% in DS group vs 40.8% in FB group (p=NS)
- **Device expulsion before returning to the hospital:** 6.2% in DS group vs 25.2% in FB group **(p=0.006)**
- **Return before scheduled induction:** 10.9% in DS group vs 27.6% in FB group **(p=0.028)**
- **Vaginal delivery rate:** 71.8% in Ds group vs 85.4% in FB group (p=NS)
- **Maternal and neonatal complications:** No significant safety issues were identified in either group
- **Maternal satisfaction with at home ripening (very satisfied):** 42.1% in DS group vs 0% in FB group **(p=0.032)**
- **Level of axiety or stress during at home period (10 point scale):** 1.5 in DS group vs 3.2 in FB group **(p=0.004)**
- **Nothing negative to report about at home cervical ripening:** 78.9% in DS group vs 27.3% in FB group

Key take away messages / comments:

- **Baseline characteristics of DILAPAN-S group were less favourable, incl. more nulliparas, fewer women with 2+ parity, significantly lower initial Bishop score and initial cervical dilatation.**
- **Despite this initial imbalance, there were no significant differences in Bishop score gain and cervical dilation gain.**
- **The higher need for additional cervical ripening in DILAPAN-S group was likely related to its less favourable baseline characteristics.**
- **Women in DILAPAN-S group experienced significantly lower rate of device expulsion and unscheduled hospital returns, underscoring the predictability and convenience of DILAPAN-S for IOL scheduling.**

- **Women in DILAPAN-S group reported significantly higher satisfaction with at home ripening, lower anxiety levels and fewer negative experiences to report. These outcomes align with previous clinical trials highlighting the gentleness of DILAPAN-S while maintaning high efficacy.**
- **Patients appreciated the ability to spend more time at home and less time in the hospital. This aligns with responses where DILAPAN-S users cited reduced hospital time as a benefit**
- **The finginds represent a real-word data which is a valuable addition to results comming from randomized clinical trials.**
- **Notice that the authors emphasized:** *„Given the perceived ease of insertion of osmotic dilators compared with Foley balloon in nulliparous patient with closed cervix, we also found a higher proportion of nulliparous patients and lower baselines SBS in the osmotic dilator group".*
- **The findings support DILAPAN-S as a favorable option for outpatient cervical ripening, with potential benefits for both patients and healthcare providers.**