EXECUTIVE SUMMARY

Cervical balloon catheter versus Dilapan-S for outpatient cervical ripening: A randomized controlled trial

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Objective:

- To evaluate if D-S is non-inferior to cervical balloon for outpatient cervical ripening based on change in BS.

Materials and methods:

- Single-blind, randomised controlled trial.
- The primary outcome was change in Bishop score. Secondary outcomes included patient satisfaction, mode of delivery, induction time, adverse maternal and neonatal outcomes and a cervical ripening failure rate (failure to place the agent, prelabour rupture of membranes prior to scheduled return to hospital, significant vaginal bleeding, need for further cervical ripening).
- A total of 80 women with unfavourable cervix (BS <6 and cervical dilation </= 2cm) was randomised (40 in each group).
- 3-5 dilators were inserted in DILAPAN-S group (DS). In the balloon group, COOK double balloon catheter (BD) was used, but only intrauterine ballon was inflated by 60ml of saline for patient comfort. Participants were discharged for outpatient ripening, with a follow-up scheduled within 24 hours.
- After the removal of the device, cervical assessment was proceeded blindly by senior member of the team.

Results:

- Nulliparous represented 70% of subjects in both group (p=NS)
- **Median change in Bishop score:** +3 points in both groups
- **Time to delivery (hours, median):** 20 hours in DS group and 17 hours in DB group (p=NS)
- **Vaginal delivery rate:** 75% in both groups
- **Cervical ripening failure rate:** 17,5% in DS group and 37,5% in DB group (p=0.045)
- **Unscheduled medical contact:** 7.5% in DS group and 35% in DB group (p<0.01)
- **Maternal and neonatal complications:** No significant differencies in safety outcomes were identified between groups.
- **Overall maternal satisfaction:** 9 in DS group and 8 in DB group (p<0.01)

Key take away messages:

- **DILAPAN-S was non-inferior to COOK double balloon catheter based on change in Bishop score and vaginal delivery rate.**
- **Women in DILAPAN-S group**
  - **were significantly more satisfied in terms of comfort, ability to complete routine activities or sleep, resulting in significantly better overall experience with the ripening process.**
  - **were significantly less likely to experience cervical ripening failure, which was mainly driven by a difference in the need for additional cervical ripening. Lower failure rates and fewer additional procedures reduce intervention times and optimize induction protocols.**
  - **had significantly fewer unscheduled contacts with the medical team compared to those having a balloon catheter. This suggests greater predictability, potentially reducing staff workload and healthcare costs, while improving patients´ confidence in outpatient care.**

- **The findings support DILAPAN-S as a favorable option for outpatient cervical ripening, with potential benefits for both patients and healthcare providers.**