EXECUTIVE SUMMARY

Outpatient Compared With Inpatient Preinduction Cervical Ripening Using a Synthetic Osmotic Dilator (HOMECARE trial)

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Objective:

- To assess whether outpatient cervical ripening with a synthetic osmotic dilator (DILAPAN-S) shortens the length of hospital stay in term pregnancies undergoing labor induction.

Materials and methods:

- Prospective, multi-center randomized clinical trial ran from 11/2018 to 11/2021 at The University of Texas Medical Branch, TX, and Columbia University Irving Medical Center, NY.
- The primary outcome was the proportion of women with hospital stay >48 hours. Further evaluated parameters were focused on efficacy and safety aspects and maternal satisfaction.
- 339 women were randomized (171 inpatient, 167 outpatient, 1 withdrawal), all with scheduled induction, 37+0 weeks or more, and an unfavorable cervix (≤3 cm dilated and ≤60 % effaced).
- Patients in the outpatient group were asked to return 12 hours after insertion or earlier if needed. Patients in the inpatient group remained in the hospital.
- Following the first round of ripening, additional ripening, oxytocin administration, and labor management were left up to the clinical providers.

Results:

- Nulliparous represented 49.7% of subjects in outpatient group and 45.6% in inpatient group.
- **Hospital stay >48 hours:** 53.% in outpatient group vs 89%in inpatient group (p<0.001)
- **Total length of hospital stay:** 54 hours and 21 minutes in outpatient group vs 62 hours and 19 minutes in inpatient group (p<0.001)
- **Vaginal delivery within 24 hours of admission:** 70% in outpatient group vs 50% in inpatient group (p<0.001)
- **Total vaginal delivery rate:** 75% in both groups
- **Required analgesics during cervical ripening:** 3.6% in outpatient group vs 15.8% in inpatient group (p<0.001)
- **Time from admission to AROM:** 6 hours and 32 minutes in outpatient group vs 17 hours and 31 minutes in inpatient group (p<0.001)
- **Time from admission to active labor:** 9 hours and 5 minutes in outpatient group vs 19 hours and 1 minute in inpatient group (p<0.0001)
- **Earlier return of outpatient patients:** 4 out of 166 returned before their scheduled time of admission and the main reasons included contractions and membrane leakage.
- **Maternal and neonatal complications:** did not differ between groups, no significant maternal or neonatal safety issues in both groups.

- **Maternal satisfaction:** patients in outpatient group were more able to walk, eat, sleep and shower than those in inpatient group. They also had lower pain scores, reported less abdominal discomfort, and felt that outpatient cervical ripening was beneficial and would choose the same approach for their subsequent pregnancy.

Key take away messages:

- **Outpatient cervical ripening with DILAPAN-S is as effective and safe as in the hospital setting.**
- **DILAPAN-S outpatient cervical ripening significantly reduces the length of hospital stay, which can help to reduce staff time requirements and may have a positive impact on the hospital budget.**
- **Out-patient use of DILAPAN-S for cervical ripening resulted ina significant reduction in the need for analgesia.**
- **In addition to the superior maternal satisfaction with DILAPAN-S, as seen in previous RCTs, outpatient cervical ripening may further improve the maternal experience and associated level of satisfaction.**
- **Only 4 out of 166 women (2.4%) in the outpatient group returned to hospital prematurely, confirming DILAPAN-S as a highly predictable cervical ripening agent with easy scheduling.**
- As mentioned by authors, this is in contrast with findings of a randomized study by Ausbeck (published in 2020) where 22% of women pre-induced by Foley in the outpatient setting returned prematurely.