Preinduction cervical ripening in an outpatient setting: a prospective pilot study of a synthetic osmotic dilator compared with a double-balloon catheter

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Objective:

- To compare the effectiveness, safety and patient satisfaction of a double-balloon catheter (DB) with a synthetic osmotic cervical dilator (OD) for pre-induction cervical ripening in an outpatient setting.

Materials and methods:

- Prospective, dual-center pilot study conducted at two German university hospitals, in Hamburg and Berlin.
- The primary outcomes included differences in the Bishop Score (BS) and cervical shortening. Pain perception at insertion and during the cervical ripening, as well as patient satisfaction, were also assessed.
- A total of 94 women with an unfavourable cervix (Bishop score < 6) near term were included. 50 women received the DB at Hamburg hospital, while 44 received the OD at Berlin hospital.
- In the OD group, up to 5 dilators were used. In the DB group, the balloon was inflated by 80ml of saline. Both devices were left in place for at least 24 hours, with participants released for outpatient ripening.
- If Bishop score remained unfavourable (BS <6), a 10mg PGE2 vaginal insert was administered for 24 hours. If cervix was favourable (BS>6), induction with oxytocin was initiated.

Results:

- Nulliparous represented 30% of subjects in DB group and 20% in OD group (p=NS)
- **Median change in BS:** +3 points with DB and +2 points with OD (p=0.002)
- **Shortening of the cervix:** -14 mm in DB group and -9 mm in OD group (p=0.003)
- **Use of 10mg PGE2 insert:** 12% with DB and 57% with OD (p<0.001)
- **Need for oxytocin:** 62% in DB group and 27% in OD group (p<0.001)
- **Vaginal delivery rate:** 70% in DB group and 82% in OD group (p=NS)
- **Device expulsion rate:** 32% in DB group and 6.8% in OD group (p=0.005)
- **Earlier return to hospital before 24 hours:** 44% in DB group and 32% in OD group (p=NS)
- **Maternal and neonatal complications:** No significant safety issues in either group.
- **Pain during insertion (VAS 0-10):** 4 points in both groups
- **Pain during cervical ripening:** 4 points with DB group and 2 points with OD group (p<0.001)
- **Ability to pain, sleep and pursue daily activities:** Significantly better in OD group (p<0.001)
- **Overall maternal satisfaction:** Similar in both groups

Key take away messages / comments:

- **The study's results should be interpreted cautiously due to its limitation of unusual methodology, with one center exclusively using DB and the other using OD. As noted by the authors, *„the results should be interpreted with caution, since there may be an individual investigator-dependent variance in assessing the BS and in measuring the cervical length“.***
- **Mechanical outpatient cervical ripening represents an effective and safe option for a defined group of women.**
- **Double balloon catheter was evaluated as significantly better in terms of Bishop score gain and cervical shortening, while the vaginal delivery rate was similar between the groups.**
- **Interestingly, DILAPAN-S followed by a PGE2 vaginal insert required significantly less oxytocin to initiate uterine contractions, suggesting the potential for a modified clinical regimen.**
- **DILAPAN-S had a significantly lower rate of spontaneous expulsions, highlighting its potential benefit of high predictability.**
- **DILAPAN-S group experienced significantly less pain during the cervical ripening process compared to those with a double balloon, aligning with its reputation for gentleness and patient comfort.**
- **DILAPAN-S women rated significantly higher their ability to sleep, relax, and perform daily activities. This makes it more compatible with outpatient settings, where maintaining daily routines is valuable.**
- **More participants with DILAPAN-S viewed outpatient cervical ripening positively, with higher percentages recommending this method for future pregnancies.**
- **Compared to other DILAPAN-S outpatient trials, more % of women returned to the hospital earlier than scheduled. This may be attributed to the extended 24-hour ripening period, as opposed to the 12-hour period in the HOMECARE trial.**