Dilapan-S®

EXECUTIVE SUMMARY

A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial)

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Objective:

- The objective of the study was to test the hypothesis that DILAPAN-S is not inferior to the Foley balloon for preinduction cervical ripening at term

Materials and methods:

- The single-center randomized controlled trial ran from November 2016 to February 2018 at The University of Texas Medical Branch, Texas, USA.
- The primary outcome was the proportion of vaginal delivery (%). Further evaluated parameters were focused on efficacy and safety aspects, as well as maternal satisfaction.
- 419 women were randomized (209 to Foley balloon; 210 to DILAPAN-S), all with 37^{+0} weeks or greater of gestation with an unfavorable cervix (≤3 cm dilated and ≤60 % effaced).
- As many DILAPAN-S dilators as possible were inserted and left in place for at least 12 hours, Foley balloon was filled with 60ml of sterile 0.9 % NaCl and left in place for 12 hours. If the cervix remained unfavorable (≤3 cm dilated and ≤60 % effaced) a second round of the assigned ripener was used.

Results:

- Nulliparous represented 41.9 % of subjects in DILAPAN-S group and 46.9 % in the Foley balloon group.
- **Total vaginal delivery rate:** 81.3 % in DILAPAN-S group vs 76.1 % in Foley balloon group
- **Vaginal delivery within 24 hours:** 47 % in DILAPAN-S group (data on file)
- **Cesarean delivery rate:** 18.8 % in DILAPAN-S group vs 23.9 % in Foley balloon group
- **Second round of dilator:** 13.1 % in DILAPAN-S group vs 9.8 % in Foley balloon group
- **Uterine tachysystole during cervical ripening:** 0 % in both groups
- **Nonreassuring fetal status during cervical ripening:** 0.5 % in DILAPAN-S group vs 1.4 % in Foley balloon group
- **Ability to always or often sleep after device insertion:** 60.9 % of women in DILAPAN-S group vs 51.0 % of women in Foley balloon group (p=0.01)
- **Ability to always or often get relaxing time:** 62.6 % of women in DILAPAN-S group vs 47.3 % of women in Foley balloon group (p=0.001)
- **Ability to always or often perform desired daily activities:** 66.7 % of women in DILAPAN-S group vs 52.7 % of women in Foley balloon group (p=0.001)

Key take away messages:

- **With 81 % of vaginal delivery rate DILAPAN-S represents a highly effective cervical ripening agent. The results indicated a trend towards more vaginal deliveries and a lower C. section rate in DILAPAN-S group vs Foley bulb.**
- **Almost 50 % of women delivered within 24 hours from device placement.**
- **DILAPAN-S achieved 87 % success rate in the first round of cervical ripening while 5 pieces for 13 hours were used.**
- **Low occurrence of adverse events confirmed DILAPAN-S favorable safety profile.**
- **DILAPAN-S is superior to a Foley balloon in maternal satisfaction during cervical ripening. Induced women were significantly more satisfied in terms of the possibility to sleep, relax and perform daily activities without limitations.**
- **Post-ripening cervical assessment was based on cervical dilation (>3 cm) and effacement (>60 %) rather than on whole Bishop score reached.**