OBSTETRICS

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.

Study Design

Pregnant women ≥37 weeks scheduled for induction with unfavorable cervix (≤3 cm dilated and ≤60% effaced) were randomly assigned to 12 hours of either Foley balloon inflated with 60 mL saline or Dilapan-S for cervical ripening. If the cervix remained unfavorable, then 1 more round of the assigned dilator was used. Management following ripening was left up to the clinical providers. The primary outcome was vaginal delivery. A satisfaction survey was also obtained after the preinduction period. Sample size was based on a noninferiority margin of 10%, 90% power, and an estimated frequency of vaginal delivery of 71% in Foley balloon and 76% in Dilapan-S.

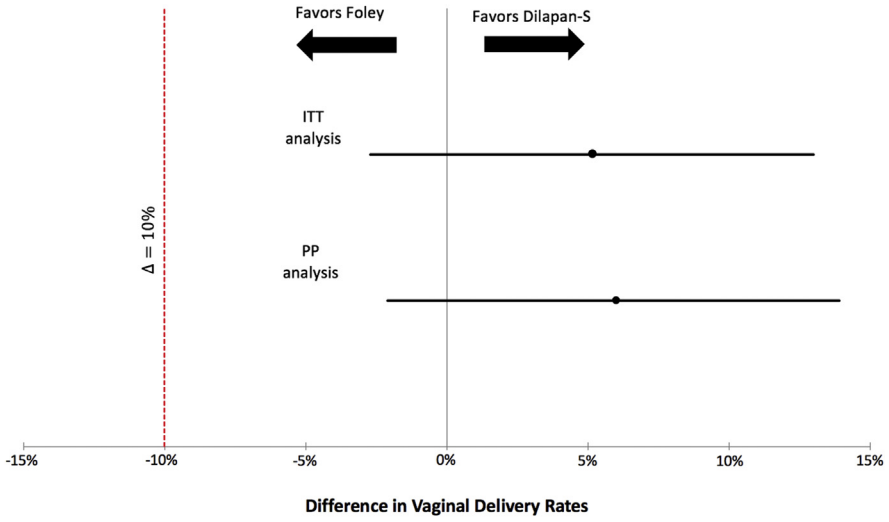
Results

From November 2016 through February 2018, 419 women were randomized (209 to Foley balloon; 210 to Dilapan-S). In the intent-to-treat analysis, vaginal delivery was more common in Dilapan-S vs Foley balloon (81.3% vs 76.1%), with an absolute difference with respect to the Foley balloon of 5.2% (95% confidence interval, −2.7% to 13.0%) indicating noninferiority for the prespecified margin (Figure). The difference was not large enough to show superiority. Noninferiority was confirmed in the per-protocol population (n = 204 in the Foley balloon, n = 188 in Dilapan-S), supporting the robustness of the results. Secondary outcomes were not different between groups, except for a longer time the device remained in place in Dilapan-S compared with the Foley balloon. Maternal and neonatal adverse events were not significantly different between groups. A priori interaction analyses showed no difference in the effect on vaginal delivery by cervical dilation at randomization, parity, or body mass index >30 kg/m^2. Patients with Dilapan-S were more satisfied than patients with the Foley balloon as far as sleep (P = .01), relaxing time (P = .001), and performance of desired daily activities (P = .001).

Conclusion

Dilapan-S is not inferior to the Foley balloon for preinduction cervical ripening at term. Advantages of Dilapan-S over Foley include Food and Drug Administration approval,

FIGURE
Difference in vaginal delivery rate between Dilapan-S and Foley balloon



Absolute difference in vaginal delivery rate (with 95% CI) between Dilapan-S and Foley balloon in the ITT and PP analysis. The 95% CI spans zero but lies wholly above the Δ margin, indicating noninferiority.

CI, confidence interval; *ITT*, intent-to-treat; *PP*, per-protocol.

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safe profile, no protrusion from the introitus, no need to keep under tension, and better patient satisfaction. ■

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The authors report no conflict of interest.