

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

Antonio F. Saad MD, Josephine Villarreal MD, Joe Eid MD, Nicholas Spencer MD, Viviana Ellis MD, Gary D. Hankins MD, George R. Saade MD

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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

### **Material and methods:**

- The single-center randomized controlled trial ran from November 2016 to February 2018 at The University of Texas Medical Branch, Texas, USA
- 419 women were randomized (209 to Foley balloon; 210 to Dilapan-S®), all with 37<sup>+0</sup> weeks or greater of gestation with an unfavorable cervix ( $\leq 3$  cm dilated and  $\leq 60\%$  effaced)
- The primary outcome was proportion of vaginal delivery (%)
- Further evaluated parameters were focused on efficacy and safety aspects, as well as maternal satisfaction
- Maternal satisfaction was assessed using a survey (before and after preinduction period)

### **Results:**

- Non-inferiority of Dilapan-S® vs Foley balloon in vaginal delivery rate was confirmed
- Vaginal delivery was more common in Dilapan-S® group vs Foley balloon (81.3% vs 76.1%)
- Both products showed highly safe profile with no safety issues
- Mothers with Dilapan-S® were statistically more satisfied than mothers with the Foley balloon as far as sleep, relaxing time and performance of desired daily activities

### **Key take away message:**

- **Dilapan-S® is non-inferior to the Foley balloon in terms of proportion of vaginal deliveries**
- **The results indicate trend to higher vaginal delivery rate and lower occurrence of C. section in Dilapan-S® group**
- **Median insertion time of 5 Dilapan-S® rods for 13 hours resulted in 87% cervical ripening success rate**
- **Minimal occurrence of adverse events with Dilapan-S® in both mothers and newborns**
- **Mothers with Dilapan-S® inserted were statistically more satisfied, as they could sleep, relax and perform daily activities without limitations**
- **Main advantages of Dilapan-S® over Foley catheter include FDA approval, safe profile, no protrusion from the introitus, no need to keep the device under tension and better maternal satisfaction**