

# A randomized trial of synthetic osmotic cervical dilator for induction of labor vs dinoprostone vaginal insert

## Background

Induction of labor is a commonly performed obstetrical intervention. Synthetic osmotic cervical dilator (DILAPAN-S) and vaginal prostaglandin E2 (dinoprostone) are methods of induction recommended by NICE in their NG207.

## Objective

This study aimed to compare the efficacy, maternal and neonatal safety, and maternal satisfaction of DILAPAN-S with those of dinoprostone.

## Study Design

This was an open-label superiority randomized controlled trial in 4 English hospitals.

Eligible participants were women ≥16 years of age undergoing induction of labor for a singleton pregnancy at ≥37 weeks' gestation with vertex presentation and intact membranes.

The women were randomly assigned to receive either DILAPAN-S or dinoprostone using a telephone randomization system minimized by hospital, parity, body mass index, and maternal age.

The induction agent was replaced as required until the cervix was assessed as favorable for labor by the Bishop score.

The primary outcome was failure to achieve vaginal delivery (i.e., or a cesarean delivery being performed). The secondary outcome measures included maternal and neonatal adverse events. Analysis was by intention-to-treat, adjusting for design variables where possible.



## Results

Between December 19, 2017 and January 26, 2021, 674 women were randomized (337 to DILAPAN-S, and 337 to dinoprostone).

The trial did not reach its planned sample size of 860 participants because of restrictions on research during the COVID-19 pandemic.

The primary outcome was missing for 2 women in the dinoprostone group.

Failure to achieve vaginal delivery (or a cesarean delivery being performed) occurred in 126 women (37.4 %) allocated to DILAPAN-S and in 115 (34.3 %) women allocated to dinoprostone (adjusted risk difference, 0.02; 95 % confidence interval, –0.05 to 0.10). There were similar maternal and neonatal adverse events between the groups.

Nulliparous represented 79.8 % of participants in DILAPAN-S and 80.7 % in dinoprostone.

First round cervical ripening success rate (defined as Series 2 not required): 78.9 % in DILAPAN-S vs 69.0 % in dinoprostone

Slow progress or failure to ripen reported as a reason for unsuccessful first rounds in 55 women in the DILAPAN-S group compared to 71 women in the dinoprostone group.

Intervention fell out in 0 women in DILAPAN-S compared to 13 women in dinoprostone.

Majority of women in the DILAPAN-S group underwent amniotomy after cervical ripening which confirms DILAPAN-S' predictability and provides an opportunity to schedule IOL procedure more efficiently.

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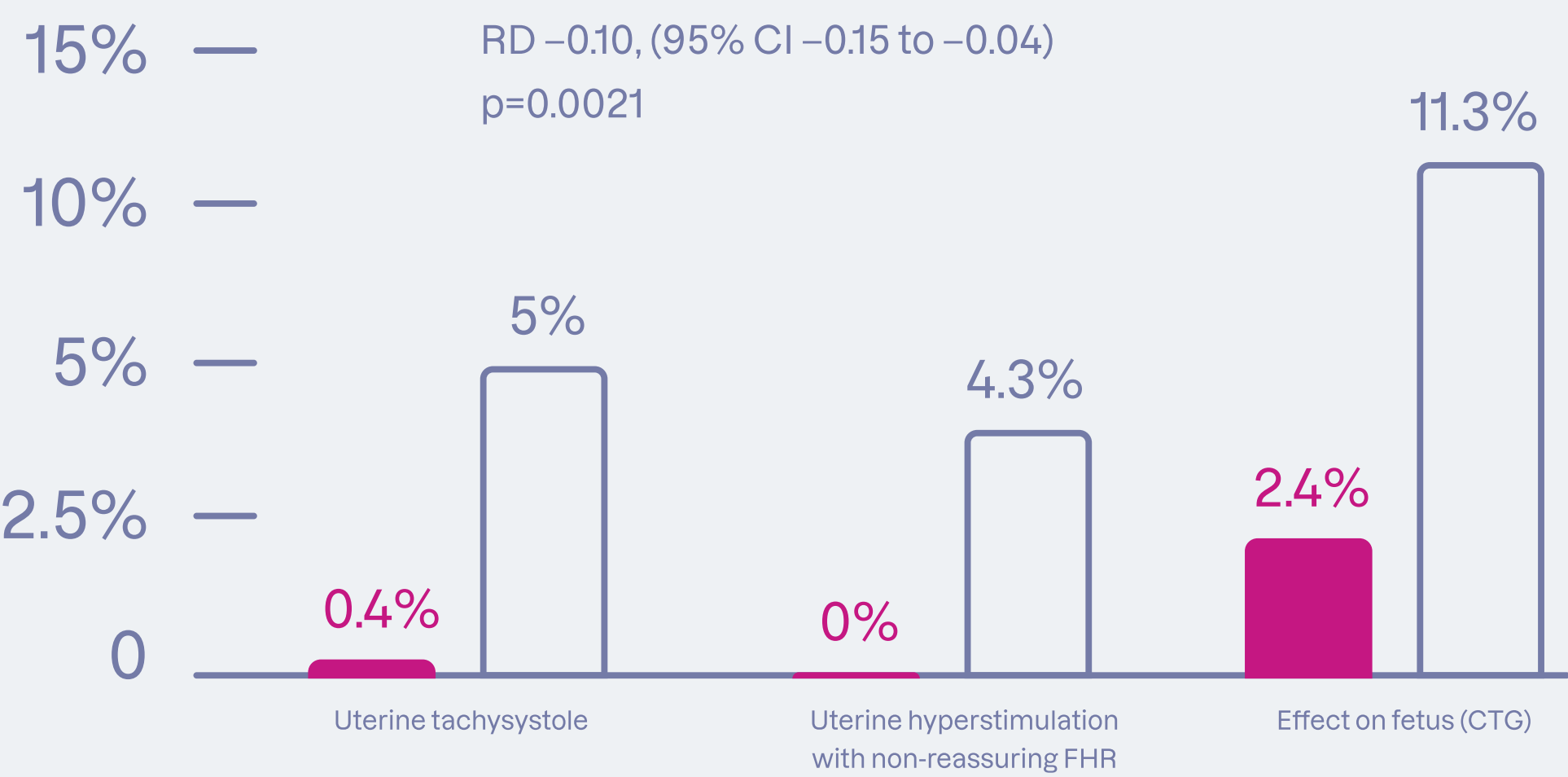
On behalf of the Synthetic Osmotic Cervical Dilator for Induction of Labor in Comparison to Dinoprostone Vaginal insErt (SOLVE) collaborative group.

Complications during cervical ripening:  
7.6 % in DILAPAN-S vs 22.6 % in dinoprostone

Uterine tachysystole:  
0.4 % in DILAPAN-S vs 5.0 % in dinoprostone

Uterine hyperstimulation with NRFHR:  
0.0 % in DILAPAN-S vs 4.3 % in dinoprostone

Effect on fetus (CTG):  
2.4 % in DILAPAN-S vs 11.3 % in dinoprostone



Further, 1 case of neonatal death, 3 cases of hypoxic-ischemic encephalopathy and 1 case of placental abruption occurred solely in the dinoprostone group.

| Maternal Satisfaction                                                                              |                                     | DILAPAN-S   | Dinoprostone |
|----------------------------------------------------------------------------------------------------|-------------------------------------|-------------|--------------|
| How much pain did you have while the drug/ device was being put in place?                          | Wong Baker Pain Scale (0–10 points) | Mean 4.3    | Mean 4.7     |
|                                                                                                    |                                     | Median 4    | Median 4     |
| Were you able to perform your desired daily activities such as walking, dressing, hygiene, shower? | Always                              | 155 (76.0%) | 104 (46.9%)  |
| Were you able to get some relaxing time?                                                           | Always                              | 108 (52.9%) | 62 (27.9%)   |
| Were you able to get some sleeping time?                                                           | Always                              | 97 (48.0%)  | 97 (48.0%)   |
| Were contractions frequent?                                                                        | Not at all                          | 73 (37.1%)  | 28 (12.7%)   |
| Were contractions intense?                                                                         | Not at all                          | 87 (44.2%)  | 34 (15.5%)   |
| Did you feel any discomfort with the drug/ device in place?                                        | Not at all                          | 92 (46.2%)  | 59 (22.7%)   |
| Please rate the overall pain that you had while the drug/device was in place.                      | Wong Baker Pain Scale (0–10 points) | Mean 3.1    | Mean 5.6     |
|                                                                                                    |                                     | Median 3    | Median 6     |

## Conclusions

Women undergoing induction of labor with DILAPAN-S have similar rates of cesarean delivery and maternal and neonatal adverse events compared with dinoprostone but with fewer instances of uterine tachysystole, hyperstimulation and adverse effects on the fetus.

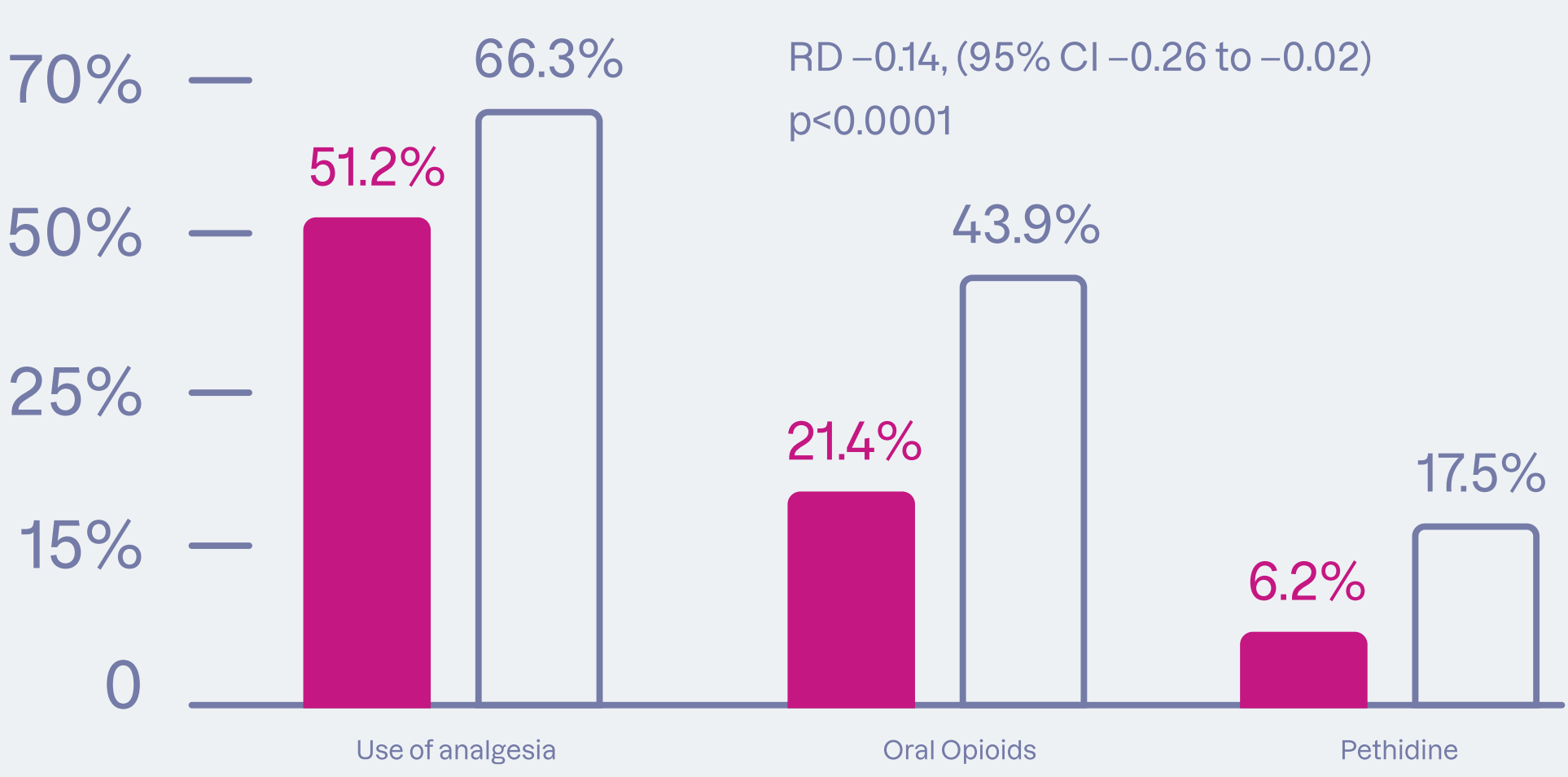
There was a lower need for re-insertion of DILAPAN-S, by approximately 10 %.

Women in the DILAPAN-S group reported substantially better satisfaction with their induction.

Use of analgesia during cervical ripening:  
51.2 % in DILAPAN-S vs 66.3 % in dinoprostone

Oral opioids:  
21.4 % in DILAPAN-S vs 43.9 % in dinoprostone

Pethidine:  
6.2 % in DILAPAN-S vs 17.5 % in dinoprostone



## Maternal satisfaction

Women in the DILAPAN-S group reported substantially better satisfaction in terms of ability to perform their desired daily activities such as walking, dressing, hygiene, shower, ability to sleep, relax, and reported less frequent and lower intense uterine contractions as well as lower pain scores both within the insertion procedure and during the ripening period.

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## Full text

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