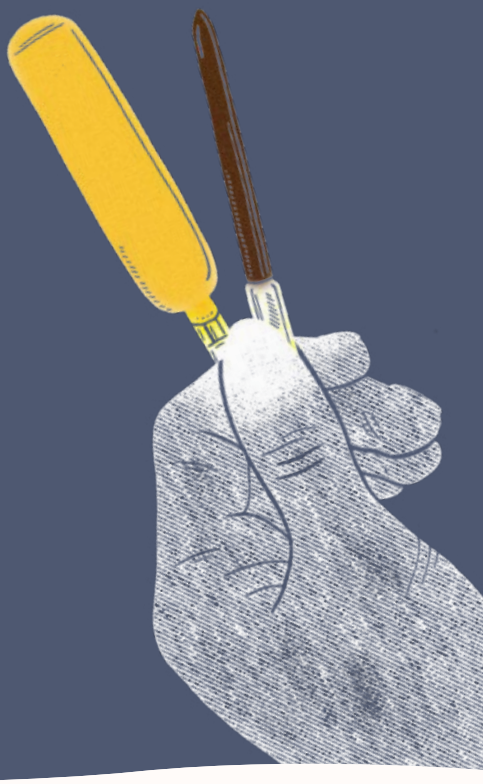
Dilapan-S®

A randomised trial of a synthetic osmotic cervical dilator for induction of labour versus dinoprostone vaginal insert (SOLVE Trial)



Study design

An open-label, superiority, randomised controlled trial in four English hospitals.
674 women were randomised (337 to DILAPAN-S and 337 to dinoprostone).

SOLVE collaborative group investigators

Janesh K Gupta, Alisha Maher, Clive Stubbs, Peter Brocklehurst, Jane P Daniels, Ms Pollyanna Hardy.

Objective

To compare the efficacy, maternal and neonatal safety, and maternal satisfaction of a synthetic osmotic cervical dilator (Dilapan-S®) with 10 mg dinoprostone vaginal delivery insert (Propess®).

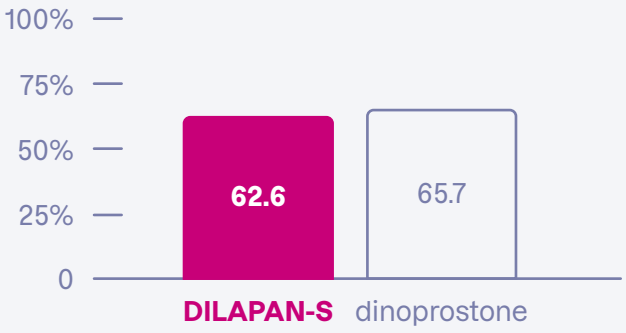
Baseline characteristics

Nulliparous 79.8 % in the DILAPAN-S group and 80.7 % in the dinoprostone group.

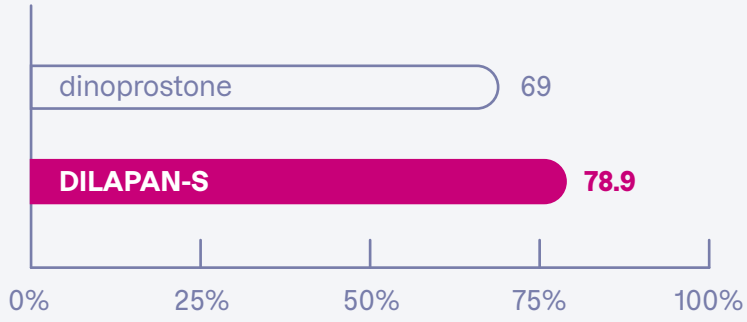
Women undergoing cervical ripening with DILAPAN-S have similar vaginal delivery rates compared to dinoprostone but with fewer instances of uterine tachysystole, hyperstimulation and adverse effects on the fetus.

More women in the DILAPAN-S group reported better maternal satisfaction and significantly less women needed analgesia.

Vaginal delivery rate



First round cervical ripening success rate



A similar vaginal delivery rate was achieved, alongside a 10% higher first round success rate.

4.7
dilators

19
hours

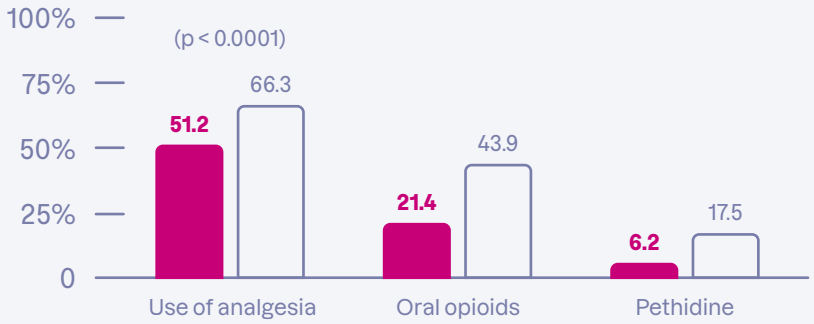
3.2
Bishop score gain

On average, 4.7 dilators inserted for 19 hours enabled a Bishop score gain of 3.2.

Analgesia need

Significantly less women needed analgesia during the cervical ripening process in the DILAPAN-S group, strong opioid analgesics in particular.

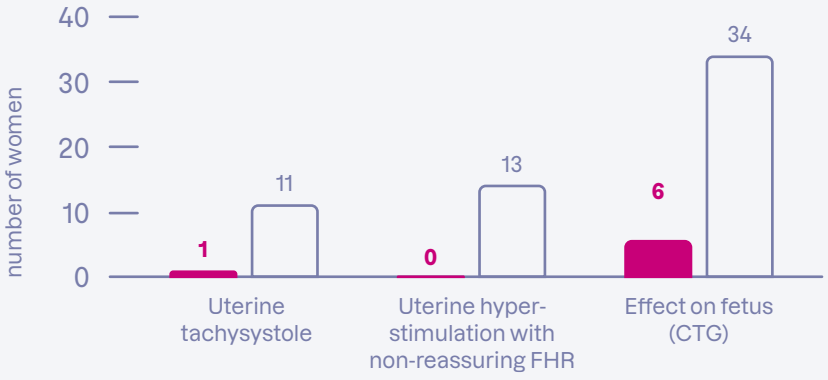
DILAPAN-S ▢ dinoprostone



Complications during cervical ripening

There were fewer instances of uterine tachysystole, hyperstimulation with non-reasuring FHR and adverse effects on the fetus in the DILAPAN-S group.

DILAPAN-S ▢ dinoprostone



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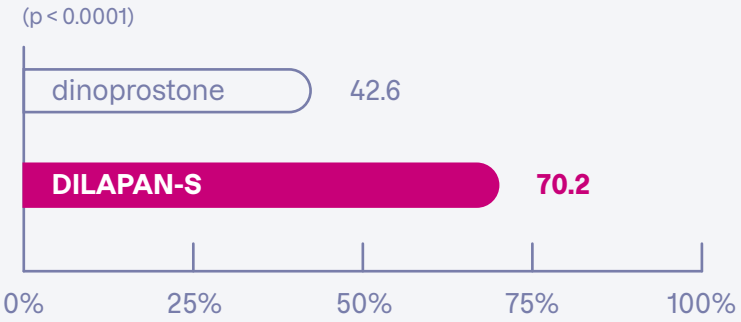
Amniotomy undertaken for induction of labor



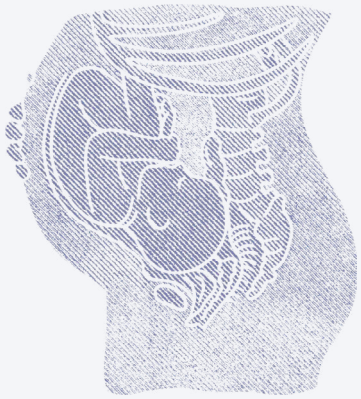
The majority of women in the DILAPAN-S group underwent amniotomy after cervical ripening.

The predictability of DILAPAN-S allows for more efficient scheduling.

Maternal satisfaction

DILAPAN-S showed substantially better outcomes for maternal satisfaction during cervical ripening.

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 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 %)	49 (22.1 %)
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



More women in the DILAPAN-S group reported:

Better satisfaction as they were able to perform their daily activities.

Less frequent and less intense uterine contractions.

Lower pain scores during both insertion and cervical ripening.

SOLVE trial – DILAPAN-S key facts

79 %
first round cervical ripening success rate

63 %*
vaginal delivery rate

10 %
higher first round success rate

0 %
uterine hyperstimulation with non reasuring fetal heart rate

* Points to consider

Due to **demands on the clinical service** not all women were able to receive a timely amniotomy once a favorable cervix had been achieved, **potentially pausing or reversing the physiological process of cervical ripening.**

Nulliparous represented almost 80 % of participants in the DILAPAN-S group and the dinoprostone group alike.

REFERENCE: Gupta J. et al. A randomized trial of synthetic osmotic cervical dilator for induction of labor versus Dinoprostone vaginal insert (SOLVE), AJOG, March 2022 DOI: https://doi.org/10.1016/j.ajogmf.2022.100628

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DILAPAN-S is manufactured by company MEDICEM Technology s.r.o., Czech republic (www.medicem.com)

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