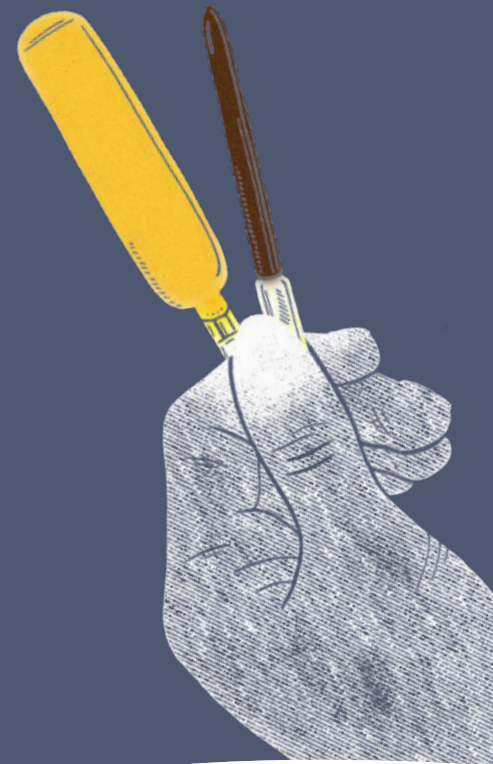




Cervical Ripening Efficacy of Synthetic Osmotic Cervical Dilator Compared With Oral Misoprostol at Term (COMRED trial)



Study design

Prospective, multi-center randomized clinical trial ran from 2018 to 2021.
307 pregnant women were randomized (151 to Dilapan-S[®]; 152 to oral misoprostol).

Principal Investigator

Rachana Gavara, MD, Department of Obstetrics and Gynecology, Lawrence Hospital, Bronxville, New York

Objective

To evaluate whether a synthetic osmotic cervical dilator is non inferior to oral misoprostol for cervical ripening.

Baseline characteristics

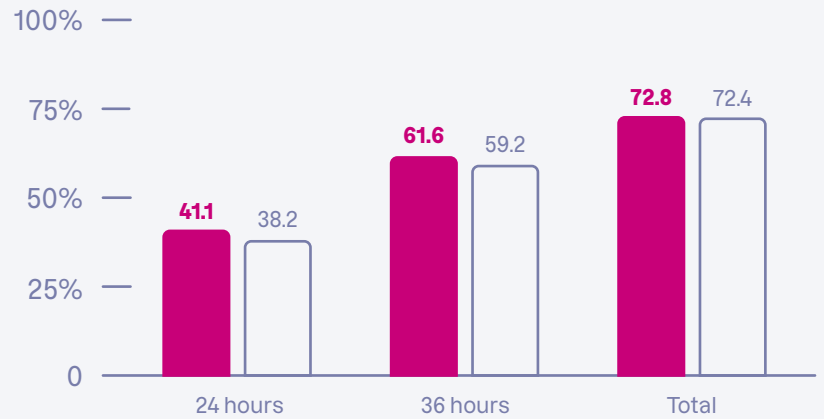
Nulliparous represented 53.6 % of the sample size in DILAPAN-S group and 53.3 % in misoprostol group.

DILAPAN-S is fully comparable to low-dose oral misoprostol 25 mcg in vaginal delivery rate while offering a better safety profile and superior maternal satisfaction.

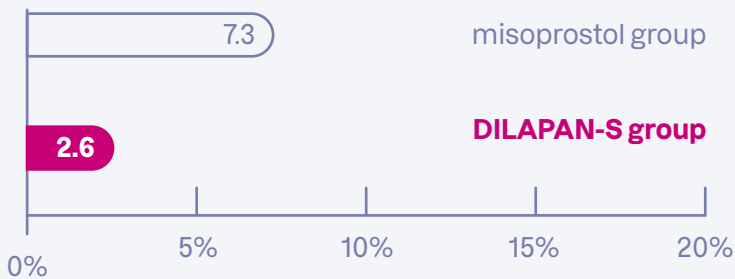
Vaginal delivery rate

Vaginal delivery rate with DILAPAN-S was fully comparable to low dose oral misoprostol.

■ DILAPAN-S □ misoprostol



Uterine tachysystole with NRFHR* during cervical ripening was lower in the DILAPAN-S group.



In contrast to misoprostol, no newborn had a **5 minute Apgar score <7** or **arterial cord blood pH <7.1** in the DILAPAN-S group.

*NRFHR = non reasuring fetal heart rate

Predictability for scheduling

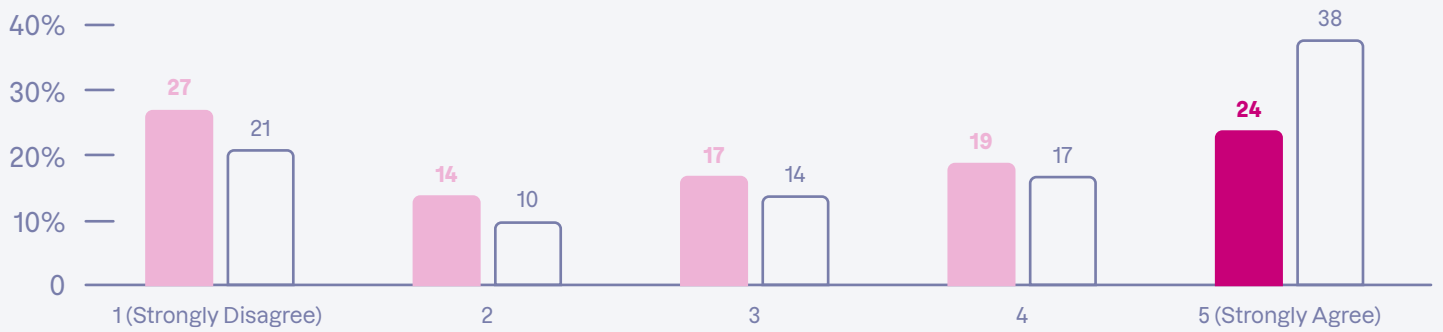
58.2 % of women in the misoprostol group didn't receive all 6 planned doses of misoprostol due to different complications associated with its use during the cervical ripening period.

DILAPAN-S may offer better predictability and allow for more efficient scheduling on the labour ward.

Maternal Satisfaction

I experienced unpleasant abdominal sensations

(DS better than MP; $p=0.03$)

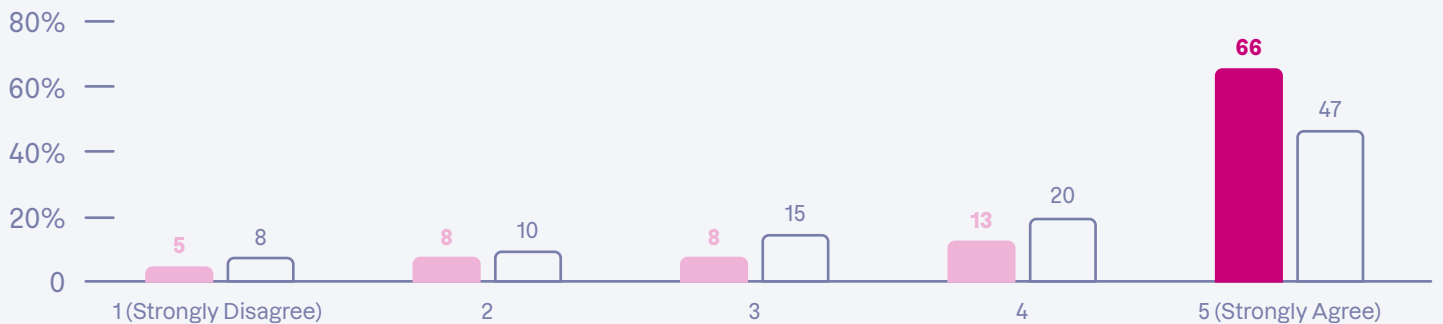


Women in DILAPAN-S group experienced significantly less unpleasant abdominal sensations.

DILAPAN-S misoprostol

I was able to sleep and rest

(DS better than MP; $p=0.02$)

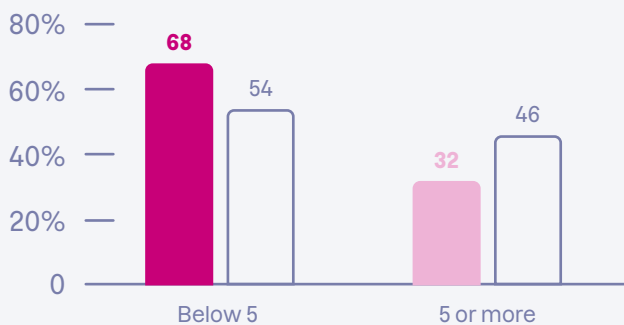


Women in DILAPAN-S group were significantly more able to rest and sleep.

DILAPAN-S misoprostol

Wong-Baker FACES® Pain Rating Scale (0-10) results

(DS better than MP; $p=0.03$)



DILAPAN-S misoprostol

Women in DILAPAN-S group reported significantly lower pain.





COMRED trial – DILAPAN-S key facts

73 %

overall rate
of vaginal delivery

40 %*

vaginal delivery
rate within 24 hours

20 %

more able to sleep
and rest

0 %

babies with
5 min Apgar score < 7 and
arterial cord blood pH < 7.1

* To consider

Vaginal delivery rate within 24 hours was fully comparable between arms; this outcome confirms that “speed of action” is related to IOL clinical protocol rather than to the method of cervical ripening. DILAPAN-S offers the same “speed of action” to complete vaginal birth as low-dose oral misoprostol.

REFERENCE: Gavara R. et al. Cervical Ripening Efficacy of Synthetic Osmotic Cervical Dilator Compared With Oral Misoprostol at Term, Obstetrics & Gynecology: May, 2022



DILAPAN-S is manufactured by company MEDICEM Technology s.r.o., Czech republic (www.medicem.com)
Company AGHealth is an authorised distributor of the product in the UK (www.aghealth.co.uk)

