

Outpatient Versus Inpatient Pre-induction Cervical Ripening Using DILAPAN-S Randomized Clinical Trial (HOMECARE)

Introduction

- Various ripening methods are available.
- Mechanical methods of cervical ripening are safe and cost-effective.
- 2019 rates of labor induction have risen to 29.4%, with a third requiring cervical ripening.
- Bolstered by their limited effect on uterine contractility, mechanical dilators have become potential agents for outpatient cervical ripening.
- DILAPAN-S, an FDA approved device for cervical ripening was non-inferior to the Foley balloon and oral misoprostol in terms of safety and efficacy with better patient satisfaction.
- Allowing pregnant women to return home after insertion is a promising strategy that lowers in-hospital healthcare costs and improves subject satisfaction.

Hypothesis

- Outpatient cervical ripening with a synthetic osmotic dilator shortens the length of hospital stay without an increase in neonatal and maternal adverse outcomes

Objective

- To assess whether outpatient cervical ripening with a synthetic osmotic dilator (DILAPAN-S) shortens the length of hospital stay in term pregnancies undergoing labor induction.

Study Design

- Multi-center prospective randomized controlled trial.
- Pregnant women scheduled for induction of labor at term with an unfavorable cervix (<3 cm dilated and <60% effaced) and without a need for maternal or fetal continuous monitoring were randomized to the outpatient or inpatient arm.
- After reassuring fetal heart rate tracing DILAPAN-S was placed.
- Women in the outpatient arm were asked to return after 12 hours or earlier if needed. A study leaflet was provided with detailed instructions, emergency contacts to appropriate study/clinical staff, and space to document any oral medication taken for pain relief (acetaminophen).
- Women in the inpatient arm remained in the hospital.
- If the cervix remained unfavorable after removal of dilators (< 3cm dilated and < 60% effaced), additional mechanical or pharmacological cervical ripening was allowed at the provider's discretion.
- After the first round, oxytocin administration, and labor management were left up to the clinical providers.
- The primary outcome was the proportion of women with hospital stay >48 hours.
- Secondary outcomes included vaginal delivery within 24, 36 and 48 hours, change in cervical dilation, change in Bishop score, analgesics used during cervical ripening, removal of DILAPAN-S <12 hours, hospital stay, time from admission to active stage of labor (defined as ≥ 6 cm cervical dilation), time from device placement to active phase, time from device placement to delivery, composite and individual adverse neonatal outcomes (Apgar score <7 at 5 minutes, Cord arterial pH<7.1, NICU admission) and maternal outcomes (total oxytocin duration, maximum oxytocin rate, postpartum hemorrhage, maternal infection).
- All analyses were by intention-to-treat.
- Each patient was also asked to complete a satisfaction survey regarding sleep, rest, pain, and activity.

Results

- The trial enrolled 339 patients (171 inpatient, 167 outpatient, and 1 withdrawal).
- Baseline characteristics of the study population are shown in Table 1.
- The proportion of women with hospital stay >48 hours was significantly lower in the outpatient group.
- The outpatient group had a shorter total length of hospital stay and shorter time from admission to active labor.
- Four out of 167 outpatient subjects were admitted <12 hours for suspected labor and rupture of membrane.

Table 1. Demographic characteristics of study participants.

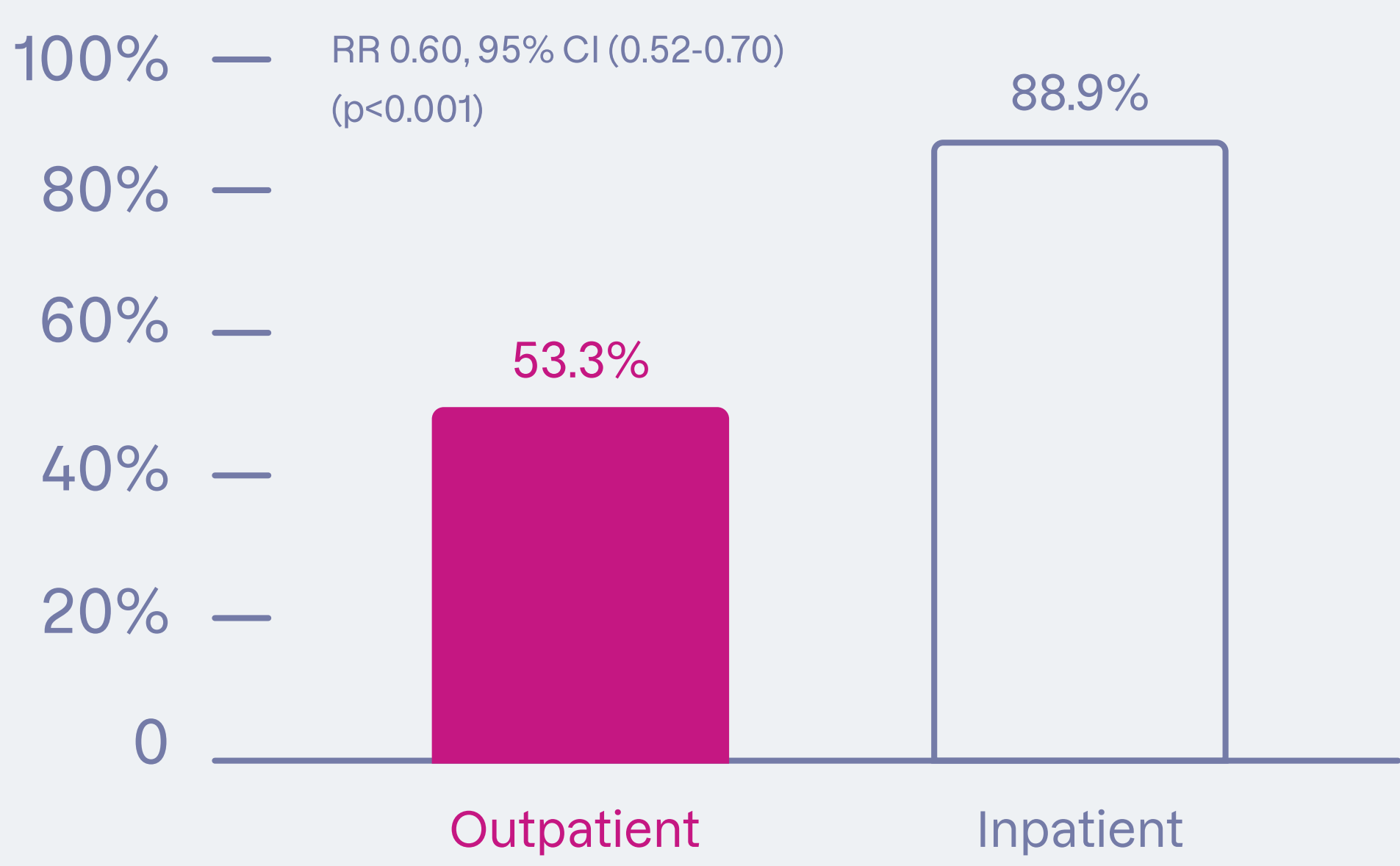
Characteristic	Outpatient (n=167)	Inpatient (n=171)
Age (y)	25.2 ± 5.6	25.9 ± 5.6
Race or ethnicity		
– Black	18 (10.8)	18 (10.5)
– White	145 (86.8)	148 (86.5)
– Hispanic	120 (71.9)	112 (65.5)
GA at randomization	39 0/7 (39 0/7–39 3/7)	39 0/7 (39 0/7–39 3/7)
Nulliparous	83 (49.7)	78 (45.6)
BMI (kg/m2) at randomization	33.3 ± 6.3	33.5 ± 6.7
Estimated fetal weight (g)	3337 ± 300	3330 ± 271
Number of device rods inserted	5 (5–6)	5 (5–6)
Bishop score at device insertion	3 (2–4)	3 (1–4)
GBS colonization	41 (24.6)	46 (26.9)

Baseline characteristics did not differ among groups.
Data is shown as mean ± standard deviation or median [range]
kg: kilograms; m2: meter square; g: grams; GBS: group B streptococcus.

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Figure 1.
Hospital stay > 48 hours.



- Delivery within 24 hours of admission was higher in the outpatient group.
- The amount of analgesic during cervical ripening was significantly lower in the outpatient group.
- Route of delivery and other maternal and neonatal outcomes were not significantly different between groups.

Figure 3.
Vaginal delivery within 24 hours and Analgesics during cervical ripening.

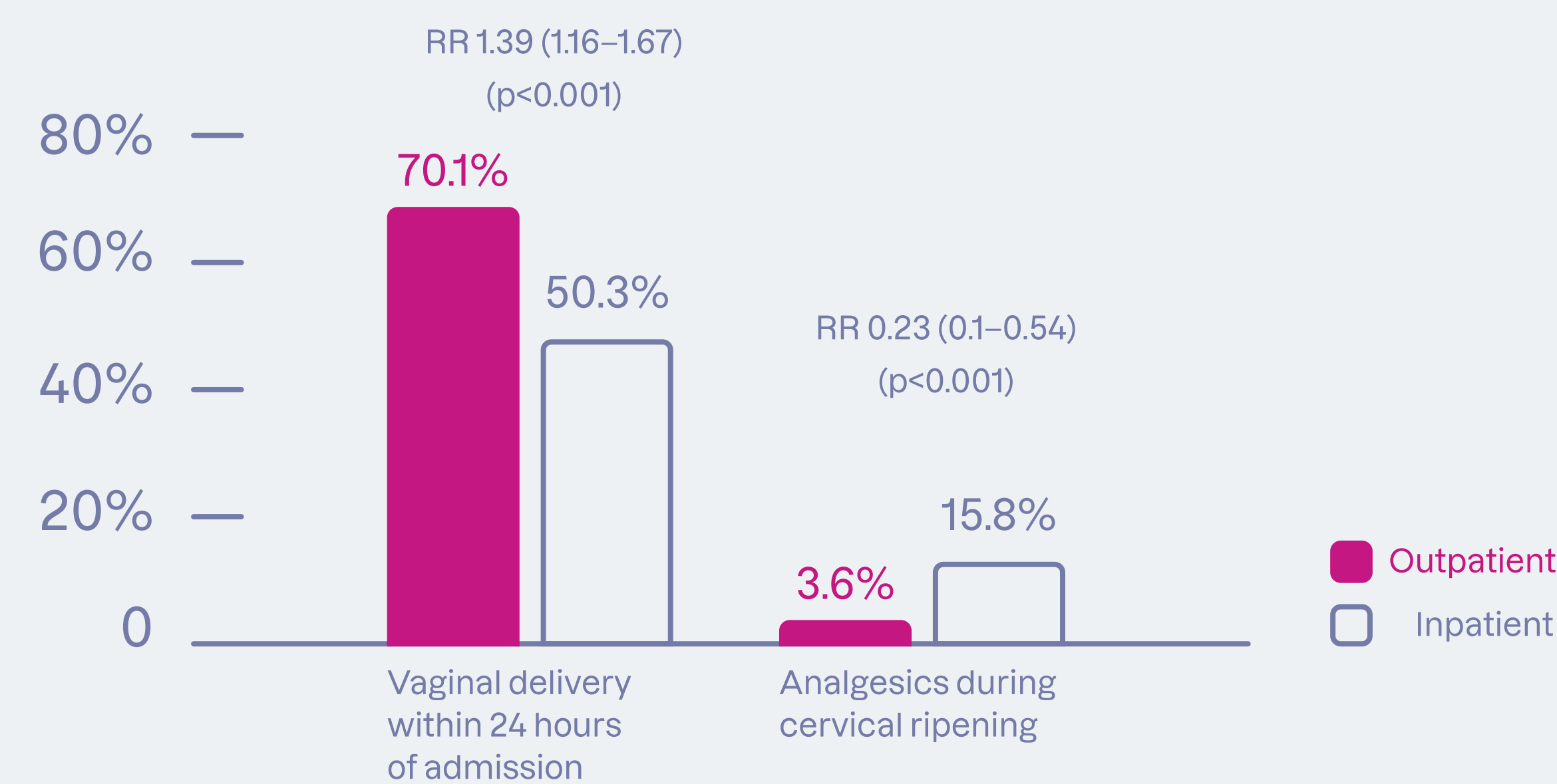
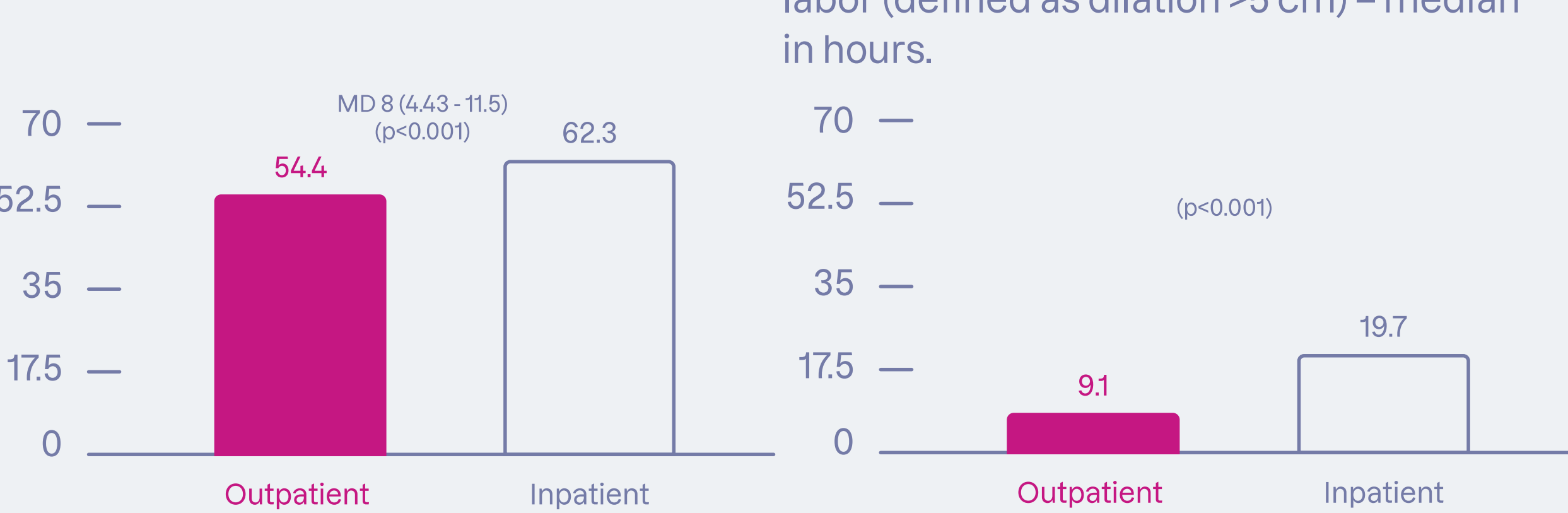
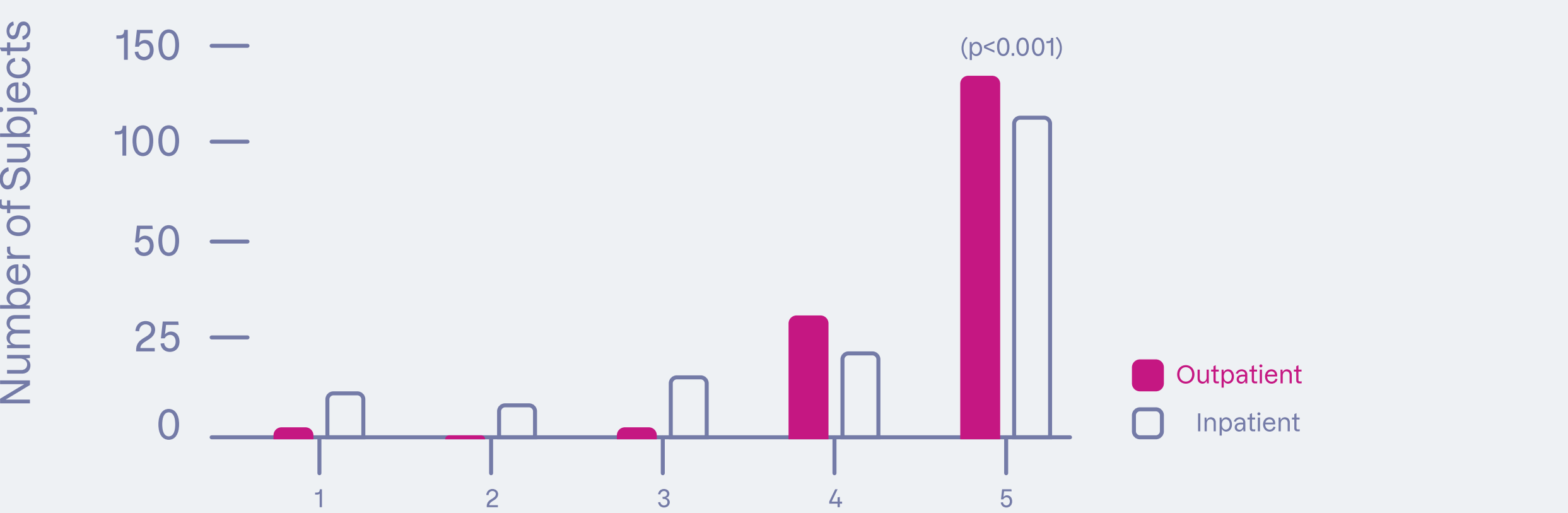


Figure 2. A
Total length of hospital stay in hours.

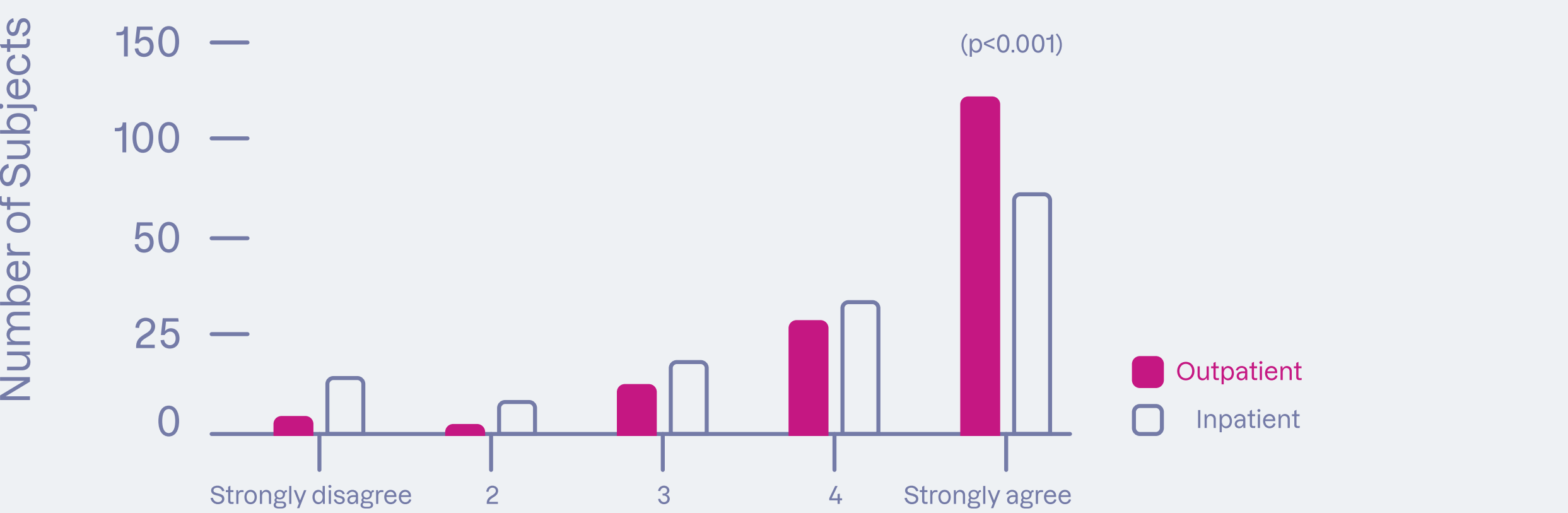


- Women were significantly more able to walk, eat, and shower in the outpatient group and felt that outpatient cervical ripening was beneficial and would choose the same approach for their subsequent pregnancy.

During the cervical ripening process, I was able to walk, eat and shower



Having my cervix soften and distended outpatient is beneficial and a great idea



Conclusions

- Outpatient cervical ripening with a synthetic osmotic cervical dilator (DILAPAN-S) significantly reduced hospital stay.
- No increase in adverse maternal or neonatal outcomes.
- The evidence supports the benefit and safety of outpatient mechanical cervical ripening.