Cervical balloon catheter vs Dilapan-S for outpatient cervical ripening: a randomized controlled trial

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BACKGROUND: As labor induction increases in the United States, safe and effective outpatient cervical ripening has been explored as a method to decrease the inpatient time burden. However, the most effective method for outpatient mechanical cervical ripening remains unclear.

OBJECTIVE: This study aimed to evaluate whether Dilapan-S is noninferior to a cervical balloon for outpatient cervical ripening based on the change in Bishop score.

STUDY DESIGN: This single-blind randomized controlled trial was conducted at a single tertiary hospital. Term patients, both nulliparous and multiparous, aged 18 to 50 years with a singleton cephalic fetus and no previous cesarean delivery who were scheduled for outpatient cervical ripening per preexisting hospital policy were eligible. Participants were randomized to single-balloon cervical ripening with a Cook catheter with 60 mL in the intrauterine balloon or placement of 3 to 5 Dilapan-S hydroscopic dilators and were discharged. Upon returning to the hospital, the cervical ripening agent was removed, a blinded cervical examination was performed, and the participants completed a satisfaction survey. Further labor induction was performed as per the obstetrical provider. The primary outcome was change in Bishop score. The secondary outcomes included patient satisfaction, mode of delivery, labor induction time, adverse maternal and neonatal outcomes, and cervical ripening failure composite (failure to place a randomized cervical ripening agent, premature rupture of membranes before a scheduled return to the hospital, significant vaginal bleeding, or need for further cervical ripening after the initial agent is removed). This study had 80% power to show noninferiority in change in Bishop score, with a margin of 2 and a standard deviation of 3.

RESULTS: From May 2022 to June 2023, 80 participants were randomized, with no difference in baseline demographic data, starting dilation, or Bishop score. Of note, 70% of the participants in each arm were nulliparous. There was no difference in change in Bishop score between Dilapan-S and the cervical balloon catheter (median change: 3.0 [interquartile range, 2.0−5.0] vs 3.0 [interquartile range, 2.0−4.5], respectively; P=.91). There was no difference in the time to delivery, mode of delivery, or maternal or neonatal outcomes. Compared with participants randomized to a cervical balloon catheter, those randomized to Dilapan-S were more satisfied with their experience than (satisfaction scale of 0−10; median: 8 [interquartile range, 5−9] vs 9 [interquartile range, 8−10], respectively; P<.01) and were less likely to experience cervical ripening failure (18 (45.0%) vs 7 (17.5%), respectively; P<.01).

CONCLUSION: Dilapan-S was noninferior to a cervical balloon catheter for outpatient cervical ripening based on the change in Bishop score. The participants were more satisfied with Dilapan-S and less likely to experience cervical ripening failure than with a cervical balloon catheter with single-balloon inflation.

Key words: balloon catheter, Bishop score, cervical ripening, Dilapan-S, induction, labor, mechanical, outpatient

Introduction

Labor induction rates are increasing in the United States, with 32.1% of all births induced in 2021,[1] a sharp increase from 23.2% 10 years earlier.[2] These rates continued to increase since the publication of the ARRIVE (A Randomized Trial of Induction Versus Expectant Management) trial, which found that patients who underwent elective labor induction at 39 weeks of gestation had a lower cesarean delivery rate with no difference in maternal or neonatal morbidity in nulliparous patients compared with those who had expectant management.[3,4] However, labor induction leads to longer labor and delivery stays, placing an increasing burden on the limited resources of labor and delivery (L&D) units.[4]

Previous studies have found that 83% of patients undergoing labor induction require cervical ripening,[5] a process that can take up to 24 hours. Multiple studies have investigated whether cervical ripening can be safely performed in an outpatient setting to decrease the time spent on L&D. These trials demonstrated that outpatient mechanical ripening decreases the time from hospital admission to delivery and the overall length of stay (LOS) with no increase in maternal or neonatal morbidity.[6] However, the most effective method of outpatient cervical ripening remains unknown.

Mechanical cervical ripening is a commonly used option for outpatient cervical ripening because it is considered safe and effective.[6,7] Mechanical ripening has traditionally been completed using 1 of 2 methods: cervical balloon catheters or intracervical rod placement.[7]

For mechanical cervical ripening, cervical balloon catheters are used by placing a Foley or Cook balloon catheter through the cervix beyond the internal os. The intrauterine balloon is inflated with sterile fluid, which places mechanical pressure on the cervix and releases endogenous prostaglandins, resulting in cervical ripening. However, in previous studies, patients reported dissatisfaction with balloon ripening compared with other methods.[8]

Dilapan-S, a synthetic hygroscopic dilating rod, was approved by the Food and Drug Administration for prelabor

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AJOG MFM at a Glance

Why was this study conducted?

This study aimed to compare 2 common methods of mechanical cervical ripening in an outpatient setting.

Key findings

This study determined that Dilapan-S is not inferior to a cervical balloon catheter for cervical ripening at term in an outpatient setting, as measured by change in Bishop score. There was no significant difference in adverse events between the groups. In addition, higher patient satisfaction was observed in the Dilapan-S group.

What does this add to what is known?

Dilapan-S has previously been found to be noninferior to a cervical balloon catheter for cervical ripening in an inpatient setting. This study shows that the same is true for outpatient ripening. Patient satisfaction is an important part of labor induction, and this trial showed that patients may prefer Dilapan-S.

cervical ripening in 2015. Since then, a randomized trial, the Dilapan-S vs Foley Balloon for Preinduction Cervical Ripening (DILAFOL) study, was completed by comparing a balloon catheter to Dilapan-S for cervical ripening.[9] This trial showed that Dilapan-S was noninferior to a balloon for cervical ripening based on the rate of vaginal delivery, with no difference in maternal or neonatal morbidity and increased patient satisfaction with Dilapan-S.[9]

This study aimed to determine whether Dilapan-S is noninferior to a cervical balloon catheter for outpatient cervical ripening.

Materials and methods

This was a randomized controlled trial (RCT) conducted at a single university-affiliated tertiary medical center. The study was approved by the local institutional review board (Mass General Brigham IRB Protocol number: 2021P002625) and registered at ClinicalTrials.gov (national clinical trial identifier: 05062343; available at https://clinicaltrials.gov/study/NCT05062343).

Participants were at least 18 years of age with a term (37 0/7 to 41 6/7 weeks of gestation) singleton fetus with cephalic presentation. Both nulliparous and multiparous patients were included in this study. Participants were eligible if they had intact membranes, a Bishop score of <6, and cervical dilation ≤2 cm. The exclusion criteria for fetal reasons included fetal growth restriction of <5th percentile, abnormal umbilical artery Doppler findings, oligohydramnios, moderate/severe polyhydramnios, and nonreassuring fetal assessment. Maternal reasons for exclusion included clinically significant vaginal bleeding, preeclampsia, hypertension requiring recent uptitration of antihypertensive medication, previous cesarean delivery, and obstetrical contraindications to vaginal birth, such as placenta previa. GBS (Group B Streptococcus) positivity was not an exclusion from outpatient ripening per hospital protocol, and prophylaxis was administered as a standard during inpatient admission for patients with GBS positivity. In addition, the participants had to be able to return easily if symptoms arose, although no specific distance limitation was placed. English- and Spanish-speaking patients were included in this study.

Participants were approached for possible participation by trained study staff via telephone calls or in person after their primary obstetrical provider had scheduled them for outpatient cervical ripening, as per the hospital policy.

On arrival for their outpatient cervical ripening appointment, all participants underwent a nonstress test ultrasound to confirm cephalic presentation and cervical examination to confirm that they still required cervical ripening (Bishop score of <6 and cervical dilation of ≤2 cm). If these criteria were met and participants continued to be interested in study participation, written informed consent was obtained, and participants were randomized to either the cervical balloon group or the Dilapan-S group.

An independent consultant created a computer-generated randomization scheme that used balanced treatment allocation in blocks of 6, stratified by parity. The resulting sequential group allocations were kept in sealed opaque envelopes until the time of randomization. The participants were not blinded to the assigned treatment group. However, the examiners who recorded the pre- and postripening Bishop scores were blinded to the treatment group.

After randomization, a cervical ripening device was inserted. For participants in both arms, a speculum was placed, and the cervix was visualized and cleaned with betadine. In the cervical balloon arm, an intracervical Cook double-balloon catheter (Cook Medical Inc, Bloomington, IN) was placed, but only the single intrauterine balloon was inflated with 60 mL of normal saline. Our institution routinely uses Cook catheters instead of Foley catheters. However, the standard institutional practice is to use only the intrauterine balloon for patient comfort, which should increase the generalizability of institutions that use 60-mL Foley catheters for cervical ripening. A balloon catheter was taped to the mother's leg under tension.

For participants in the Dilapan-S (Medicem Inc, Prague, Czech Republic) arm, 3 to 5 rods were inserted into the cervical canal under direct visualization according to the manufacturer's instructions. The number of rods used was based on participant tolerability and the provider's ability to place them.

Participants in both arms were discharged with strict return precautions, including calling or returning to the hospital for any bleeding, rupture of membranes, strong regular contractions consistent with labor, excessive pain, or other concerns. The participants were instructed to contact the medical team if the device or devices were expelled at home so that they would not need to

return to the hospital for that reason alone.

Participants were asked to return to the hospital for the inpatient portion of their prescheduled inpatient labor induction encounter, approximately 12 hours after placement, with an allowable range of 6 to 24 hours after cervical ripening agent placement per existing hospital policy.

If the participants were unable to tolerate their assigned study treatment, they were offered other institutionally approved options for outpatient cervical ripening, including Dilapan-S, cervical balloon catheter, or oral misoprostol. The participants were included in the primary intention-to-treat (ITT) analysis.

Upon return to the hospital, 1 member of the clinical team removed the cervical ripening device, and a separate senior member of the team (third year resident, certified nurse midwife (CNM), maternal-fetal medicine fellow, or attending) who was blinded to the treatment arm performed a sterile cervical examination and assigned a 5-item Bishop score per standard clinical practice.[10,11] Participants were given a patient satisfaction survey to complete after device removal.

Subsequently, the patient's clinical team completed the remainder of the labor induction per standard protocol.

Trained research staff abstracted data from the medical records, including demographics, past medical history, and relevant obstetrical and neonatal outcomes.

Outcomes

The primary outcome was change in Bishop score. This was single blinded as clinicians assigned the initial Bishop score before randomization and clinical staff assigning the postripening Bishop score were blinded to the treatment arm. Participants were not blinded to the treatment arm given the extravaginal portion of the cervical balloon.

The secondary outcomes included Bishop score at device removal, dilation at device removal, overall satisfaction, pain/discomfort with placement, experience with cervical ripening at home, chorioamnionitis, cesarean delivery rate, time from admission to delivery, and maternal and fetal LOS. In addition, the maternal morbidity composite of blood transfusion, endometritis, wound infection, venous thromboembolism, hysterectomy, or intensive care unit admission was calculated.

The secondary neonatal outcomes included neonatal intensive care (NICU) admission, NICU admission for >48 hours, and a composite neonatal morbidity outcome, including any one of the following: culture-proven neonatal sepsis, neonatal blood transfusion, hypoxic-ischemic encephalopathy, intraventricular hemorrhage grade 3 or 4, or therapeutic hypothermia.

In addition, we collected a cervical ripening failure composite, defined as any of the following: failure to place a randomized cervical ripening agent, premature rupture of membranes before the scheduled return to the hospital, significant vaginal bleeding, or need for further cervical ripening after the initial agent is removed.

Given that the goal of outpatient ripening is to decrease the burden on labor, delivery staff, and resources, we also recorded any unscheduled contact with the medical system before the planned return to the hospital, including telephone calls and unscheduled returns to the outpatient clinic or L&D.

Participant satisfaction was assessed using a written survey that was completed after mechanical dilator removal but before hospital discharge. The questionnaire consisted of 8 questions. Of note, 5 questions were scored on a 5-point Likert scale, 2 questions were assessed using a standard 10-point pain scale (0 = no pain and 10 = worst pain imaginable), and the overall patient satisfaction question used a 10-point scale (0 = completely dissatisfied and 10 = completely satisfied) based on marketing research that showed a better distribution of scores when a 10-point scale was used for satisfaction.[12,13]

Statistical analysis

We hypothesized that Dilapan-S would be noninferior to a cervical balloon catheter for cervical ripening at term based on the change in Bishop score. The primary analysis was performed on the ITT population.

Demographic and baseline characteristic analyses and primary and secondary outcome analyses were performed on the ITT population. The primary outcome analysis was repeated for each protocol population. Demographic and baseline characteristics were compared using Fisher exact and chi-square tests, as appropriate.

Continuous variables were assessed for normality, and the Student *t* test or Wilcoxon rank-sum test was used, as appropriate. Change in Bishop score was not normally distributed. Therefore, nonparametric tests were used for comparison. The questionnaire was analyzed using the Cochran-Armitage test for trends in questions based on the Likert scale and Wilcoxon rank-sum tests for 10-point scale questions.

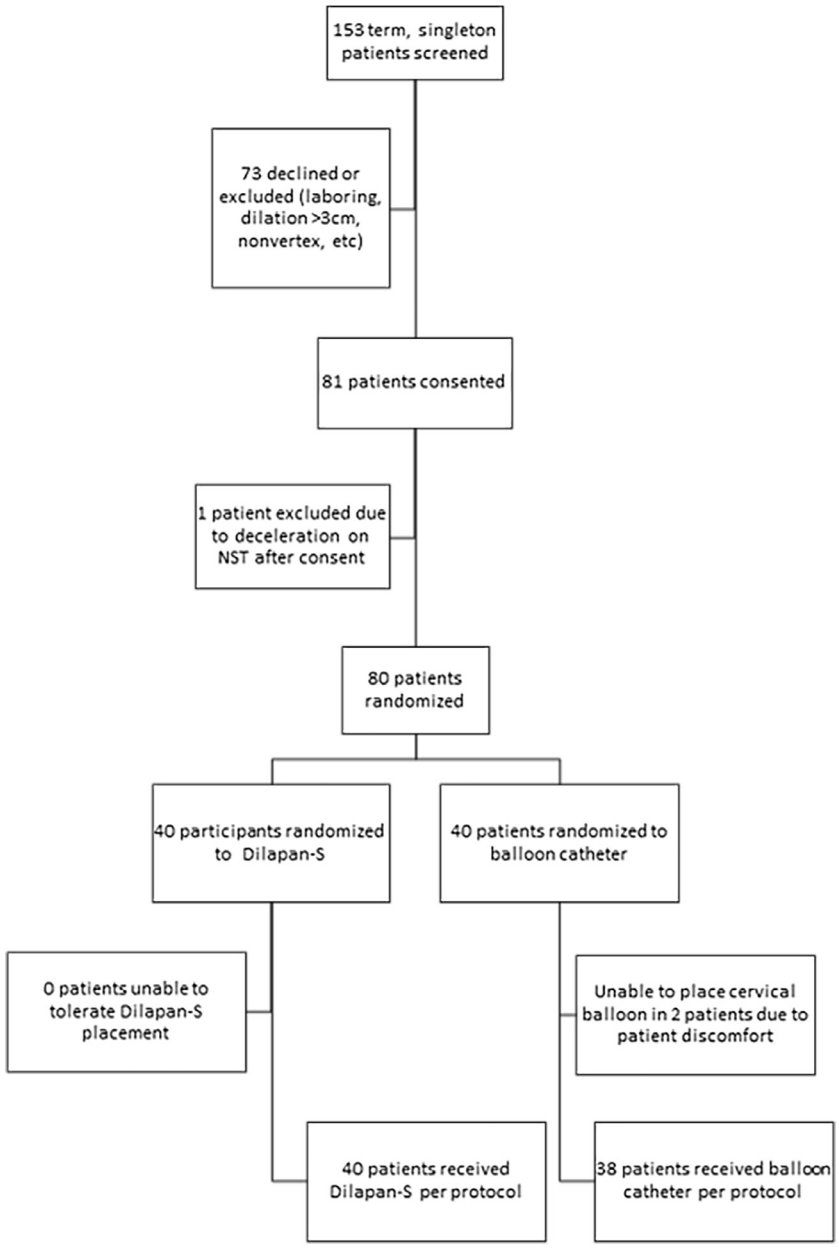
For all analyses, a 2-sided significance level of $P<.05$ was considered statistically significant. Analyses were performed using SAS software (version 9.3; SAS Institute, Cary, NC).

Given the study design of noninferiority trial with 1:1 randomization comparing Dilapan-S with Cook catheter with the primary outcome of change in Bishop score, we defined a noninferiority margin of 2 with a standard deviation of 3, which was estimated from the DILAFOL study.[9] A type I α error of 0.05 was selected. Assuming 90% power and a 2-sided *P* value, we would need 39 participants in each arm for a total of 78 participants. However, we enrolled 80 patients to ensure sample size adequacy given that loss to follow-up was not anticipated.

Results

From May 2022 to June 2023, 153 patients were approached for the study, and 81 provided consent. However, 80 participants were randomized (40 in the cervical balloon catheter group and 40 in the Dilapan-S group) (Figure 1). Of note, 1 participant consented but was found to be ineligible before randomization based on deceleration in the nonstress test. No postrandomization

FIGURE 1
Flowchart of the study inclusion



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withdrawal or loss to follow-up was observed.

All 40 participants randomized to the Dilapan-S group had Dilapan-S placed per protocol. Of the 40 participants randomized to the cervical balloon catheter group, 2 participants could not tolerate balloon placement because of discomfort. These participants received oral misoprostol per predefined protocol to allow participants who failed the placement of randomized agents to select another of the approved outpatient ripening methods per institutional protocol.

There was no difference in baseline demographic data, starting dilation, or starting Bishop score between the groups (Table 1). Of note, 70% of the participants in each arm were nulliparous. The median gestational age was 39.2 weeks in both groups, and the most common indication for labor induction was elective. The median number of Dilapan-S rods placed was 5 in the Dilapan-S group.

For our primary outcome, there was no difference in change in Bishop score between the Dilapan-S and cervical balloon catheter groups (median change in Bishop score: 3.0 [interquartile range (IQR), 2.0−5.0] vs 3.0 [IQR, 2.0−4.5], respectively; P=.91) (Table 2). In addition, noninferiority was confirmed in the per-protocol analysis (median change in Bishop score: 3.0 [IQR, 2.0 −5.0] in the Dilapan-S group vs 3.0 [IQR, 2.0−4.5] in cervical balloon catheter group; P=.94).

There was no difference in Bishop score at device removal, dilation at device removal, overall satisfaction, reported pain/discomfort with placement, patient experience with cervical ripening at home, chorioamnionitis, cesarean delivery rate, time from admission to delivery, maternal and fetal LOS, or neonatal or maternal composite morbidity outcomes (Table 2).

Regarding the patient satisfaction survey, 38 participants (95.0%) randomized to the Dilapan-S group and 39 participants (97.5%) randomized to the Cook balloon catheter group completed the survey. There was no difference between the groups in terms of anxiety before ripening (P=.66) or discomfort with ripening agent placement (P=.45). Participants randomized to the Dilapan-S group were more satisfied with comfort (P<.01), ability to complete routine activities (P<.01), and sleep (P<.01) than those randomized to the cervical balloon catheter group (Figure 2). Compared with participants randomized to the cervical balloon catheter group, those randomized to the Dilapan-S group reported no difference in overall pain experienced with cervical ripening (scale of 0−10; median: 6 [IQR, 4−6] vs 4 [IQR, 3−6]; P=.19) and were more satisfied with their overall experience (scale of 0−10; median: 8 [IQR, 5−9] vs 9 [IQR, 8−10]; P<.01) (Figure 2 and Supplementary Figure).

Participants randomized to the Dilapan-S group were less likely to experience our predefined composite cervical

TABLE 1
Baseline characteristics of the Dilapan-S and cervical balloon groups

Characteristic[a]	Dilapan-S (n=40)	Cervical balloon (n=40)
Age (y)	32.0 (29.0–35.5)	34.0 (30.0–36.5)
BMI at delivery (kg/m^2)	30.7 (25.8–35.0)	30.7 (25.8–35.0)
BMI of >30 kg/m^2	7 (17.5)	4 (10.0)
Gestational age (wk)	39.2 (39.0–40.2)	39.2 (39.0–40.0)
Nulliparous (%)	28 (70.0)	28 (70.0)
Race		
Asian	3 (7.5)	2 (5.0)
Black	6 (15.0)	2 (5.0)
White	27 (67.5)	33 (82.5)
Other	4 (10.0)	3 (7.5)
Ethnicity		
Hispanic	5 (12.5)	6 (15.0)
Maternal comorbidities		
Gestational diabetes mellitus	6 (15.0)	4 (10.0)
Chronic hypertension	3 (7.5)	3 (7.5)
Gestational hypertension[b]	1 (2.5)	0 (0)
Bishop score at randomization[c]	3.0 (2.0–4.0)	2.0 (1.5–3.5)
Dilation at randomization (cm)	0 (0–1)	0 (0–1)
Time CR agent was in place (h)	11.4 (10.2–13.1)	11.7 (9.0–13.3)
Indication for labor induction		
Late term	4 (10.0)	2 (5.0)
Maternal	11 (27.5)	8 (20.0)
Fetal	1 (2.5)	3 (7.5)
Elective	24 (60.0)	27 (67.5)
Birthweight (g)	3427 (3223–3730)	3420 (3061–3648)

Data are presented as number (percentage) or median (interquartile range).

BMI, body mass index; *CR*, cervical ripening.

[a] There was no significant difference between the groups. Percentages may not total 100 because of rounding; [b] Diagnosed in the intrapartum period; [c] Bishop scores range from 0 to 13 with <6 being considered unfavorable for labor induction.

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ripening failure outcome than those randomized to the cervical balloon catheter group (7 [17.5%] vs 18 [45.0%], respectively; *P*<.01), which was mainly driven by a difference in the need for additional cervical ripening (7 [17.5%] vs 13 [32.5%], respectively; *P*=.12), although no individual component of the composite differed between groups. Participants randomized to the Dilapan-S group were less likely to have unscheduled contact with the medical team than those randomized to the cervical balloon catheter group (3 [7.5%] vs 14 [35.0%], respectively; *P*<.01) (Table 2). Of note, 1 participant in the Dilapan-S arm expelled the cervical ripening agent at home but still returned as scheduled.

Comment

Principal findings

Dilapan-S was noninferior to the cervical balloon catheter for cervical ripening based on the change in Bishop score (median change: 3 vs 3, respectively; *P*=.91). Patients were more satisfied with Dilapan-S, and patients with Dilapan-S were less likely to experience cervical ripening failure.

Results in the context of what is known

The DILAFOL study, published in 2019, compared Dilapan-S and cervical balloon catheter for inpatient ripening with a primary outcome of vaginal delivery.[8] Similar to our trial, the DILAFOL study found no difference in cervical ripening, labor outcomes, or rates of vaginal birth between Dilapan-S and cervical balloon catheter but did find increased patient satisfaction in the participants who received Dilapan-S. Our study expands on the DILAFOL study findings by extending them to the outpatient setting as the findings of an inpatient ripening study may not be generalizable to the outpatient setting.

In addition, in the DILAFOL study, almost 1 in 5 participants (18.2% in the Foley catheter group and 16.7% in the Dilapan-S group) required analgesia for pain relief during agent placement. Analgesia was not used in our study. Thus, our study may provide reassurance that patients can tolerate mechanical ripening placement in an outpatient setting without analgesia.

Since the completion of this study, another trial comparing hygroscopic cervical dilators (Dilapan-S) with cervical ripening balloon catheters for outpatient cervical ripening was published.[15] This trial found no difference in the primary outcome of time from admission to delivery and interestingly found no difference in patient satisfaction. However, their results are dichotomized into "satisfied" vs "dissatisfied." Our study may provide further insights into the nuances that lead patients to feel satisfied with their outpatient cervical ripening experience, which can lead clinicians to better tailor outpatient cervical ripening protocols to be acceptable to patients.

Clinical implications

This study compared Dilapan-S with a cervical balloon catheter for cervical ripening in an outpatient setting and

TABLE 2
Primary and secondary outcomes for Dilapan-S and cervical balloon (intention-to-treat analysis)

Outcomes	Dilapan-S (n=40)	Cervical balloon (n=40)	*P* value
Change in Bishop score[a]	3.0 (2.0–5.0)	3.0 (2.0–4.5)	.91
Total Bishop score after CR	6.0 (5.0–7.0)	5.5 (4.0–7.0)	.91
Cervical dilation after CR (cm)	3.0 (3.0–4.0)	3.0 (2.0–4.0)	.25
L&D admission to delivery (h)	20.1 (13.9–26.2)	17.0 (11.7–28.4)	.89
Maternal LOS (d)	3.2 (2.7–4.7)	2.9 (2.7–3.9)	.98
Mode of delivery			
Vaginal	30 (75.0)	30 (75.0)	1
Cesarean	10 (25.0)	10 (25.0)	1
Chorioamnionitis	5 (12.5)	6 (15.0)	.75
Maternal morbidity composite	3 (7.5)	2 (5.0)	1
Blood transfusion	2 (5.0)	1 (2.5)	1
Endometritis	1 (2.5)	0 (0)	1
Wound infection	0 (0)	1 (2.5)	1
VTE	0 (0)	0 (0)	
Hysterectomy	0 (0)	0 (0)	
ICU admission	0 (0)	0 (0)	
5-min Apgar score	9 (9–9)	9 (9–9)	1
NICU admission	5 (12.5)	5 (12.5)	1
NICU admission of >48 h	3 (7.5)	5 (12.5)	.71
Neonatal LOS (d)	2 (2–3)	2 (2–3)	.65
Neonatal composite	1 (2.5)	0 (0)	1
Culture-proven sepsis	0 (0)	0 (0)	
Blood transfusion	0 (0)	0 (0)	
HIE	0 (0)	0 (0)	
IVH grade 3 or 4	0 (0)	0 (0)	
Therapeutic hypothermia	1 (2.5)	0 (0)	1
Composite cervical ripening failure	7 (17.5)	18 (45.0)	.01
Inability to place CR	0 (0)	2 (5.0)	.49
Need for further ripening	7 (17.5)	13 (32.5)	.12
Cervical laceration	0 (0)	0 (0)	
PROM while home	0 (0)	2 (5.0)	.49
Significant vaginal bleeding	0 (0)	1 (2.5)	1
Unscheduled contact with medical system	3 (7.5)	14 (35.0)	<.01
Triage telephone call	2 (5.0)	10 (25.0)	.01
Unscheduled return	1 (2.5)	4 (10.0)	.16

Data are presented as number (percentages) or median (interquartile range).

CR, cervical ripening; *HIE*, hypoxic-ischemic encephalopathy; *ICU*, intensive care unit; *IVH*, intraventricular hemorrhage; *L&D*, labor and delivery; *LOS*, length of stay; *NICU*, neonatal intensive care unit; *PROM*, premature rupture of membranes; *VTE*, venous thromboembolism.

[a] Bishop scores range from 0 to 13 with <6 being considered unfavorable for labor induction.

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showed noninferiority of Dilapan-S for change in Bishop score. Previous studies have shown that patient satisfaction increases when given choices for labor induction methods,[8] and this study showed that both cervical ripening balloon catheter and Dilapan-S are effective options for outpatient cervical ripening. Dilapan-S was less likely to result in cervical ripening failure than the cervical balloon catheter, although there was no significant difference in the time from admission to delivery.

Although the Bishop score may be considered less clinically relevant than the time to delivery or mode of delivery, it was chosen because of its direct relevance to the outpatient focus of this trial. The Bishop score is the primary measure of cervical ripening and readiness for labor induction. Given the outpatient ripening focus of this trial, the Bishop score is a marker for the "success" of outpatient ripening and has been used previously as a primary outcome in cervical ripening studies.[14]

Although these were secondary outcomes, it should also be noted that there was no difference in the time to delivery or mode of delivery (Table 2).

Research implications

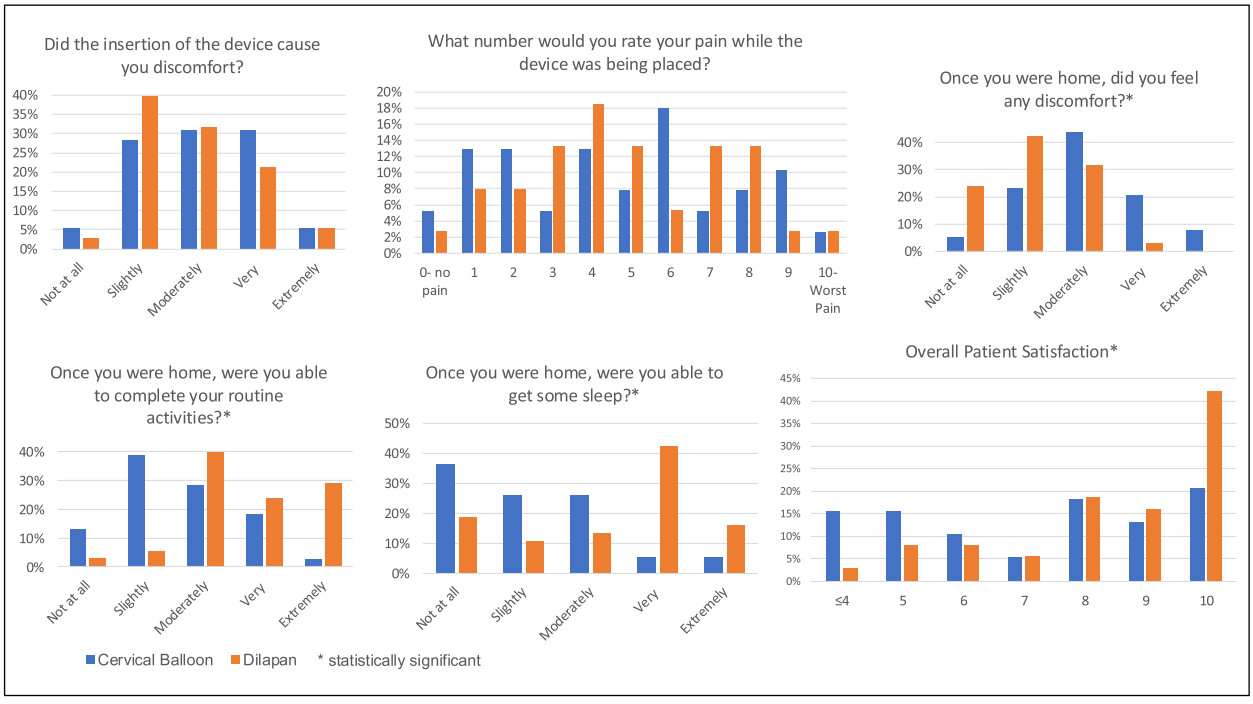
This was a small RCT. Given that safety outcomes are rare, adequately powered, and large, RCTs should continue to be performed to demonstrate the safety of outpatient ripening and to determine the optimal method for outpatient cervical ripening.

Strengths and limitations

The greatest strength of this study is its single-blind, randomized design. This study was a pragmatic trial. Thus, it is reproducible and should be easily incorporated into existing outpatient ripening protocols for cervical ripening.

Some limitations of the study are general limitations of outpatient ripening. Only patients who are low risk with no hypertensive disorder of pregnancy or preexisting diabetes mellitus were included. However, this is largely the population that is offered outpatient ripening. Thus, our study should be appropriately generalizable to the

FIGURE 2
Patient satisfaction survey result



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population eligible for outpatient cervical ripening.

Of note, 1 notable limitation in our study is the interexaminer reliability of the Bishop score given that different examiners were performing the prerandomization and postripening cervical examination. However, there should be no bias toward either arm given the blinded nature of these examinations and previous studies have found examiners to be within 1 point of each other 66% of the time.[13] In addition, we limited examiners to senior providers (third year resident, CNM, fellow, or attending) to minimize this variability.

Finally, we were underpowered to detect differences in many of our secondary outcomes, most notably safety outcomes, given their rare occurrence.

Conclusions

Dilapan-S was noninferior to a cervical balloon catheter for outpatient cervical ripening based on the change in Bishop score, with no difference in mode of delivery, LOS, or maternal or neonatal outcomes. The participants were more satisfied with the Dilapan-S than with the cervical balloon catheter. Programs offering outpatient mechanical ripening should consider adding Dilapan-S to the outpatient ripening protocols. ■

CRediT authorship contribution statement

Rachel L. Wood: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Clarissa Bluemm:** Data curation, Project administration. **Sarah C. Lassey:** Conceptualization, Writing – review & editing. **Sarah E. Little:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Software, Supervision, Writing – review & editing. ■

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ajogmf.2025.101608.

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This study was registered at ClinicalTrials.gov (identification number: NCT05062343; https://clinicaltrials.gov/study/NCT05062343). This study was first registered on September, 30, 2021. The first patient was enrolled on May 17, 2022.

This study was presented as a poster at the 44th annual meeting of Society for Maternal-Fetal Medicine, National Harbor, MD, February 10–14, 2024.

Individual patient data will be available. Individual participant data that underlie the results reported in this article will be shared after deidentification (text, tables, figures, and appendices). The study protocol will also be available. These will be available beginning 9 months and ending 36 months after article publication to investigators whose proposed use of the data has been approved by an independent review committee for an individual participant data meta-analysis. Requests can be made to the corresponding author.

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