Randomized control trial comparing hygroscopic cervical dilators to cervical ripening balloon for outpatient cervical ripening

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BACKGROUND: Outpatient term preinduction cervical ripening with mechanical agents has been associated with reduced length of stay, decreased cesarean delivery rates, low maternal and neonatal complications, and increased incidence of vaginal delivery within 24 hours.

OBJECTIVE: This study aimed to demonstrate equivalent efficacy between synthetic hygroscopic dilators and the single-balloon catheter for outpatient cervical ripening.

STUDY DESIGN: This randomized control equivalence trial compared synthetic hygroscopic dilators with the 30-mL silicone single-balloon catheter in primiparous and multiparous patients undergoing labor induction. The primary outcome was time from admission to delivery, with a prespecified 3-hour margin of equivalence. The secondary objectives were patient outcomes and perspectives.

RESULTS: Between March 1, 2019, and May 31, 2021, 1605 patients met the screening criteria, and 174 patients completed the study. The mean admission-to-delivery time was equivalent at 18.01 hours for the dilator group vs 17.55 hours for the balloon group (P=.04). The cesarean delivery rate of primiparous patients was similar at 28.1% with dilators vs 29.7% with the balloon. The groups had similar median cervical dilation and pain scores on insertion and admission. Overall patient satisfaction was high, 92.8% with dilators vs 96.2% with the balloon. The balloon group had significantly higher rates of early admission and device expulsion.

CONCLUSION: Although the enrollment goal was not met, our study suggests that synthetic hygroscopic dilators and the single-balloon catheter for outpatient cervical ripening are both efficacious with similar time from admission to delivery, pain scores, and patient satisfaction with the procedure.

Key words: cervical ripening, labor induction, outpatient, single-balloon catheter, synthetic hygroscopic dilators

Introduction

The rate of labor induction in the United States has increased from approximately 10.0% of pregnancies in 1990 to nearly 29.4% in 2019.[1,2] A landmark study of term labor induction in nulliparous patients, titled A Randomized Trial of Induction Versus Expectant Management (ARRIVE Trial), demonstrated reduced rates of cesarean delivery and preeclampsia but demonstrated an increased median duration of length of stay in labor and delivery.[3] Labor induction rates have further increased since the ARRIVE trial.[4] Although economic analysis suggests that the cost of labor induction vs spontaneous labor is neutral, term labor induction results in increased resource use in labor and delivery, posing a significant challenge because of a finite number of labor beds and staffing shortages.[3,5]

EDITOR'S CHOICE

For patients presenting for labor induction with an unfavorable cervical examination, preinduction cervical ripening has been shown to decrease the risk of cesarean delivery (vs oxytocin alone) (17% vs 32%; relative risk [RR], 0.55; 95% confidence interval [CI], 0.33 −0.91).[6] Mechanical methods of cervical ripening include balloon catheters or hygroscopic dilators, such as natural seaweed laminaria and synthetic osmotic dilators. The mechanism of action of mechanical methods is hypothesized to be the result of direct physical pressure on the internal cervical os and the release of prostaglandins from the decidua, adjacent membranes, and/or cervix.[7]

Inpatient mechanical ripening with hygroscopic dilators or balloon catheters demonstrates similar rates of vaginal delivery and maternal and neonatal adverse events, with dilators associated with increased patient satisfaction scores, although head-to-head comparison data are limited.[8] Mechanical cervical ripening is not associated with an increased risk of preterm birth in a subsequent pregnancy.[9] The incidence of hyperstimulation is lower with mechanical methods than pharmacologic methods and is considered by the American College of Obstetricians and Gynecologists (ACOG) to be appropriate for the outpatient setting.[10]

In 2001, a randomized trial comparing outpatient vs inpatient use of the Foley catheter for preinduction cervical ripening demonstrated similar efficacy and safety with a reduction of hospital stay of 9.6 hours.[11] A recent meta-analysis of 8 trials, including 740 patients, confirms that outpatient cervical ripening with the balloon catheter reduces the time from admission to delivery by 7.24 hours (16.36±9.70 hours for outpatient vs 23.86±14.0 hours for inpatient; 95% CI, −11.03 to −3.34).[12] Outpatient compared with inpatient cervical ripening using synthetic hygroscopic dilators was shown to increase the incidence of vaginal delivery within

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AJOG MFM at a Glance

Why was this study conducted?

This trial assessed the efficacy of synthetic hygroscopic dilators compared with the single-balloon catheter as mechanical methods for outpatient cervical ripening.

Key findings

Synthetic hygroscopic dilators were equivalent to the single-balloon catheter in time from admission to delivery for term prelabor cervical ripening in the outpatient setting.

What does this add to what is known?

Although the recruitment goals were not met, synthetic hygroscopic dilators seem to be an efficacious additional option for outpatient cervical ripening.

24 hours (70.1% for outpatient vs 50.3% for inpatient; RR, 1.39; 95% CI, 1.16−1.67) and decrease the proportion of participants with hospital stays longer than 48 hours (53.0% for outpatient vs 89.0% for inpatient; RR, 0.60; 95% CI, 0.52−0.70).[13]

Materials and Methods

This prospective randomized control trial was designed to show equivalent efficacy of the intracervical synthetic osmotic dilator made of a patented hydrogel (Aquacryl) Food and Drug Administration approved for this indication (Dilapan-S), to the transcervical 30-cc silicone Foley catheter in term, outpatient, preinduction cervical ripening for low-risk primiparous and multiparous patients The trial was approved by Ochsner Health Institutional Review Board (IRB) (October 18, 2018) and Northwell Health IRB (February 22, 2022) and conducted at Ochsner Baptist Hospital. Clinical trial registration was obtained (ClinicalTrials.gov; registration number: NCT03752073). The trial followed the Consolidated Standards of Reporting Trials guidelines (Figure).[14] Enrollment was conducted between March 1, 2019, and May 31, 2021. Of note, although we obtained IRB approval and attempted enrollment at a second site (Northwell Health), no enrollment occurred.

Eligible patients were 18 to 40 years of age, desired or required labor induction, and were between 37.0 and 41.5 weeks of gestation based on reliable estimation as defined by ACOG.[15] Patients were eligible for inclusion if they had a Bishop score of <6, cervical dilation of ≤2 cm, and a reactive nonstress test. Patients were excluded if they were not able to consent in English (because of limited access to formal translation services) and for various clinical features listed in Table 1. Eligible, consented patients were randomized using a confidential computer-generated variable block randomization scheme, which was stratified for parity, prepared by study statisticians, and uploaded into the Research Electronic Data Capture (REDCap; University Medical Center, Nashville, TN).[16] Study data were collected and managed using REDCap electronic data capture tools hosted at Ochsner Clinic Foundation.

For consistency between study arms, all patients underwent speculum examination and povidone-iodine wipe of the cervix. Synthetic hygroscopic dilators were placed using ring forceps to grasp the plastic hub of the rod. Up to 3 rods were placed. Vaginal packing was omitted to reduce the risk of a retained foreign body. The silicone single-balloon catheter was chosen because of the minimal allergenicity and stiffer property of silicone, and a volume of 30 mL was better tolerated in the outpatient setting. Balloon catheters were placed using ring forceps to grasp the proximal aspect of the catheter. After inflation with 30-mL sterile saline, an umbilical cord clamp was placed on the distal end of the catheter (to prevent efflux of cervical mucus but allow removal of saline), and the catheter was taped to the patient's thigh without tension. Pain on device insertion was assessed with a 10-point visual analog scale. Patients were discharged home with standard labor precautions and were scheduled for labor induction within 24 hours.

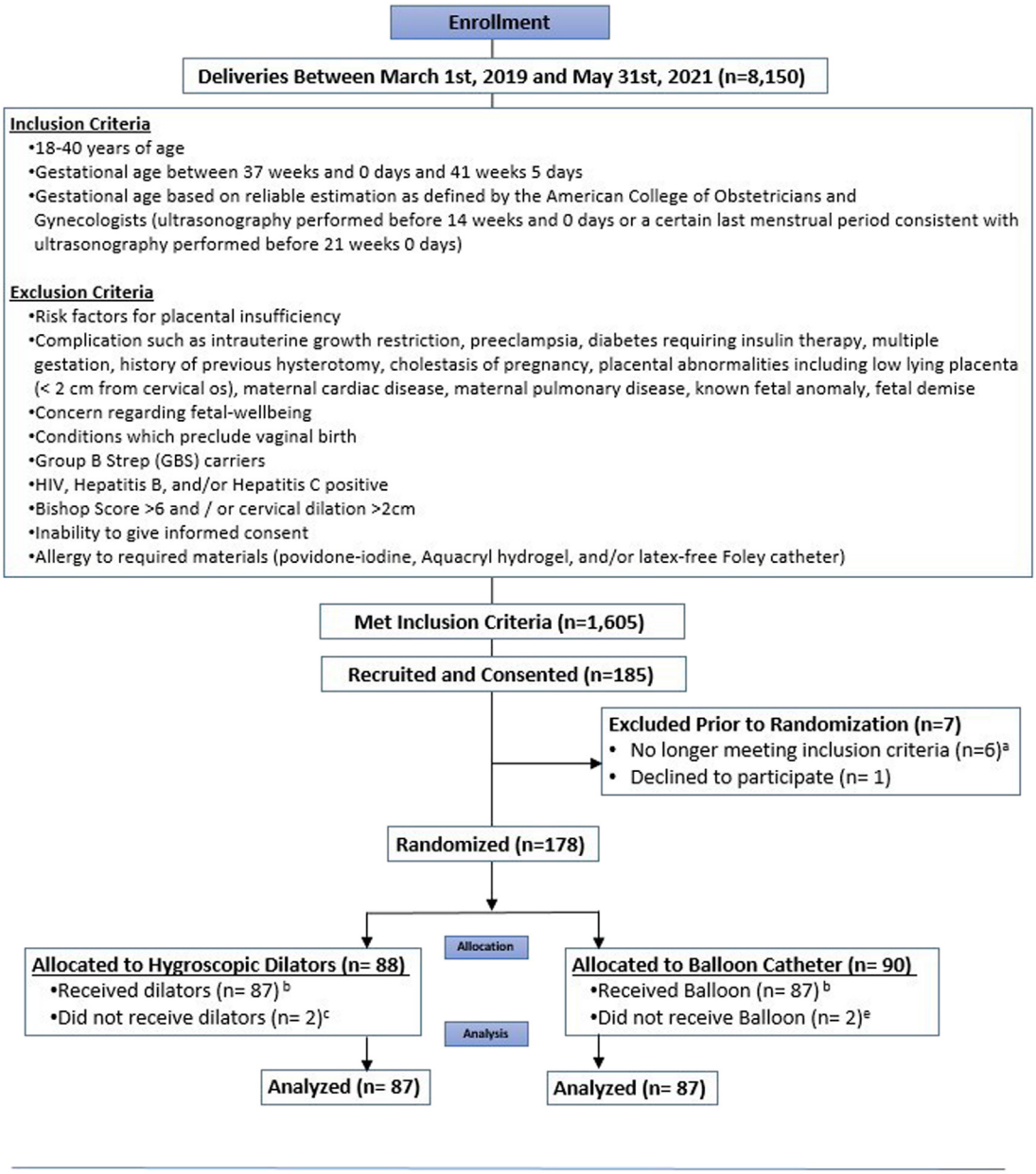
On admission for labor induction, history and physical included documentation of the status of the cervical ripening device, patient's pain scale, cervical examination, and careful accounting of both in situ and spontaneously expelled devices. Device removal and labor induction proceeded at the discretion of the patient's clinical health professional. No device remained in place for >24 hours.

A postpartum survey was administered to assess patients' comfort levels, acetaminophen and diphenhydramine use, and satisfaction. A postdischarge medical record review by study personnel assessed medical history, obstetrical history, demographic information (self-reported ethnicity and self-reported race), delivery outcomes, and postpartum events.

The primary outcome was time from admission to delivery, measured in hours from admission to time of birth. The secondary outcomes included clinical outcomes, such as change in dilation from insertion to delivery, early admission or device expulsion before the scheduled labor induction time, rates of cesarean delivery, and adverse outcomes as defined by ACOG (shoulder dystocia, intra-amniotic infection, endometritis, postpartum hemorrhage, fetal neonatal intensive care unit admission, 5- and 10-minute Apgar score of <7, arterial cord pH of <7.12, arterial cord base excess of <12, a composite adverse perinatal outcome, serious maternal morbidity, or maternal death).[17,18] Furthermore, the secondary outcomes included patient-reported perspectives, such as pain scores on admission and insertion, acetaminophen and diphenhydramine use, patient preferences for home management, and overall patient satisfaction.

The power analysis for the hypothesis of equivalence in the time from admission to delivery between the synthetic hygroscopic cervical dilators and the single-balloon catheter arms was based

FIGURE
CONSORT diagram



a. Patients did not meet inclusion criteria due to having a nonreactive NST (n= 3), COVID-19 positive (n= 1), elevated blood pressures (n= 1), or found to have advanced dilation (n= 1).
b. One patient was randomized to balloon catheter but ultimately received hygroscopic dilators. This patient was analyzed in the dilator group as per protocol.
c. Two patients were randomized to the hygroscopic dilators group but did not have the device placed due to pain upon speculum exam (n=1) and found to be breech (n=1).
d. Two patients were randomized to the balloon catheter group but did not have the device placed due to elevated blood pressure (n=1) or found to have advanced dilation (n=1)

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TABLE 1
Exclusion Criteria

Exclusion criteria
1. Patients between 18 and 40 y of age
2. Bishop score must be <6, and cervical dilation must be ≤2 cm
3. Able to give informed consent
4. No concern for fetal well-being (such as preeclampsia; fetal growth restriction; oligohydramnios; previous cesarean delivery; nonreassuring fetal antenatal testing, defined as minimal or absent variability, abnormal baseline, presence of decelerations; and need for inpatient monitoring during labor induction)
5. Absence of conditions that preclude vaginal birth (such as placenta previa, active HSV, and malpresentation)
6. GBS carrier
7. Active labor
8. Patients who are HIV, hepatitis B, or hepatitis C positive
9. Patients allergic to povidone-iodine or any element of the cervical ripening devices
10. Other serious medical conditions deemed by the attending physician to preclude outpatient cervical ripening

GBS, Group B Streptococcal Carrier; *HSV*, herpes simplex virus.

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on evidence that outpatient cervical ripening with the balloon catheter resulted in a 6-hour decreased time on labor and delivery.[11] Of note, 3 hours was established as a clinically significant margin of equivalence based on the ideal minimum power of 80% and alpha level of .05, requiring 150 patients in each arm (a total of 300 patients). Moreover, 5 patients did not have their assigned device placed. Demographic, clinical data, and patient perspectives were summarized according to treatment arms using means, standard deviations, medians, quartiles, and proportions as appropriate. Randomization was stratified at mode of delivery, and analyses were performed to perform 2 two-sided *t* tests. The secondary outcomes regarding patient perspectives were summarized on the basis of the number of surveys completed in each treatment arm. Data were analyzed using R Studio (version 3.53; Posit PBC, Boston, MA).

Results

During the study period, 8150 deliveries occurred. Of note, 1605 patients met the screening criteria. Out of 185 recruited participants, 174 patients completed the study (Figure). Approximately 10% of eligible patients were enrolled. Baseline demographic and clinical characteristics were similar between the synthetic hygroscopic dilator and single-balloon catheter groups (Table 2). Of note, 4 patients were randomized but did not have either device placed. Moreover, 1 patient was randomized to the catheter group but received dilators. The data are reported as both per protocol and intention to treat and demonstrate similar outcomes.

Overall time estimates from admission to delivery were 18.01 hours for patients randomized to synthetic hygroscopic dilators and 17.55 hours for patients randomized to the single-balloon catheter (Table 3). The difference in time between the 2 groups was 0.46 hours (90% CI, −2.42 to 2.16). Using 3 hours of margin of equivalence, the 2 devices are considered equivalent (*P*=.04). The time estimates from admission to vaginal delivery were 15.37 hours for dilators and 15.94 hours for the catheter (90% CI, −1.69 to 2.83; *P*=.04) and were considered equivalent. The time estimates from admission to cesarean delivery were 26.87 hours for dilators and 22.96 hours for the catheter (90% CI, −9.00 to 1.18; *P*=.62), not considered equivalent. A similar result was found when results were analyzed as intention to treat: the time estimates from admission to delivery were 17.88 hours for dilators and 17.68 hours for the catheter, with the mean time difference between the 2 groups of 0.2 hours (90% CI, −2.5 to 2.1; *P*=.02).

The synthetic hygroscopic dilators and the single-balloon catheter groups had similar median cervical dilation on insertion and admission. The median change in cervical dilation from insertion to admission was 2 cm. The range of cervical dilation on admission for patients randomized to dilators was 0.5 to 10.0 cm and for the catheter was 0 to 6 cm. Patients who did not achieve cervical change between insertion and admission were included in the analyses but were considered outpatient treatment failures; all patients were primiparous, and the methods were similar, with 6 failures total (3.5%), 4 dilators and 2 catheters.

Of note, 8 patients who received the single-balloon catheter were discharged home after insertion and presented before their scheduled labor induction time because of contractions (n=5), premature rupture of membranes (n=2), and heavier than expected bleeding (n=1). The overall unscheduled admission rate was 4.6%, 5.2% for primiparous patients and 2.6% for multiparous patients. No patient who received synthetic hygroscopic dilators was admitted early, and this difference was considered statistically significant (*P*=.007). Of note, 8 patients experienced prelabor expulsion of the device of an average of 9.75±4.17 hours after insertion. Moreover, 1 patient experienced both prelabor expulsion and labor symptoms and, thus, was included in both groups as only patients who experienced expulsion with labor symptoms were instructed to present to the hospital. No hygroscopic dilator was expelled spontaneously (*P*=.007).

The rates of cesarean delivery of primiparous patients were similar at 29.7% for synthetic hygroscopic dilators and

TABLE 2
Patient characteristics

Variable	Overall (N=174)	Device: Hygroscopic dilator (n=87)	Device: Balloon catheter (n=87)	*P* value[a]
Age (y)	31 (27–34)	31 (27–34)	31 (28–34)	.4
Self-reported race				.3
Asian	1 (0.6)	1 (1.2)	0 (0)	
Black	22 (12.6)	13 (14.9)	9 (10.3)	
Hispanic	4 (2.3)	3 (3.5)	1 (1.2)	
Non-Hispanic White	147 (84.5)	70 (80.4)	77 (88.5)	
Estimated gestational age at enrollment (wk)	39.5 (39.1–40.1)	39.4 (39.1–40.2)	39.5 (39.1–40.1)	.7
Parity at admission				.4
0	135 (77.6)	64 (73.6)	71 (81.6)	
1	27 (15.5)	17 (19.5)	10 (11.5)	
2	11 (6.3)	5 (5.8)	6 (6.9)	
3	0 (0)	0 (0)	0 (0)	
4	1 (0.6)	1 (1.1)	0 (0)	
BMI (kg/m^2)	31.6 (28.0–36.0)	31.2 (28.7–35.4)	32.0 (27.85–36.4)	.7
Bishop score on insertion	2 (1–3)	2 (1–3)	2 (1–3)	.3
Cervical dilation on insertion (cm)	1.0 (0.5–1.0)	1.0 (0.5–1.0)	1.0 (0.0–1.0)	.2

Data are presented as median (interquartile range) or number (percentage), unless otherwise indicated.

BMI, body mass index.

[a] Wilcoxon rank-sum test; Fisher exact test for count data with simulated *P* values (based on 2000 replicates); Pearson chi-square test; Fisher exact test.

Lu. Comparison of 2 mechanical methods of outpatient ripening of the cervix (CORC trial). Am J Obstet Gynecol MFM 2024.

28.1% for the single-balloon catheter (Table 4). Of note, 1 multiparous patient required a cesarean delivery.

The incidences of common intrapartum and postpartum maternal and neonatal complications were low and similar (Table 4). There was 1 adverse maternal event in the single-balloon catheter group, a severe postpartum

TABLE 3
Primary patient outcome

Time from admission to delivery (h) Per protocol	Overall (N=174)	Hygroscopic dilator (n=87)	Balloon (n=87)	90% CI	*P* value[a]
Overall	17.78	18.01	17.55	0.46 (−2.42 to 2.16)	.02[b]
Vaginal delivery		15.37	15.94	−0.57 (−1.69 to 2.83)	.04[b]
Cesarean delivery		26.87	22.96	3.91 (−9.00 to 1.18)	.62

Intention to treat	Overall (N=174)	Hygroscopic dilator (n=86)	Balloon (n=88)	90% CI	*P* value[a]
Overall	17.78	17.88	17.68	0.2 (−2.5 to 2.1)	0.02[b]
Vaginal delivery		15.37	15.94	−0.57 (−1.69 to 2.83)	0.04[b]
Cesarean delivery		26.75	23.25	3.25 (−2.42 to 2.16)	0.57

Data are presented as mean±standard deviation, median (interquartile range), or number (percentage), unless otherwise indicated.

[a] Wilcoxon rank-sum test; Fisher exact test for count data with simulated *P* value (based on 2000 replicates); Pearson chi-square test; Fisher exact test; [b] XXX.

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TABLE 4
Secondary patient outcomes

Variable	Overall (N=174)	Device		*P* value[a]
		Hygroscopic dilator (n=87)	Balloon (n=87)	
Per protocol				
Bishop score on admission	4.0 (3.0–5.0)	4.0 (2.0–5.0)	4.0 (3.5–5.0)	.4
Cervical dilation on admission	3.0 (2.0–4.0)	3.0 (2.0–3.0)	3.0 (2.0–4.0)	.52
Change in cervical dilation from insertion to admission (cm)	2.0 (1.0–3.0)	2.0 (1.0–3.0)	2.0 (1.0–3.0)	.3
Treatment failures (no cervical change)	6 (3.5)	4 (4.5)	2 (2.3)	.7
Early admission				.007[b]
Early admission	8 (4.6)	0 (0)	8 (9.2)	
No early admission	166 (95.4)	87 (100.0)	79 (90.8)	
Device expulsion before admission				.007[b]
Early expulsion	8 (4.6)	0 (0)	8 (9.2)	
No early expulsion	166 (95.4)	87 (100.0)	79 (90.8)	
Mode of delivery among primiparous patients				.94
Vaginal delivery	92 (68.2)	43 (67.2)	49 (69.0)	
Vacuum-assisted vaginal delivery	4 (3.0)	2 (3.1)	2 (2.9)	
Cesarean delivery	39 (28.8)	19 (29.7)	20 (28.1)	
Mode of delivery among multiparous patients				1.00
Vaginal delivery	38 (97.4)	22 (95.7)	16 (100.0)	
Vacuum-assisted vaginal delivery	0 (0)	0 (0)	0 (0)	
Cesarean delivery	1 (2.6)	1 (4.3)	0 (0)	
Shoulder dystocia				.7
Shoulder dystocia	7 (4.1)	4 (4.7)	3 (3.6)	
No shoulder dystocia	166 (96.0)	82 (95.4)	84 (96.6)	
Unknown	1	1	0	
Suspected intra-amniotic infection				.3
Intra-amniotic infection	14 (8.1)	5 (5.9)	9 (10.3)	
No intra-amniotic infection	158 (91.9)	80 (94.1)	78 (89.7)	
Unknown	2	2	0	
Endometritis				.5
Endometritis	1 (0.6)	1 (1.2)	0 (0)	
No endometritis	172 (99.4)	85 (98.8)	87 (100.0)	
Unknown	1	1	0	
Postpartum hemorrhage				>.9
Postpartum hemorrhage	6 (3.5)	3 (3.5)	3 (3.5)	
No postpartum hemorrhage	166 (96.5)	82 (96.5)	84 (96.6)	
Unknown	2	2	0	
NICU admission				.2
NICU admission	3 (1.7)	0 (0)	3 (3.5)	
No NICU admission	169 (98.3)	85 (100.0)	84 (96.6)	

(continued)

TABLE 4
Secondary patient outcomes *(continued)*

Variable	Overall (N=174)	Device: Hygroscopic dilator (n=87)	Device: Balloon (n=87)	*P* value[a]
Unknown	2	2	0	
5-min Apgar score				.3
<7	9 (5.2)	6 (7.1)	3 (3.5)	
>7	163 (94.8)	79 (92.9)	84 (96.6)	
Unknown	2	2	0	
10-min Apgar score				>.9
<7	2 (1.2)	1 (1.2)	1 (1.2)	
>7	168 (98.8)	83 (98.8)	85 (98.8)	
Unknown	4	3	1	
Arterial cord gas pH				>.9
<7.12	5 (21.7)	3 (20.0)	2 (25.0)	
>7.12	18 (78.3)	12 (80.0)	6 (75.0)	
Unknown	151	72	79	
Arterial cord base excess				>.9
<12	20 (95.2)	12 (92.3)	8 (100.0)	
>12	1 (4.8)	1 (7.7)	0 (0)	
Unknown	153	74	79	
Adverse fetal outcome	0	0	0	
Maternal morbidity				>.9
Maternal morbidity	1 (0.6)	0 (0)	1 (1.2)	
No maternal morbidity	171 (99.4)	86 (100.0)	85 (98.8)	
Unknown	2	1	1	
Maternal mortality	0	0	0	
Pain score at insertion	3.0 (2.0–5.0)	3.0 (2.5–5.0)	3.0 (2.0–5.0)	.5
Pain score at admission	1 (1–3)	1 (1–3)	1 (1–4)	.6
Unknown	1	1	0	

Data are presented as mean±standard deviation, median (interquartile range), or number (percentage), unless otherwise indicated.

NICU, neonatal intensive care unit.

[a] Wilcoxon rank-sum test; Fisher exact test for count data with simulated *P* value (based on 2000 replicates); Pearson chi-square test; Fisher exact test; [b] XXX.

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hemorrhage requiring transfusion and uterine compression sutures, and was unlikely related to the balloon catheter.

The median pain scores were 3 for both synthetic hygroscopic dilator and single-balloon catheter groups on insertion and 1 for both groups on admission. A similar number of patients required acetaminophen or diphenhydramine to manage outpatient symptoms after insertion.

Of patients who completed postpartum questionnaires (163/174 [93.6%]), 97.6% expressed a preference for home management (98.8% for synthetic hygroscopic dilators and 96.2% for the single-balloon catheter). Satisfaction with the outpatient procedure (extremely satisfied or reasonably satisfied) was similar, with 92.7% for dilators and 96.2% for the catheter. Common themes among patient comments included overall satisfaction, preference for home, discomfort level, and functional interference with usual activity at home (Table 5).

Discussion

Principal findings

This prospective randomized trial suggested similar efficacy of outpatient cervical ripening using either synthetic hygroscopic dilators or single-balloon

TABLE 5
Patient survey results

Variable	Overall (N=163)	Hygroscopic dilator questionnaires received (n=82)[a]	Balloon questionnaires received (n=81)[a]	*P* value
Acetaminophen use				.2
No use	87 (54.04)	49 (59.76)	38 (48.10)	
500 mg	11 (6.83)	3 (3.66)	8 (10.13)	
>500 mg	63 (39.13)	30 (36.59)	33 (41.77)	
Unknown	13	5	8	
Diphenhydramine use				>.9
No	124 (76.54)	63 (76.83)	61 (76.25)	
Yes	38 (23.46)	19 (23.17)	19 (23.75)	
Unknown	12	5	7	
Patient preference for home management				.4
Preferred home management	156 (97.50)	81 (98.78)	75 (96.15)	
Did not prefer home management	4 (2.50)	1 (1.22)	3 (3.85)	
Unknown	14	5	9	
Patient satisfaction				.5
Satisfied	153 (94.45)	77 (92.77)	76 (96.20)	
Dissatisfied	9	6 (7.23)	3 (3.80)	
Unknown	12	4	8	

[a] The secondary outcomes regarding patient perspectives were summarized on the basis of the number of surveys completed in each treatment arm.
Lu. Comparison of 2 mechanical methods of outpatient ripening of the cervix (CORC trial). Am J Obstet Gynecol MFM 2024.

catheter regarding the primary endpoint of time from admission to delivery with low rates of complication and similar rates of patient satisfaction. Despite unfavorable cervical examinations, patients tolerated the placement of both devices. Pain scores at insertion and admission were similar. Overall, treatment failures (absence of cervical change) were rare but slightly more common in the dilator group, likely because of erroneous placement in the posterior fornix. Patients who experienced the onset of labor before their scheduled labor induction (considered an unfavorable event by patients and primary providers) were infrequent, similar between primiparous and multiparous patients, and all in the balloon catheter arm.

This trial demonstrated high patient satisfaction with the outpatient procedure in both groups (Table 5). Patients preferred to be home. Most respondents who commented about pain expressed satisfaction with the process despite discomfort. Patient comments elicited more complaints regarding the balloon catheter, such as restricted movement, difficulty using the bathroom, discomfort from tape, or tape failure. Such complaints were not noted regarding the synthetic hygroscopic dilators, which were contained in the vagina (Table 6).

Results in the context of what is known

Previous studies evaluating synthetic hygroscopic dilators demonstrated the efficacy and safety for preinduction term cervical ripening. Three randomized trials evaluated inpatient cervical ripening using synthetic hygroscopic dilator for term pregnancies. Saad et al[8] compared the synthetic hygroscopic dilator with the single-balloon catheter and found dilators to be noninferior to the catheter method regarding safety and efficacy with better patient satisfaction. Gavara et al[19] compared the synthetic hygroscopic dilator with low-dose oral misoprostol and found dilators to be noninferior regarding vaginal delivery within 36 hours, with better patient satisfaction. Gupta et al's[20] randomized clinical trial study showed similar cesarean delivery rates with synthetic hygroscopic dilators compared with dinoprostone vaginal insert in a mainly nulliparous population. Maternal and neonatal adverse events were similar in both inpatient interventions. Saad et al[13] compared the synthetic hygroscopic dilator in the inpatient and outpatient settings and found an increased incidence of vaginal delivery within 24 hours and high patient satisfaction and a rate of early presentation to the hospital of 2.4%. Our study adds to the limited literature comparing the synthetic hygroscopic dilator with the

single-balloon catheter specifically in the outpatient setting.

Clinical implications

Patients commonly underestimate the physical and emotional challenges of labor induction, such as the time needed to achieve active labor and the limitations on oral intake and mobility. The option of outpatient cervical ripening by either method was effective and resulted in high patient satisfaction. Although an additional visit for device placement and coordination to ensure timely admission to the hospital is necessary, the outpatient setting was preferred. No patient in our study had a delay in device removal. Synthetic hygroscopic dilators seem to result in fewer early admissions and spontaneous expulsions than balloon catheters.

Research implications

Further research regarding a cost analysis comparing outpatient use of synthetic hygroscopic dilators and the singe-balloon catheter, including cost of the device and equipment, patient and provider acceptance, and length of stay on labor and delivery, is needed. Although this study was conducted primarily in the antenatal testing unit, the ideal location for placement of the mechanical device would be the provider's office, reducing potential costs. Outpatient placement of synthetic hygroscopic dilators is a feasible office procedure, analogous to procedures, such as intrauterine device placement, and is a billable service.

Future studies might expand on appropriate candidates for outpatient cervical ripening. The decision to exclude Group B Streptococcal carrier (GBS)-positive patients in our study was conservative, and additional trials to assess the theoretical risk of intra-amniotic infection or fetal GBS sepsis in this population may illuminate whether such patients may safely undergo outpatient cervical ripening.

The data suggesting the efficacy of dual cervical ripening (mechanical combined with pharmacologic methods) are intriguing, particularly for multiparous patients.[21,22] Further research may find that outpatient cervical ripening is primarily advantageous for the primiparous patient.

Strengths and limitations

The strengths of our study include randomization and the exclusive focus on the outpatient setting. Although recruitment fell short of our goal and we cannot rule out a small difference between the methods, the metrics measured suggest that these 2 methods are similar for the primary outcome of time from admission to delivery and secondary objectives of clinical outcomes and patient perspectives. Overall, this trial demonstrated that a program of outpatient cervical ripening with either mechanical method is effective, safe, and satisfactory to patients.

We found that both primiparous and multiparous patients benefited from outpatient ripening with a low incidence of spontaneous labor, although early hospital presentation because of labor symptoms was more common in the single-balloon catheter group.

The limitations of our study include our inability to enroll the number of patients prescribed by the recruitment

TABLE 6
Patient comments on outpatient cervical ripening

Theme	Representative patient comments
Overall satisfaction	
Hygroscopic dilator	"Although there was some discomfort at insertion and removal and random times, the benefit of being home and shorter hospital stay far outweighed the minor discomfort."
Balloon catheter	"My thoughts if I had this option again: I would definitely seek outpatient cervical ripening if I were in a similar position as I had positive results with some discomfort."
Preference for home	
Hygroscopic dilator	"Any time at home safely is valuable."
Balloon catheter	"I was happy I was able to go out to dinner and spend time with my family."
Pain or comfort	
Hygroscopic dilator	"I took a shower and ate and slept comfortably." "Initial cramping and then after a few hours I was comfortable and could not tell it was there."
Balloon catheter	"Cramping and contractions but once I got home and ate and laid down I was able to sleep and they went away." "I had cramping at home. It would have been difficult to care for my children if they were home."
Functional interference	
Hygroscopic dilator	"I enjoyed being able to move around as needed."
Balloon catheter	"Catheter restricted movement, hard to clean after use of the bathroom." "A little leaking out of catheter tube."

Lu. Comparison of 2 mechanical methods of outpatient ripening of the cervix (CORC trial). Am J Obstet Gynecol MFM 2024.

power analysis; thus, our outcomes should be interpreted with caution. This was due to several factors, primarily the COVID-19 pandemic and logistical challenges at the first and second enrollment sites. Patients and their providers were often reluctant to engage in the randomization process, preferring 1 method over another. A competing clinical protocol was introduced at the first site, and enrollment was no longer possible. IRB approval at the second site was delayed 15 months to achieve a data-sharing agreement, and concern regarding the patient's ability to tolerate outpatient use at the second site was difficult to overcome. This was an open-label trial, and bias could have affected the observed results. However, objective outcomes, such as the time from insertion to delivery and the rate of cesarean delivery, are less subject to bias and seem similar. Generalizability is limited as this was a single-site study limited to low-risk patients. Finally, in the inpatient setting, balloons filled to 80 mL and a maximum of 5 synthetic hygroscopic rods reduce the time from labor induction to delivery. Because of the use in the outpatient setting and desire to minimize patient discomfort, including unplanned presentation to the hospital, the single-balloon catheter was filled to 30 mL, and a maximum of 3 synthetic hydroscopic rods was placed, which may have increased the time from placement to delivery.

Conclusions

All labor and delivery units are currently challenged to accommodate the demand for elective and indicated labor inductions. Outpatient cervical ripening is effective, safe, and satisfactory to patients. Although recruitment goals were not met, patients were satisfied, and 1 method was not superior to the other. When combined with other evidence-based, proactive labor induction interventions, time in the labor and delivery setting can be minimized without compromising cesarean delivery rates or maternal and neonatal outcomes. Practitioners and nursing leaders should work together to promote patient-centered care and optimize the use of outpatient and labor and delivery resources. ■

CRediT authorship contribution statement

Anjanique Mariquit R. Lu: Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing. **Brenda Lin:** Data curation, Formal analysis, Writing – original draft, Writing – review & editing. **Disha Shahani:** Data curation, Formal analysis, Methodology, Software, Validation, Writing – review & editing. **Kristen Demertzis:** Formal analysis, Project administration, Writing – original draft, Writing – review & editing. **Jolene Muscat:** Writing – review & editing. **Elizabeth Zabel:** Investigation, Project administration, Writing – review & editing. **Payton Olson:** Conceptualization, Data curation, Investigation, Writing – review & editing. **Olivia Manayan:** Data curation, Investigation, Writing – review & editing. **Emily Nonnamaker:** Conceptualization, Formal analysis, Methodology, Visualization, Writing – review & editing. **Joy Fest:** Project administration, Writing – review & editing. **Brigid McCue:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing, Supervision. ■

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References

1. Martin JA, Hamilton BE, Osterman MJK, Driscoll AK. Births: final data for 2019. Natl Vital Stat Rep 2021;70:1–51.

2. Godfrey E, Chevarley FM, Rosenberg HM, Kochanek KD, Feinleib M. Mortality surveillance system: models from the second year. Vital Health Stat 20 1994(22):1–91.

3. Grobman WA, Rice MM, Reddy UM, et al. Labor Induction versus Expectant Management in Low-Risk Nulliparous Women. N Engl J Med 2018;379:513–23.

4. Gilroy LC, Al-Kouatly HB, Minkoff HL, McLaren Jr. RA. Changes in obstetrical practices and pregnancy outcomes following the ARRIVE trial. Am J Obstet Gynecol 2022;226:716.e1–716.e12.

5. Einerson BD, Nelson RE, Sandoval G, et al. Cost of elective labor induction compared with expectant management in nulliparous Women. Obstet Gynecol 2020;136:19–25.

6. Boulvain M, Kelly A, Lohse C, Stan C, Irion O. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2001(4): CD001233.

7. El Maradny E, Kanayama N, Halim A, Maehara K, Sumimoto K, Terao T. Biochemical changes in the cervical tissue of rabbit induced by interleukin-8, interleukin-1beta, dehydroepiandrosterone sulphate and prostaglandin E2: a comparative study. Hum Reprod 1996; 11:1099–104.

8. Saad AF, Villarreal J, Eid J, et al. A randomized controlled trial of dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). Am J Obstet Gynecol 2019; 220:275.e1–9.

9. de Vaan MD, Ten Eikelder ML, Jozwiak M, et al. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2023; 2019:CD001233.

10. ACOG practice bulletin no. 107: induction of labor. Obstet Gynecol 2009;114:386–97.

11. Sciscione AC, Nguyen L, Manley J, Pollock M, Maas B, Colmorgen G. A randomized comparison of transcervical Foley catheter to intravaginal misoprostol for preinduction cervical ripening. Obstet Gynecol 2001;97:603–7.

12. Pierce-Williams R, Lesser H, Saccone G, et al. Outpatient cervical ripening with balloon catheters: a systematic review and meta-analysis. Obstet Gynecol 2022; 139:255–68.

13. Saad AF, Gavara R, Senguttuvan RN, et al. Outpatient compared with inpatient preinduction cervical ripening using a synthetic osmotic dilator: a randomized clinical trial. Obstet Gynecol 2022;140:584–90.

14. Schulz KF, Altman DG, Moher D, GROUP CONSORT. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Obstet Gynecol 2010; 115:1063–70.

15. Committee opinion no 700: methods for estimating the due date. Obstet Gynecol 2017;129:e150–4.

16. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research Electronic Data Capture (REDCap) - a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377–81.

17. Committee opinion no. 712: intrapartum management of intraamniotic infection. Obstet Gynecol 2017;130:e95–e101.

18. Committee on Practice Bulletins-Obstetrics Practice bulletin no. 183: postpartum hemorrhage. Obstet Gynecol 2017;130: e168–86.

19. Gavara R, Saad AF, Wapner RJ, et al. Cervical ripening efficacy of synthetic osmotic cervical dilator compared with oral misoprostol at term: a randomized controlled trial. Obstet Gynecol 2022;139:1083–91.
20. Gupta JK, Maher A, Stubbs C, et al. A randomized trial of synthetic osmotic cervical dilator for induction of labor vs dinoprostone vaginal insert. Am J Obstet Gynecol MFM 2022;4:100628.
21. Levine LD, Downes KL, Elovitz MA, Parry S, Sammel MD, Srinivas SK. Mechanical and pharmacologic methods of labor induction: a randomized controlled trial. Obstet Gynecol 2016;128:1357–64.
22. Bauer AM, Lappen JR, Gecsi KS, Hackney DN. Cervical ripening balloon with and without oxytocin in multiparas: a randomized controlled trial. Am J Obstet Gynecol 2018; 219:294.e1–6.

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