Evaluation of an Outpatient Cervical Ripening Program Using Osmotic Dilators and Foley Balloon Catheters

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Abstract

Objective This study aimed to describe patient characteristics, satisfaction, and outcome measures for patients undergoing outpatient cervical ripening.

Study Design A retrospective cohort study using electronic health record data from March 2020 to March 2022 from a large health system. The sample included patients with a low-risk singleton pregnancy undergoing outpatient cervical ripening with either an osmotic dilator or Foley balloon catheter. A subset of patients completed satisfaction surveys. Frequencies and means were used to describe the population and conduct comparisons by device type. Inverse probability of treatment weighted estimates were generated to address baseline differences between patients in the two device groups.

Results Outpatient cervical ripening was completed by 120 patients (80 osmotic dilators and 40 Foley balloon catheters). The mean time from insertion to inpatient admission was 16.2 ± 4.8 hours. The mean change in simplified Bishop score (SBS) was 1.8 ± 1.4 and the mean change in dilation was 1.8 ± 1.1 cm. There were no differences in the amount of cervical change by device type. Patients returned earlier than planned 16.7% of the time, primarily for contractions or rupture of membranes. Following outpatient cervical ripening, the time from admission to delivery was 19.9 ± 10.3 hours, with no difference by device type. Vaginal delivery occurred for 74.8% of patients. Patients reported overall satisfaction with the outpatient cervical ripening experience, with the highest satisfaction among those with osmotic dilators. Patients with both device types stated they would recommend outpatient cervical ripening to others, and experienced low levels of stress and discomfort at home prior to hospital admission.

Conclusion Patients participating in outpatient cervical ripening with osmotic dilators or Foley balloon catheters experienced clinically meaningful changes in dilation and SBSs while at home and reported general satisfaction with the outpatient program experience.

Keywords

- cervical ripening
- induction
- Foley balloon
- Dilapan-S
- osmotic dilator
- outpatient

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Key Points

- Outpatient use of osmotic dilators or Foley balloon catheters improved Bishop scores.
- Patient and device complications were comparable to other research findings.
- Patients reported overall satisfaction with outpatient cervical ripening.

Induction of labor (IOL) rates have been rising in the United States, reaching 25.7% in 2017.[1] Approximately 83% of induction patients require cervical ripening.[2] The ARRIVE (A Randomized Trial of Induction Versus Expectant Management) trial[3] findings related to planned induction at 39 weeks for low-risk nulliparous patients have resulted in increased patient and provider requests for induction, posing a challenge for hospitals.[3–5]

Outpatient cervical ripening programs may help address health care facility capacity limitations associated with increased IOL demand. Pharmacological methods are less suitable for outpatient use due to risks requiring patient monitoring.[6,7] Research on outpatient use of mechanical cervical ripening methods has primarily focused on Foley balloon catheters relative to the inpatient setting.[6,8–15] Dilapan-S (Medicem, Boston, MA), an osmotic dilator, was approved by the Food and Drug Administration (FDA) in 2015 for cervical ripening in the third trimester.[16–19] While outcomes for osmotic dilators have been documented in the inpatient setting,[16–21] limited studies have examined outpatient use.[22,23] Osmotic dilator use in the outpatient setting may be received better by patients because, unlike Foley balloon catheters, nothing protrudes from the vagina and no tension is applied.[20] Insufficient data are available on patient satisfaction, safety, and efficacy of outpatient cervical ripening programs, with a particular lack of data on osmotic dilators.[24,25]

This study examines a pilot outpatient mechanical cervical ripening program. Specific aims include (1) describing process measures for patients participating in outpatient cervical ripening, (2) describing outcome measures, and (3) evaluating patient satisfaction with this process.

Materials and Methods

We conducted a retrospective, observational study using electronic health record (EHR) data from March 2020 to March 2022 for patients participating in an outpatient cervical ripening pilot. We also conducted a prospective patient satisfaction survey from December 2021 to September 2023. The difference in the time periods of the two research activities was a result of the Institutional Review Board (IRB) approval timing for the prospective survey component.

The outpatient cervical ripening program was piloted at two hospitals in the same health system serving a major metropolitan area. Delivery volume at these two hospitals is approximately 7,500 deliveries each year. Deliveries at these hospitals are conducted by providers (obstetricians, family physicians, and certified nurse midwives) from health system-owned clinics as well as clinical practices outside the health system (community clinics and private practices).

The outpatient cervical ripening pilot program, using either a Foley balloon catheter or osmotic dilators, was started at one hospital in March 2020, and the second in June 2020. Outpatient cervical ripening was available for low-risk pregnant patients with singleton pregnancy and gestational age of $39^{0/7}$ to $40^{6/7}$ weeks. *Low risk* was defined as a viable fetus, maternal vital signs within normal limits, reactive fetal nonstress test (NST) prior to device insertion, and cephalic presentation. Patients were not eligible if they had known vasa previa, placenta previa, low-lying placenta, placenta abruption, vaginal bleeding, prior cesarean, gestational or pregestational diabetes, estimated fetal weight $>$4,500 g, suspected or confirmed chorioamnionitis, clinically active genital infection, hypertensive disorders of pregnancy, ruptured membranes, polyhydramnios, maternal cardiac or renal disease, uterine tachysystole or hypertonus, maternal fever, unreliable transportation or no telephone access, or any contraindication to IOL. In October 2020, criteria for outpatient cervical ripening also extended to include patients with gestational diabetes well-controlled with diet if gestational age was $39^{0/7}$ to $40^{6/7}$ weeks as well as patients with gestational hypertension at $\geq 37^{0/7}$ weeks with blood pressure $<$150/100 mm Hg and preeclampsia laboratory studies were normal within the last 24 hours.

Recommended candidates for outpatient cervical ripening were patients with cervical dilation $<$2 cm and Bishop score $<$6, or per provider discretion. Device type was not dictated by the program criteria and was based only on provider preference. Final assessment for eligibility, placement of the cervical ripening devices, and monitoring prior to sending patients home, took place either in the prenatal clinic or the labor and delivery triage unit in the hospitals. Following device placement, fetal heart rate, and uterine activity were monitored electronically for 30 minutes. A reactive NST was required prior to discharge. Patients received education and were instructed to contact their provider and return to the hospital if they experienced pain, contractions, leakage of fluid, bleeding, decreased fetal movement, or device expulsion. They were instructed to bring any expelled device with them to the hospital to confirm no dilators were retained. A cervical exam was completed prior to device placement and upon removal. All patients were scheduled for IOL no later than 24 hours following device insertion. Upon arrival for delivery, the obstetric provider removed osmotic dilators or the Foley balloon catheter, and a cervical exam was performed. Labor induction was then managed by the obstetric provider according to the usual ripening and induction protocols.

Patients were included in the outpatient cervical ripening group if they attended an appointment for device insertion, met inclusion criteria for the program, and proceeded with

the outpatient cervical ripening. Patients were excluded if they underwent inpatient cervical ripening or if their plan of care changed at the time of device insertion. The study was determined exempted by the health system IRB. Data collection was conducted via an extract from the EHR and chart review. To identify patients who potentially met the inclusion criteria, patients with procedure codes for cervical ripening with a mechanical device or unspecified cervical ripening were extracted. Charts were reviewed to confirm if cervical ripening was intended to be outpatient and identified device type and treatment course.

Patient demographics and pregnancy characteristics included age, race, ethnicity, preferred language, insurance type (private/public), and parity. Race and ethnicity were collected via patient self-report during the registration process and were included in the study to describe patients receiving outpatient cervical ripening and to examine differences by device type. Patients may report more than one race with the categories of American Indian/Alaska Native, Asian, Black/African American, Native Hawaiian/Pacific Islander, and White recorded in the EHR. Ethnicity is measured as Hispanic/Latina (yes, no). Measures related to cervical ripening and induction outcomes included gestational age, number of osmotic dilators inserted, whether patient care switched to inpatient after the observation period (with documentation of reason), whether patients returned prior to their scheduled IOL admission (with documentation of reason), and hours of outpatient cervical ripening. Measures of cervical ripening effectiveness were based on the simplified Bishop score (SBS[26]; 0–9 point scoring system based on cervical dilatation, effacement, and station), and mode of delivery (vaginal or cesarean). SBS and dilation were collected from the record at the time of device insertion and at the time of inpatient admission and were used to calculate changes that occurred during outpatient cervical ripening. We also calculated the time from the start of outpatient cervical ripening (device insertion) to hospital admission, the time from IOL admission to delivery, and the length of stay (LOS) from IOL admission to discharge. We documented other cervical ripening agents or devices used after admission and hours of oxytocin use before delivery. Maternal complications assessed included hemorrhage (quantitative blood loss >1,000 mL), infection (sepsis, chorioamnionitis, and endometritis), and readmission within 30 days. Neonatal outcomes included neonatal intensive care unit (NICU) or special care nursery (SCN) admission, fetal demise, and Apgar scores at 1 and 5 minutes.

Survey data were prospectively collected from December 2021 to September 2023 from a subset of 30 patients following outpatient cervical ripening, regardless of device type. Patients responding to the survey were different from those depicted in ►Fig. 1 for the quantitative analysis due to the differential timing of the prospective survey component of the study. Seven of the survey participants were also included in the retrospective portion of the study (i.e., completed survey within the timeframe of data collection for the outpatient ripening sample). Patients consented to participate and have data extracted from their EHR to link

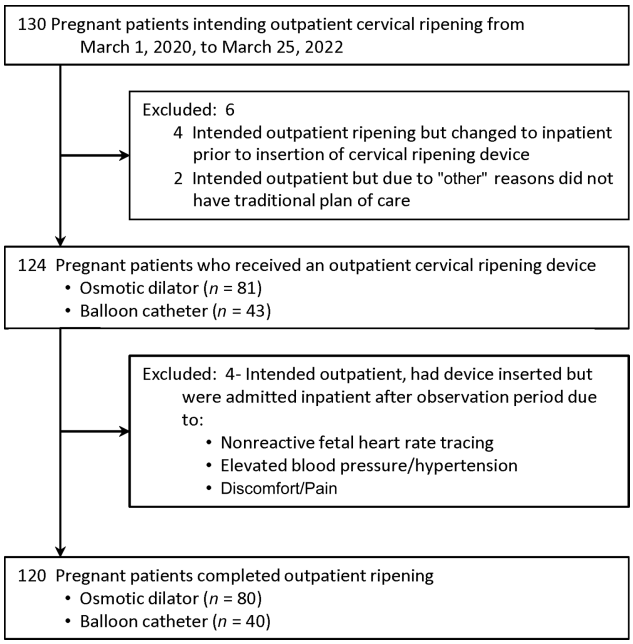

Fig. 1 Study sample identification process.

their survey responses. The paper survey consisted of 12 questions and took patients approximately 5 minutes to complete during their delivery hospitalization. Patient satisfaction was measured using open-ended questions and Likert scale measures were used to assess pain and anxiety during various parts of the process. Additionally, patients provided feedback on their likelihood of using outpatient cervical ripening for future pregnancies and whether they would recommend this method to others.

Summary statistics were used to describe patient demographic and clinical characteristics as well as maternal and neonatal outcomes for the entire cohort and stratified by device type. Given differences between patients in each device group for baseline measures potentially related to outcomes, we created the inverse probability of treatment weights using propensity scores. This method makes the two device-type groups more comparable with respect to observed patient characteristics that can be assessed using the standardized difference in means, with an absolute value less than 0.1 considered comparable.[27] Due to the small sample size, the final model for device type (i.e., propensity score) was selected based on obtaining reasonable balance for the presumed but limited number of confounding factors, namely age, race (White vs. non-White), parity (0, 1, or 2 +), and dilation at the initiation of cervical ripening (0, 1, 1.5, 3, or unknown). Both unadjusted and adjusted (i.e., weighted) analyses of outcomes were performed. For unweighted analysis, the comparison of means was assessed with the difference in means with 95% confidence intervals (CIs) and *t*-test, and the comparison of proportions was assessed with risk difference with 95% CIs (specifically, Newcombe hybrid-score limits[28]) and chi-square test. Adjusted analysis used weighted linear regression with robust standard errors that account for weighting and non-normality of outcomes. For binary outcomes with (unweighted) expected cell counts less

than 5, the unadjusted analysis used Fisher's exact test, and adjusted analyses were not reported because Wald-type tests and CIs may not be valid. For surveys of patient satisfaction, frequencies were reported for all respondents and by device type. Open-ended responses were categorized into themes. Analyses were conducted using Stata 17 (Stata Corp, College Station, TX) and SAS Enterprise Guide software (SAS Institute Inc., Cary, NC).

Results

Of 130 pregnant patients who intended outpatient cervical ripening, 10 were excluded; 6 were admitted for inpatient care prior to insertion of the cervical ripening device and 4 were admitted after an observation period following device placement (►Fig. 1). Reasons for the transition to inpatient admission included nonreactive NST, discomfort/pain (Foley balloon), and elevated blood pressure/hypertension (osmotic dilator). The final outpatient cervical ripening sample included 120 patients, of which 80 used an osmotic dilator and 40 used a Foley balloon. Three patients with cervical ripening at <39 weeks gestation were included in the sample criteria specific to gestational hypertension without signs or symptoms of preeclampsia. One patient completed outpatient cervical ripening with an osmotic dilator, returned to the hospital, and received additional cervical ripening procedures but ultimately was discharged home. The patient returned 5 days later for inpatient IOL resulting in a cesarean delivery. This patient was included in the baseline and process measure but did not contribute to delivery-related measures.

Most patients were White (89.2%), English-speaking (99.2%), had private insurance (91.7%), and nulliparous (68.1%; ►Table 1). Patient race differed by device type, with the Foley balloon group including Black (10.0%) and American Indian (2.5%) patients while the osmotic dilator group did not include patients from these groups but did include patients of Asian race (3.8%), multiple races (1.3%), and Native Hawaiian/Pacific Islander race (1.3%; which are groups not represented in the Foley balloon catheter group), $p = 0.008$. Device choice also differed by hospital with 95.0% of osmotic dilator patients at Hospital A and 45% of Foley balloon patients at Hospital B, $p < 0.001$. Hospital A also had a higher volume of patients overall with 81.7% of the study sample. Although not statistically significant, there were more patients with a parity of two or more in the Foley balloon catheter group (12.5 vs. 3.8%) and generally fewer nulliparous patients in the Foley balloon group (62.5 vs. 70.9%). The mean dilation (standard deviation) at device insertion was 1.0 ± 0.7 cm, and the mean SBS at insertion was 2.5 ± 1.4. These baseline measures varied by device with higher average dilation values for the Foley balloon group at the time of insertion (1.3 ± 0.6 cm) compared with the osmotic dilator group (0.8 ± 0.7 cm, $p < 0.001$). Baseline SBS was more favorable in the Foley balloon group on average (3.1 ± 1.2) compared with the osmotic dilator group (2.2 ± 1.3, $p = 0.001$) at device insertion.

Prior to weighting, there were large differences with respect to age, race, parity, and dilation at initiation. After weighting, all absolute standardized differences were lower, and the largest value was 0.11 for age with the rest all under 0.1 (►Supplementary Table S1 [available in the online version]). These results indicate that the weighted treatment groups are similar with respect to these characteristics, however, the balance could not be obtained for some other severely imbalanced factors, namely hospital.

Results comparing the two devices were similar between the weighted and unadjusted samples (►Table 2), so the weighted results are presented for comparison. Of the entire cohort, 13.3% reported expulsion of the cervical ripening device while at home, and expulsion was more common among patients with a Foley balloon (25.2%) compared with those with an osmotic dilator (6.2%), $p = 0.006$. Patients returned prior to their scheduled induction in 16.7% of the cases. This was more common for patients with a Foley balloon (27.6 vs. 10.9%, $p = 0.028$). Reasons for early return to the hospital were contractions (10.8%), rupture of membranes (4.2%), and vaginal bleeding (1.7%).

The mean time from device insertion to IOL admission was 16.2 ± 4.8 hours, with a range from 2.3 to 24.8 hours (►Table 2). Patients with the Foley balloon returned approximately 4 hours earlier (13.7 ± 5.0) than patients with osmotic dilators (17.5 ± 3.8), $p < 0.001$. The mean SBS at IOL admission was 4.3 ± 1.6, which represents an average increase of 1.8 ± 1.4 points in SBS during outpatient ripening. Dilation at IOL admission was 2.8 ± 1.2 cm, which represents an average increase of 1.8 ± 1.1 cm during outpatient ripening.

During IOL admission, 50.8% of patients were given additional cervical ripening agents or devices with the most common being use of misoprostol. Ten patients (8.4%) had additional mechanical devices, all from the osmotic dilator group (►Table 2). Among patients given oxytocin ($n = 110$) during IOL after return to the hospital, mean use was 11.9 ± 7.7 hours, with no difference by device (►Table 2). Time from IOL admission to delivery was 19.9 ± 10.3 hours, with no significant difference by device. Total LOS was 55.1 ± 15.4 hours for vaginal delivery patients and 102.7 ± 28.9 hours for cesarean deliveries. LOS did not differ by device for vaginal deliveries.

Vaginal deliveries occurred for 74.8% of patients. The proportion having vaginal deliveries was higher (but not significantly different) among the Foley balloon group (85.4%) compared with the osmotic dilator group (71.8%), $p = 0.088$. Complications occurring for patients undergoing outpatient cervical ripening included hemorrhage (3.4%), infection (4.2%), and readmission (2.5%; ►Table 3). There were no cases of uterine rupture. All deliveries resulted in a live birth. Apgar score of <7 at 1 minute occurred for 5.0% of infants and no infants had Apgar score of <7 at 5 minutes. NICU or SCN transfers occurred for 6.7% ($n = 8$) of infants with no difference by device type.

Prospective surveys were completed by 30 patients (11 Foley balloon group and 19 osmotic dilator group). Overall, 83.4% ($n = 25$) of patients said they were satisfied or very satisfied with their outpatient ripening experience. Survey participants were similar to the full study sample with

Table 1 Outpatient cervical ripening program patient characteristics, stratified by device type

	Total ($n = 120$)	Osmotic dilator ($n = 80$)	Foley balloon ($n = 40$)	*p*-Value
Age (y), mean ± SD	32.1 ± 4.3	32.5 ± 4.3	31.3 ± 4.2	0.170
Race				
American Indian/Alaska Native	1 (0.8)	0 (0)	1 (2.5)	0.008
Asian	3 (2.5)	3 (3.8)	0 (0)	–
Black/African American	4 (3.3)	0 (0)	4 (10.0)	
Multiple	1 (0.8)	1 (1.3)	0 (0)	
Native Hawaiian/Pacific Islander	1 (0.8)	1 (1.3)	0 (0)	
White	107 (89.2)	74 (92.5)	33 (82.5)	
Unknown	3 (2.5)	1 (1.3)	2 (5.0)	
Hispanic ethnicity	6 (5.0)	5 (6.3)	1 (2.5)	0.662
Preferred language				
English	119 (99.2)	80 (100)	39 (97.5)	0.333
Somali	1 (0.8)	0 (0)	1 (2.5)	–
Insurance type				
Private	110 (91.7)	75 (93.8)	35 (87.5)	0.243
Medicaid/Medicare	10 (8.3)	5 (6.3)	5 (12.5)	–
Location				
Hospital A	98 (81.7)	76 (95.0)	22 (55.0)	<0.001
Hospital B	22 (18.3)	4 (5.0)	18 (45.0)	–
Admitting provider type				
OB-Gyn	118 (98.3)	78 (97.5)	40 (100)	0.552
Certified nurse midwife	2 (1.7)	2 (2.5)	0 (0)	–
Gestational age on insertion, median [IQR], wk	39.7 [39.2, 40.3]	39.9 [39.3, 40.4]	39.4 [39.0, 40.1]	
37–38	3 (2.5)	3 (3.8)	0 (0)	0.550
39–41	117 (97.5)	77 (96.3)	40 (100)	–
Parity				
0	81 (68.1)	56 (70.9)	25 (62.5)	0.213
1	30 (25.2)	20 (25.3)	10 (25.0)	–
2+	8 (6.7)	3 (3.8)	5 (12.5)	
Dilation at insertion	($n = 111$)	($n = 72$)	($n = 39$)	
Mean ± SD	1.0 ± 0.7	0.8 ± 0.7	1.3 ± 0.6	<0.001
Median [IQR]	1 [0.5, 1.5]	1 [0, 1.5]	1 [1, 1.5]	–
SBS at insertion	($n = 99$)	($n = 61$)	($n = 38$)	
Mean ± SD	2.5 ± 1.4	2.2 ± 1.3	3.1 ± 1.2	0.001
Median [IQR]	3 [2, 3]	2 [1, 3]	3 [2, 4]	–

Abbreviations: IQR, interquartile range; SBS, simplified Bishop score; SD, standard deviation.
Data are presented as number (%) unless otherwise specified.

regard to age and race (►**Tables 1** and **4**). Among patients who used osmotic dilators, 42.1% were "very satisfied" and 47.4% were "satisfied" with the experience. In contrast, no patients who used Foley balloons reported they were "very satisfied," and 72.7% were "satisfied." Using a 10-point scale ranging from "no discomfort" to "very uncomfortable," patients reported 5.2 (total sample) as their level of comfort during device placement, 5.4 for those who used osmotic dilators, and 4.8 for patients who used Foley balloons. The level of comfort while at home among the total sample was 2.87, 2.5 for patients using osmotic dilators, and 3.5 for patients using Foley balloons (►**Table 4**). When rating the amount of anxiety/stress while at home with the device, a 2.1 average was reported on a 10-point scale of anxiety (0 being no anxiety). This measure was higher among the balloon catheter group (3.2) when compared with the osmotic

Table 2 Outpatient cervical ripening program process, timing, and outcome measures

	Unweighted[a]					Weighted[b]			
	Total ($n=120$)	Osmotic dilators ($n=80$)	Foley balloon ($n=40$)	Mean difference 95% CI	*p*-Value	Osmotic dilators	Foley balloon	Mean difference 95% CI	*p*-Value
Device expulsion before returning to hospital									
Yes	16 (13.3)	5 (6.3)	11 (27.5)	−21.2 [−37.0, −7.8]	0.001	6.2	25.2	−19.0 [−34.4, −3.7]	0.006
No	104 (86.7)	75 (93.8)	29 (72.5)			93.8	74.8		
Return before scheduled induction	20 (16.7)	9 (11.3)	11 (27.5)	−16.3 [−32.4, −1.9]	0.024	10.9	27.6	−16.7 [−33.4, −0.02]	0.028
Reason for return prior to scheduled induction									
ROM	5 (4.2)	4 (5.0)	1 (2.5)	2.5 [−8.3, 10.0]	0.664	4.1	3.3	0.9	–
Contractions/Labor	13 (10.8)	5 (6.3)	8 (20.0)	−13.8 [−28.9, 1.6]	0.031	6.8	20.6	−13.9	
Vaginal bleeding	2 (1.7)	0 (0)	2 (5.0)	−5.0 [−16.5, 0.8]	0.109	0	3.7	−3.7	
Hours from insertion to IOL admission[c]									
Mean ± SD	16.2 ± 4.8	17.5 ± 3.9	13.6 ± 5.3	3.9 [2.1, 5.6]	<0.001	17.5 ± 3.8	13.7 ± 5.0	3.9 [2.0, 5.7]	<0.001
Median [IQR]	16.8 [12.4, 19.6]	17.5 [15.3, 20.7]	15.0 [11.4, 17.1]	–		17.7 [15.3, 20.6]	15.0 [11.6, 16.9]	–	
Range	2.3–24.8	8.0–24.8	2.3–23.1			8.0–24.8	2.3–23.1		
SBS at IOL admission	($n=115$)	($n=75$)	($n=40$)						
Mean ± SD	4.3 ± 1.6	4.1 ± 1.7	4.7 ± 1.3	−0.6 [−1.2, 0]	0.063	4.2 ± 1.7	4.7 ± 1.2	−0.5 [−1.1, 0.1]	0.078
Median [IQR]	4 [3, 5]	4 [3, 5]	5 [4, 6]			4 [3, 5]	5 [4, 5]		
Change in SBS	($n=96$)	($n=58$)	($n=38$)						
Mean ± SD	1.8 ± 1.4	1.9 ± 1.3	1.6 ± 1.5	0.4 [−0.2, 0.9]	0.187	1.9 ± 1.3	1.6 ± 1.5	0.3 [−0.4, 0.9]	0.429
Dilation at IOL admission	($n=120$)	($n=80$)	($n=40$)						
Mean ± SD	2.8 ± 1.2	2.6 ± 1.2	3.1 ± 1.2	−0.5 [−1.0, −0.1]	0.030	2.7 ± 1.2	3.0 ± 1.2	−0.3 [−0.8, 0.2]	0.188
Median [IQR]	3 [1.8, 3.5]	3 [1.5, 3.5]	3 [2, 4]			3 [2, 3.5]	3 [2, 4]		
Change in dilation	($n=111$)	($n=72$)	($n=39$)						
Mean ± SD	1.8 ± 1.1	1.8 ± 1.1	1.8 ± 1.2	−0.1 [−0.5, 0.4]	0.699	1.8 ± 1.1	2.0 ± 1.2	−0.2 [−0.7, 0.3]	0.373
Additional ripening agents/ devices after return for IOL	61 (50.8)	45 (56.3)	16 (40.0)	16.3 [−2.6, 33.4]	0.093	54.6	40.8	13.8 [−7.1, 34.6]	0.200
Specific agents/devices									

Table 2 (*Continued*)

	Unweighted[a]					Weighted[b]			
	Total ($n=120$)	Osmotic dilators ($n=80$)	Foley balloon ($n=40$)	Mean difference 95% CI	*p*-Value	Osmotic dilators	Foley balloon	Mean difference 95% CI	*p*-Value
Cytotec/Misoprostol	60 (50.0)	44 (55.0)	16 (40.0)	15.0 [−3.9, 32.2]	0.121	53.6	40.8	12.8	–
Cervadil/Dinoprostone	4 (3.3)	4 (5.0)	0 (0)	5.0 [−4.3, 12.2]	0.300	4.4	0	4.4	
Foley	2 (1.7)	2 (2.5)	0 (0)	2.5 [−6.5, 8.7]	0.552	2.4	0	2.4	
Cook catheter	8 (6.7)	8 (10.0)	0 (0)	10.0 [0.0, 18.5]	0.051	9.2	0	9.2	
Successful ripening followed by delivery	$n=119$[d]	$n=79$[d]	$n=40$						
Mode of delivery									
Cesarean	30 (25.2)	24 (30.4)	6 (15.0)	15.4 [−1.3, 28.8]	0.068	28.2	14.6	13.6 [−2.0, 29.3]	0.088
Vaginal	89 (74.8)	55 (69.6)	34 (85.0)			71.8	85.4		
Hours of oxytocin use before delivery, mean ± SD[e]	11.9 (7.7)	12.1 ± 8.0	11.5 ± 7.2	0.5 [−2.6, 3.7]	0.734	12.0 ± 7.9	12.0 ± 7.7	−0.1 [−3.5, 3.5]	0.996
Hours from IOL admission to delivery, mean ± SD	19.9 ± 10.3	20.8 ± 11.0	18.1 ± 8.4	2.7 [−1.3, 6.6]	0.182	20.2 ± 10.8	18.8 ± 8.4	1.4 [−2.4, 5.2]	0.461
Vaginal delivery LOS (hours), mean ± SD	55.1 ± 15.4	56.3 ± 17.8	53.1 ± 10.7	3.3 [−3.4, 10.0]	0.337	54.9 ± 17.1	53.5 ± 10.6	1.3 [−4.6, 7.2]	0.643
Cesarean delivery LOS (hours), mean ± SD	102.7 ± 28.9	106.2 ± 30.4	88.7 ± 17.3	17.5 [−9.1, 44.2]	0.188	106.7 ± 29.8	91.8 ± 14.9	14.9 [−1.4, 31.2]	0.072

Abbreviations: CI, confidence interval; IOL, induction of labor; IQR, interquartile range; LOS, length of stay; ROM, rupture of membranes; SBS, simplified Bishop score; SD, standard deviation.
[a]Data are presented as *n* (%) unless otherwise specified.
[b]Data are represented as percentages unless otherwise specified.
[c]Two patients are missing time from insertion to inpatient admission.
[d]One patient completed outpatient cervical ripening, was admitted for induction, and received pharmacological and additional ripening devices, which were unsuccessful. The patient was discharged home and was admitted 5-days later for inpatient induction, resulting in a successful delivery. The patient completed outpatient cervical ripening, and data was used in baseline and process measure analyses. The patient's delivery data was excluded from delivery-related analyses given the 5-day delay.
[e]Oxytocin use before delivery is for 110 patients (9 did not use oxytocin).

Table 3 Outpatient cervical ripening program cervical outcome measures

	Unweighted[a]				
	Total ($n = 119$)	Osmotic dilator ($n = 79$)[a]	Foley balloon ($n = 40$)	Difference Mean [95% CI]	*p*-Value
Complications					
Uterine rupture	0 (0)	0 (0)	0 (0)	–	
Hemorrhage, QBL >1,000 mL	4 (3.4)	4 (5.1)	0 (0)	5.1 [−4.2,12.3]	0.299
Hemorrhage, vaginal deliveries ($n = 89$)	1 (1.1)	1 (1.8)	0 (0)	1.8 [−8.4, 9.6]	1.000
Hemorrhage, cesarean deliveries ($n = 30$)	3 (10.0)	3 (12.5)	0 (0)	12.5 [−27.4, 31.0]	1.000
Infection composite[b]	5 (4.2)	4 (5.1)	1 (2.5)	2.6 [−8.3, 10.1]	0.662
Readmission within 30 days	3 (2.5)	2 (2.5)	1 (2.5)	0.0 [−10.5, 6.6]	1.000
Neonatal measures					
Birth outcome, fetal demise	0 (0)	0 (0)	0 (0)	–	
Apgar score, 1 minute					
< 7	6 (5.0)	5 (6.3)	1 (2.5)	−3.8 [−7.2, 11.8]	0.662
≥ 7	113 (95.0)	74 (93.7)	39 (97.5)	–	
Apgar score, 5 minutes					
< 7	0 (0)	0 (0)	0 (0)	–	
≥ 7	119 (100)	79 (100)	40 (100)		
Transferred to NICU/SCN	8 (6.7)	7 (8.9)	1 (2.5)	6.4 [−5.0, 14.9]	0.265
Birth weight (g)					
$< 2,500$	0 (0)	0 (0)	0 (0)	–	0.504
2,500–3,999	108 (90.8)	73 (92.4)	35 (87.5)		–
$\geq 4,000$	11 (9.2)	6 (7.6)	5 (12.5)		

Abbreviations: CI, confidence interval; QBL, quantitative blood loss; NICU, neonatal intensive care unit; SCN, special care nursery.
Data are presented as *n* (%).
[a]One patient completed outpatient cervical ripening, was admitted for induction and received pharmacological and additional ripening devices, which were unsuccessful. The patient was discharged home, admitted for induction 5 days later, and successfully delivered. The patient's completed outpatient cervical ripening data were used in baseline and process measure analyses. Data were excluded from delivery-related analyses given the 5-day delay.
[b]Infection composite: chorioamnionitis, endometritis, and sepsis.

dilator group (1.3; $p = 0.004$). All patients responded saying they would recommend outpatient cervical ripening. When reporting on the open-ended question regarding what they liked most about outpatient cervical ripening most responses ($n = 25$, 83%) were related to the patient's ability to be home, "*That it [mechanical ripening device] was comfortable after it was inserted and that I could go home after. It also dilated me to 3 cm.*" The patients using osmotic dilators also shared they liked the reduced hospital time ($n = 4$, 13%) and the comfort of device use ($n = 5$, 17%). Patients using Foley balloons also commented on the effectiveness of the device ($n = 3$, 10%). In terms of what they liked least about the experience, most patients ($n = 18$, 60%) had nothing negative to report. A few patients ($n = 3$) who had ripening with osmotic dilators commented on the discomfort during placement, "*the insertion was painful since I was barely dilated.*" While there were no comments regarding pain at placement from the Foley balloon group, however, three of those patients noted discomfort related to the tubing protruding from the vagina (►**Table 4**).

Discussion

The primary purpose of this study was to examine the implementation of an outpatient program that used two mechanical cervical ripening devices, in the context of growing demand for IOL. To date, the literature on outpatient cervical ripening has focused on single mechanical method compared across settings,[22,29,30] or compared with inpatient pharmacological methods[15,23] or outpatient pharmacological,[31,32] and a few studies of pharmacological methods compared between inpatient and outpatient settings.[7,33] Patients in the outpatient program with either mechanical device had positive cervical changes while at home and reported satisfaction with the experience. Being able to spend more time at home and less time in the hospital

Table 4 Patient satisfaction survey responses

	Total ($n = 30$)	Osmotic dilators ($n = 19$)	Foley balloon ($n = 11$)	*p*-Value
Age (years), mean ± SD	34.4 ± 4.2	35.3 ± 4.0	33.0 ± 4.3	0.150
Race				
Asian	1 (3.0)	1 (5.2)	0 (0)	0.810
Black/African American	2 (6.7)	1 (5.2)	1 (9.0)	–
White	26 (86.7)	17 (89.5)	9 (81.8)	
Unknown	1 (3.0)	0 (0)	1 (9.0)	
Hispanic ethnicity	1 (3.0)	1 (5.2)	0 (0)	1.000
Comfort and anxiety, mean ± SD				
Level of comfort during placement[a]	5.2 (2.1)	5.4 (2.0)	4.8 (2.4)	0.463
Level of comfort with cervical ripening while you were at home[a]	2.9 (1.9)	2.5 (1.9)	3.5 (1.6)	0.159
Anxiety or stress during your cervical ripening at home[b]	2.1 (1.7)	1.5 (1.0)	3.2 (2.1)	0.004
Education and concerns				
Adequate education about when to call your pregnancy care provider	30 (100)	19 (100)	11 (100)	
Adequate education about when to return after device insertion	30 (100)	19 (100)	11 (100)	
Education received prepared the patient for the experience	27 (90.0)	16 (84.2)	11 (100)	0.279
Would recommend cervical ripening at home to others	30 (100)	19 (100)	11 (100)	–
Patient had concerns during at-home cervical ripening	5 (16.7)	2 (10.5)	3 (27.3)	0.327
Overall satisfaction with your at-home cervical ripening				
Very dissatisfied	0 (0)	0 (0)	0 (0)	0.032
Dissatisfied	0 (0)	0 (0)	0 (0)	–
Neutral	5 (16.7)	2 (10.5)	3 (27.3)	
Satisfied	17 (56.7)	9 (47.4)	8 (72.7)	
Very satisfied	8 (26.7)	8 (42.1)	0 (0)	
What did you like about cervical ripening at home?				
Being able to be at home	25 (56.8)	14 (50.0)	11 (68.8)	–
Not being in the hospital/less time in hospital	5 (11.4)	4 (14.3)	1 (6.2)	
Being with family	2 (4.5)	1 (3.6)	1 (6.2)	
No discomfort/comfort	5 (11.4)	5 (17.9)	0 (0)	
Effectiveness of device	5 (11.4)	2 (7.0)	3 (18.8)	
Starting process with no drugs/“natural”	2 (4.5)	2 (7.0)	0 (0)	
Was there anything you did NOT like about cervical ripening at home?				
No issues or no response	18 (60.0)	15 (78.9)	3 (27.3)	–

(*Continued*)

Table 4 (*Continued*)

	Total ($n = 30$)	Osmotic dilators ($n = 19$)	Foley balloon ($n = 11$)	*p*-Value
Discomfort with foley string	3 (10.0)	0 (0)	3 (27.3)	
Discomfort during placement	3 (10.0)	3 (15.8)	0 (0)	
Stress/anxiety while at home	1 (3.3)	0 (0)	1 (9.1)	
Discomfort at home/trouble sleeping	1 (3.3)	0 (0)	1 (9.1)	
Effectiveness	3 (10.0)	1 (5.3)	2 (18.2)	
Contractions/Pain	1 (3.3)	0 (0)	1 (9.1)	

Abbreviation: SD, standard deviation.
Data are *n* (%) unless otherwise specified.
[a]Response options for level of comfort: 0 = no discomfort; 10 = very uncomfortable.
[b]Response options for anxiety or stress: 0 = no anxiety; 10 = worst anxiety.

contributed to patient satisfaction. Process and outcome measures align with other research findings for each device. Surveys indicate patients were generally satisfied with the outpatient process.

Few studies have described the outpatient use of osmotic dilators.[22,23] Kummer et al[23] described 96 outpatient cervical ripening cases in Germany. Patients in this study were comparable to the osmotic dilator subset of patients in our study regarding age (32.7 [Kummer et al] vs. our study 32.5 years). After outpatient cervical ripening, the average time from admission to delivery was also comparable (20.4 vs. 20.8 hours). Differences were noticed related to vaginal delivery (81.2% [Kummer et al, which includes both vaginal delivery and vacuum extraction] vs. 69.6%,) and cesarean delivery (17.7 vs. 30.4%). One possible factor contributing to differential delivery methods is fewer nulliparous women in Kummer et al's outpatient cohort (54.2% [Kummer et al] vs. 70.9%), or the potential of more instrument-assisted vaginal deliveries performed in Europe than in our U.S. sample may have been cesarean section. Saad et al[22] conducted a randomized controlled trial (RCT) that included 167 outpatient osmotic dilator cases (compared with inpatient osmotic dilator use). The patients with outpatient osmotic dilators reported a similar vaginal delivery rate (71%) to our findings.[22] While our study had a higher proportion of patients returning to the hospital prior to their scheduled time of admission (2.4% [Saad et al] vs. 11.3%) reasons for return were similar across studies and generally did not represent any safety concerns. Of note, our study found similar rates of maternal hemorrhage as the RCT and lower overall infection rates.[22]

Transcervical Foley balloon catheters have been identified as safe for outpatient use.[34] Outpatient cervical ripening with Foley balloon catheters in previous studies[29] has shown an average cesarean delivery rate of 21%, which is higher than the 15.0% in our study. Patients returning prior to their scheduled induction were similar in our study (i.e., active labor, discomfort, contractions, device expulsion) when compared with those reported by an RCT from Ausbeck et al, studying outpatient Foley balloon catheter use (22.2% [Ausbeck et al] vs. our 27.5%).[35]

A meta-analysis reviewing maternal satisfaction in outpatient cervical ripening found three RCTs and one non-RCT, including 1,707 women, and congruent to our study found patients reporting positive feelings and high satisfaction with the outpatient induction experience.[25] Studies comparing patient satisfaction between outpatient and inpatient recipients found that overall patients were satisfied with the process in both settings and would desire the same method for future cervical ripening.[9,15] None of these studies included patients receiving osmotic dilators.[9,15] With regard to pain, Beckman et al, compared outpatient pain scores to an inpatient pharmacological method and found higher pain scores in their Foley balloon catheter group, whereas between our two mechanical methods pain scores did not differ significantly between groups.[15]

Findings from this study represent the experience of a clinical program, rather than a clinical trial. A strength of this study is the description of the real-world implementation of such a pilot in two large hospital settings to inform other clinical programs. In this context, providers in the outpatient setting have the choice of which device type they will place, with device choice influenced by familiarity, clinical training, and patient factors. Given the perceived ease of insertion of osmotic dilators compared with Foley balloon in nulliparous patients with closed cervix, we also found a higher proportion of nulliparous patients and a lower baseline SBS in the osmotic dilator group. While our weighted analysis corrected for these baseline intergroup differences, this is one limitation of the study compared with an RCT. While we are unable to include a cost analysis related to devices or other cervical ripening agents in this study, it is possible that cost differences between the devices or pricing changes during the study period could have affected provider choice for the

device. This pilot program was further limited by intermittent pauses in the outpatient cervical ripening program and all elective IOL in our hospital system during surges, to not overwhelm bed capacity.

The study is underpowered to detect differences between device types for rare maternal and neonatal outcomes. While we noted a trend toward higher infection and hemorrhage rates in the osmotic dilator group, this was not statistically significant and may be due to underlying differences between the groups if providers preferentially chose osmotic dilators in patients with perceived difficult insertions. In a subsequent manuscript, we plan to compare how these observations compare with an inpatient cervical ripening cohort. While our study demonstrates similar effectiveness of osmotic dilators compared with Foley balloons for cervical ripening and did not find any statistically significant increased risks in either group, continued surveillance of infection and hemorrhage rates in patients receiving outpatient cervical ripening is warranted. Further evaluations of comprehensive outpatient programs may be informative for guidelines and clinical program development as demand for IOL increases. Another limitation of our study is that we were only able to collect satisfaction surveys on 30 patients, thus results from the survey data should be interpreted in the context of the small sample size.

Conclusion

In conclusion, both osmotic dilators and Foley balloon catheters resulted in similar improvement in SBS on admission with low reported complications. Patients reported overall satisfaction and low pain/anxiety at home with the outpatient cervical ripening experience.

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Conflict of Interest

None declared.

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