OBSTETRICS

A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial)

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OBJECTIVE: The objective of the study was to test the hypothesis that Dilapan-S is not inferior to the Foley balloon for preinduction cervical ripening at term.

STUDY DESIGN: Pregnant women ≥37 weeks scheduled for induction with unfavorable cervix (≤3 cm dilated and ≤60% effaced) were randomly assigned to 12 hours of either Foley balloon inflated with 60 mL saline or Dilapan-S for cervical ripening. If the cervix remained unfavorable, then 1 more round of the assigned dilator was used. Management following ripening was left up to the clinical providers. The primary outcome was vaginal delivery. A satisfaction survey was also obtained after the preinduction period. Sample size was based on a noninferiority margin of 10%, 90% power, and an estimated frequency of vaginal delivery of 71% in Foley balloon and 76% in Dilapan-S.

RESULTS: From November 2016 through February 2018, 419 women were randomized (209 to Foley balloon; 210 to Dilapan-S). In the intent-to-treat analysis, vaginal delivery was more common in Dilapan-S vs Foley balloon (81.3% vs 76.1%), with an absolute difference with respect to the Foley balloon of 5.2% (95% confidence interval, −2.7% to 13.0%) indicating noninferiority for the prespecified margin. The difference was not large enough to show superiority. Noninferiority was confirmed in the per-protocol population (n = 204 in the Foley balloon, n = 188 in Dilapan-S), supporting the robustness of the results. Secondary outcomes were not different between groups, except for a longer time the device remained in place in Dilapan-S compared with the Foley balloon. Maternal and neonatal adverse events were not significantly different between groups. A priori interaction analyses showed no difference in the effect on vaginal delivery by cervical dilation at randomization, parity, or body mass index >30 kg/m^2. Patients with Dilapan-S were more satisfied than patients with the Foley balloon as far as sleep ($P = .01$), relaxing time ($P = .001$), and performance of desired daily activities ($P = .001$).

CONCLUSION: Dilapan-S is not inferior to the Foley balloon for preinduction cervical ripening at term. Advantages of Dilapan-S over Foley include Food and Drug Administration approval, safe profile, no protrusion from the introitus, no need to keep under tension, and better patient satisfaction.

Key words: cervical ripening, Dilapan-S, induction, labor, mechanical

In the United States, 23% of pregnant women undergo labor induction.[1] A recent randomized controlled trial showed that elective labor induction at term in low-risk nulliparous women is associated with a lower risk of cesarean delivery and preeclampsia, with no increase in adverse perinatal morbidities.[2] Hence, one can assume that labor induction rates will increase.

The majority of women undergoing induction have unfavorable cervixes and require cervical ripening agents.[3] The ultimate approach to cervical ripening remains to be determined.[4] The ideal cervical ripening agent should be one that is inexpensive, effective, and safe. Mechanical methods of cervical ripening are safe and cost effective and have been used for decades.[5]

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The most commonly used mechanical cervical ripening method in the United States relies on the insertion of a Foley balloon beyond the internal os and inflation with 30−60 mL of saline. The Foley catheter is then placed under tension to exert pressure from the balloon on the internal os.

Dilapan, a hygroscopic cervical dilator made from a patented hydrogel (Aquacryl), has been used in the past for cervical ripening for early gestation uterine evacuation. The original Dilapan was in production until 1997. Because of concerns of fragmentation, a better-quality version (Dilapan-S, Super version) with improved material and mechanical properties was developed. Dilapan-S was approved by the Food and Drug Administration (FDA) for cervical ripening in the third trimester in 2015.

The Dilapan-S rods are inserted into the cervical canal, are contained within the vagina, and do not require tension. Dilapan-S works by absorbing fluid from cervical canal cells, resulting in reversible cell membrane dehydration and softening. In addition, the increase in the rod's volume creates a mechanical stretch and leads to the release of endogenous prostaglandins, causing cervical ripening. Recently a multicenter prospective cohort study showed that Dilapan-S is a safe and effective method for cervical ripening in term gestations.[6]

Currently there are no published randomized trials comparing this novel version of this device to other methods of cervical ripening. Because of the potential advantages of Dilapan-S (eg, FDA approval, no protrusion from the introitus, and no need for tension), we aimed to compare this new method with the current standard for mechanical cervical ripening. We performed a noninferiority randomized clinical trial comparing Dilapan-S with the Foley balloon for cervical ripening in term pregnancies.

Materials and Methods

Study design and oversight

This was a single-center, randomized, open-label trial. Medicem (Prague, Czech Republic) funded the trial. The University of Texas Medical Branch Perinatal Research Division and the

AJOG at a Glance

Why was this study conducted?

We conducted a level 1 clinical trial comparing Dilapan-S with the current standard for mechanical cervical ripening, the Foley balloon.

Key findings

Dilapan-S is not inferior to the Foley balloon for preinduction cervical ripening at term. Both methods did not differ in adverse effects. Better patient satisfaction was noted in the Dilapan-S group.

What does this add to what is known?

This is a randomized controlled trial evaluating the newer version, Dilapan-S, as a preinduction cervical ripening agent at term.

principal investigator (A.S.) coordinated the study, data collection, and management independently from the sponsor. An independent third party performed the data analysis. The institution's ethics committee approved the protocol.

Before randomization, written informed consent was obtained from all participating subjects. An independent data and safety monitoring committee performed the study monitoring. All the authors back the accuracy and completeness of the data and the adherence of the study to the protocol. This study was reported according to Consolidated Standards of Reporting Trials guidelines.[7]

Screening and recruitment

Pregnant women who were at 37 weeks 0 days or greater of gestation with an unfavorable cervix (≤3 cm dilated and ≤60% effaced) and a live singleton fetus in cephalic presentation, who had no contraindication to vaginal delivery, and who had a scheduled induction of labor were screened for eligibility. Subjects with ruptured membranes, favorable cervix, estimated fetal weight >5000 g for nondiabetic or >4500 g for diabetic, chorioamnionitis, prior uterine scar, active vaginal bleeding, or nonreassuring fetal status requiring immediate delivery were excluded.

Randomization and management

Women presenting to our unit for induction of labor, and who met eligibility criteria and consented, were randomly assigned in a 1:1 ratio to either Dilapan-S (DS) or Foley balloon (FB). The randomization sequence was created independently using a computer-generated randomization and was concealed from those responsible for recruiting participants into the study by keeping it in a file cabinet with access restricted to research staff.

Women assigned to the DS group underwent continuous cardiotocograph monitoring for 20 minutes before the device (Dilapan-S; rod size: 4 × 65 mm) was placed. The cervix was visualized with a sterile vaginal speculum and cleaned with iodine. As many rods as possible were inserted into the cervical canal under direct visualization as per the manufacturer's instructions for use.

The patient was instructed to report any excessive bleeding, pain, or other concerns and not to remove the rods herself. The dilators were left in place for at least 12 hours but no longer than 24 hours. Patients remained in the hospital but were allowed to ambulate, shower, and perform regular activity as long as a reactive and reassuring continuous cardiotocograph was documented after placement of the device. If the cervix remained unfavorable after extraction of the dilators (<3 cm dilated and not more than 60% effaced), a second round of DS was used, in this case for a maximum of 12 hours.

Women in the FB group underwent the same procedures described i8n the previous text but had instead an FB tip introduced past the internal cervical os and filled with 60 mL of sterile 0.9% NaCl. The free end of the Foley catheter was taped to the patient's thigh and kept under tension. Unless the FB came out spontaneously or the patient went into labor, it was left in place for at least 12 hours, and a second round with the FB was used if the cervix remained unfavorable. Pre- and postplacement procedures were identical to the DS group.

In both groups, if the cervix remained unfavorable after the second round of assigned cervical dilator, only pharmacological cervical ripening was allowed.

If the cervix was deemed ripe (≥3 cm and ≥60% effacement) and the patient was not in labor, induction with oxytocin was started. Oxytocin was started at 2 milliunits/min and increased at a rate of 2 milliunits/min or less every 10 minutes until an adequate contraction pattern was achieved. Initial maximum dose was 20 milliunits/min. The maximal dose was increased to 30 milliunits/min after faculty staff approval. Prostaglandins in practice in our facility included dinoprostone 0.5 mg per 3 g (2.5 mL gel), misoprostol (25 μg vaginal tablets), or dinoprostone 10 mg vaginal insert.

Trained and certified research staff members abstracted data from the medical records. It included demographics, past medical history, and relevant outcomes. Participants were interviewed by research personnel immediately after insertion and postpartum and completed a satisfaction survey to rate their cervical ripening experience.

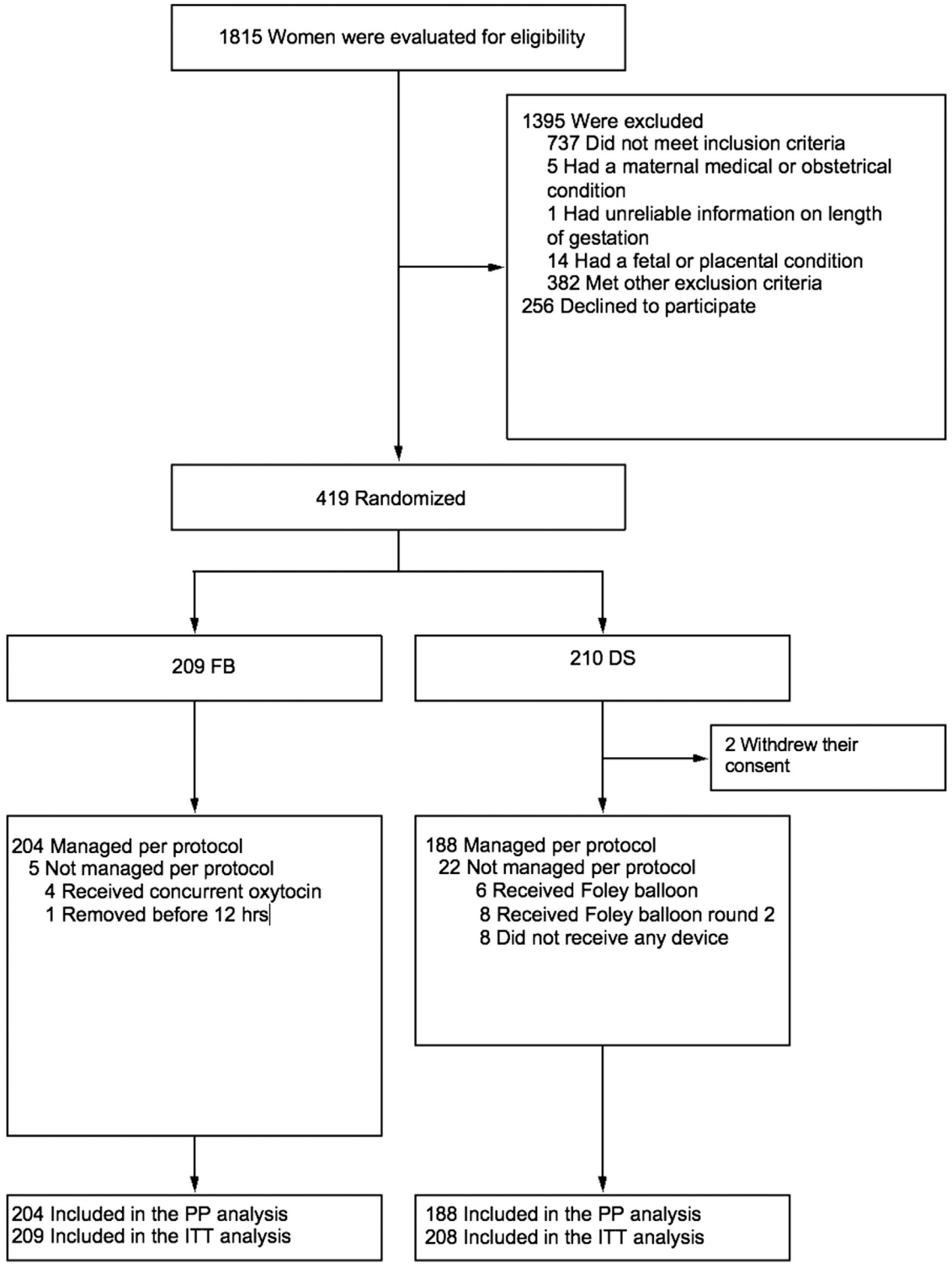
Outcomes

The primary outcome was vaginal delivery. Prespecified subgroup analyses for the primary outcome were cervical dilation at randomization, parity, and body mass index (≥30 kg/m^2 vs <30 kg/m^2).

Prespecified secondary outcomes were change in Bishop score, operative vaginal delivery, cesarean delivery, time to active stage of labor (defined as time to cervical dilation >5 cm), induction to delivery time (defined as pharmacologic agent initiation to delivery), device placement to delivery time, hospital stay, total time device in place, regional anesthesia, analgesia during cervical ripening, and patient satisfaction.

Patient satisfaction was assessed using a survey that was completed by the

FIGURE 1
Eligibility, randomization, delivery, and assessment



Per-protocol analysis includes study subjects who did not experience any major protocol violation that would have affected the endpoints being assessed. The intent-to-treat analysis included study subjects who were in the arm group they were originally allocated, regardless of treatment they actually received.

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TABLE 1
Maternal characteristics at baseline[a]

Characteristic	Treatment group	
	Foley balloon (n = 209)	Dilapan-S (n = 210)
Age, y		
Median	25	25
Range	18–44	18–44
Race or ethnic group, n, %		
White	30 (14.4)	35 (16.7)
Black	28 (13.4)	22 (10.5)
Asian	2 (1)	0 (0)
Hispanic	147 (70.3)	153 (72.9)
Other, unknown, or more than 1 race	2 (1)	0 (0)
History of pregnancy loss, n, %		
No previous pregnancy loss	147 (70.3)	156 (74.3)
Previous pregnancy loss	62 (29.7)	54 (25.7)
Length of gestation at randomization, wks		
Median	39.0	39.0
Range	39.0–41.0	37.0–41.0
Indication for delivery, n, %		
Elective induction of labor	156 (74.6)	154 (73.3)
Hypertension	21 (10.0)	24 (11.4)
Postterm pregnancy	6 (2.9)	8 (3.8)
Cholestasis	4 (1.9)	5 (2.4)
Diabetes	11 (5.3)	7 (3.3)
IUGR	5 (2.4)	3 (1.4)
Oligohydramnios	6 (2.9)	4 (1.9)
Other	9 (4.3)	13 (6.2)
Group B Streptococcus positive	62 (30.1)	60 (28.7)
Nulliparous	98 (46.9)	88 (41.9)
Multiparous	111 (53.1)	122 (58.1)
BMI at randomization[b]		
Median	30.8	30.67
Range	18.4–57.4	16.4–54.5
Modified Bishop score at randomization[c]		
Median	3	3
Range	0–7	0–8
Score <6, n/total n, %[c]	193 (94.6)	193 (97.5)

Data are represented as n (percentage) unless otherwise specified.

BMI, body mass index; *IUGR*, intrauterine growth restriction.

[a] There were no significant differences between the groups. Percentages may not total 100 because of rounding; [b] The BMI is the weight in kilograms divided by the square of the height in meters; [c] Modified Bishop scores range from 0 to 12; a score <6 reflects an unfavorable cervix.

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patient immediately after mechanical dilator placement and again after device extraction but before hospital discharge. The questionnaire consisted of 11 questions that were scored on a 5 point Likert scale[8] (Supplemental Figure). Pain at placement and during cervical ripening was assessed using a visual analog scale.[9] The survey and analog scales were in English or Spanish.

Statistical analysis

We hypothesized that DS would be noninferior to FB for preinduction cervical ripening at term. The primary analysis was conducted on both the intent-to-treat (ITT) and per-protocol (PP) populations according to the recommendations for a noninferiority hypothesis.[10] The ITT population included subjects who were analyzed in accordance with their randomized study treatment (ie, in the treatment group they were originally allocated, regardless of treatment actually received). The PP population was comprised of all the subjects who actually received the assigned intervention (either DS or FB) and did not experience any major protocol violations that would affect the primary outcome.

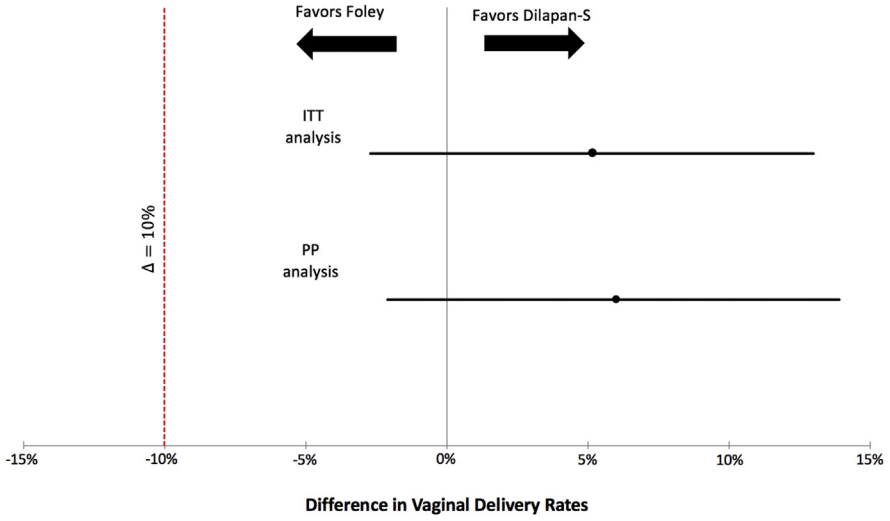
The analyses for the demographic and baseline characteristics, as well as the secondary and safety outcomes, were performed on the ITT population. A sensitivity analysis was also performed for the safety outcomes after excluding subjects who received both devices.

Analysis of the questionnaire was performed by the Cochran-Armitage test for trend.[11,12] $P < .05$ was considered significant.

The analysis was performed after data lock by an independent third party, blinded to the dilator assignment. Because of the noninferiority design, 2 blinded analyses were performed for the primary outcome (group A noninferior to group B and group B noninferior to group A) and then unblinded after both analyses were completed.

On the basis of noninferiority margin of 10%[13] and a frequency of vaginal delivery of 71% in FB and 76% in DS,[14,15] a

FIGURE 2
Difference in vaginal delivery rate between Dilapan-S and Foley balloon



Absolute difference in vaginal delivery rate (with 95% CI) between Dilapan-S and Foley balloon in the ITT and PP analysis. The 95% CI spans zero but lies wholly above the Δ margin, indicating noninferiority.

CI, confidence interval; *ITT*, intent-to-treat; *PP*, per-protocol.

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minimum sample size of 364 women was needed to provide a power of 90% with a 1-sided alpha level of 0.025. If we estimate a protocol adherence of 87%, then 420 consented patients would be needed.

Results

From November 2016 through February 2018, a total of 1815 women were screened for eligibility. Four hundred twenty women consented and 419 (23%) were randomized (209 in FB; 210 in DS) (Figure 1). One woman was consented but was found to be ineligible before she was randomized. Protocol deviations occurred in 27 participants for a total protocol adherence of 93% (better than the estimated protocol adherence of 87%).

TABLE 2
Route of delivery according to trial group (intent-to-treat analysis)

Outcomes	Treatment group DS (n = 208)	Treatment group FB (n = 209)	Risk difference, % (95% CI)[a]	*P* value
Primary outcome				
Vaginal delivery	169 (81.3)	159 (76.1)	5.2 (−2.7 to 13.0)	.197
Secondary outcomes				
Operative vaginal delivery	9 (4.8)	6 (2.9)	1.9 (−2.0 to 6.1)	.307
Cesarean delivery	39 (18.8)	50 (23.9)	−5.2 (−13.0 to 2.7)	.197
Spontaneous vaginal delivery	159 (76.4)	153 (73.2)	3.2 (−5.1 to 11.5)	.446

Data are represented as n (percentage) or mean unless otherwise specified.

CI, confidence interval; *DS*, Dilapan-S; *FB*, Foley balloon.

[a] Risk difference is expressed as the rate in the Dilapan-S group minus the rate in the Foley group (95% CI).

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At the time of randomization, 92% of the participants had an unfavorable Bishop score (ie, a score <6). Baseline characteristics at randomization were similar among groups (Table 1). The median number of Dilapan-S rods placed was 5.[2-8] The most common indication for delivery was elective induction, which was performed at or after 39 weeks. All inductions before 39 weeks were medically indicated, with hypertension being the most common indication, followed by diabetes.

In the ITT analysis, vaginal delivery was more common in DS vs FB (81.3% vs 76.1%), with an absolute difference with respect to the FB of 5.2% (95% confidence interval [CI], −2.7% to 13.0%), indicating noninferiority for the prespecified margin. The difference was not large enough to show superiority (Figure 2). Noninferiority was confirmed in the PP analysis (absolute difference, 6%; 95% CI, −2.1% to 13.9%), supporting the robustness of the finding (Figure 2).

Tables 2 and 3 summarize the delivery outcomes in the FB vs DS groups in both PP and ITT analyses, respectively. Secondary outcomes were not different between groups, except for a longer time the device remained in place in DS (774.1 ± 295 minutes) compared with the FB group (666 ± 319 minutes; $P = .0005$; Table 4).

Additional ripening interventions were required after 24 hours in 3 women in the DS group (1.6%) vs 1 in the FB group (0.5%). One of these patients had a cesarean delivery (in the DS group) and the other 4 delivered vaginally. Safety outcomes relevant to device placement such as cervical laceration, accidental rupture of membranes, fragmentation, retraction, or entrapment were not different between groups (Table 5).

More vaginal bleeding was noted in the DS group, compared with FB but did not reach statistical significance ($P = .12$) (Table 5). Maternal infectious morbidity and neonatal adverse events were not significantly different between groups.

The results of the safety analyses did not change after excluding subjects who received both devices. A priori interaction analyses showed no difference in

TABLE 3
Route of delivery according to trial group (per protocol analysis)

Outcome	Treatment group DS (n = 188)	FB (n = 204)	Risk difference, % (95% CI)[a]	*P* value
Primary outcome				
Vaginal delivery	155 (82.4)	156 (76.5)	6 (−2.1 to 13.9)	.144
Secondary outcomes				
Operative vaginal delivery	9 (4.8)	6 (2.9)	1.8 (−2.2 to 6.2)	.344
Cesarean delivery	33 (17.6)	48 (23.5)	−6.0 (−13.9 to 2.1)	.144
Spontaneous vaginal delivery	146 (77.7)	150 (73.5)	4.1 (−4.4 to 12.5)	.342

Data are represented as n (percentage) or mean unless otherwise specified. *CI*, confidence interval; *DS*, Dilapan-S; *FB*, Foley balloon.

[a] Risk difference is expressed as the rate in the Dilapan-S group minus the rate in the Foley group (95% CI).

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vaginal delivery between FB and DS according to cervical dilation at randomization, parity, or body mass index. Patients in DS were more satisfied than patients in FB as far as sleep ($P = .01$), relaxing time ($P = .001$), and performance of desired daily activities ($P = .001$) (Figure 3).

Comment

Principal findings

We found that pregnancies undergoing cervical ripening with DS was noninferior to FB in achieving vaginal delivery. While the rate of vaginal delivery was higher in the DS vs FB group, the difference was not large enough to show superiority. Our findings were consistent between the PP and the ITT populations, confirming the robustness of the results.

Given our findings, we are confident that Dilapan-S is not less effective than the Foley balloon in achieving vaginal delivery and may be considered as a good alternative when preinduction mechanical cervical ripening is desired. Our interaction analysis showed that the benefits of DS are not affected by baseline cervical status, parity, or obesity.

TABLE 4
Secondary outcomes according to trial group (intent-to-treat analysis)

Outcome	Treatment group FB (n = 209)	DS (n = 208)	*P* value[a]
Change in Bishop score	3 [−3 to 9]	2 [−2 to 11]	.73
Second round of mechanical dilator	21 (9.8)	26 (13.1)	.35
Time to active stage of labor (minutes)[b]	1011 [913–1074]	1152 [1092–1205]	.21
Induction to delivery (minutes)	565 [495–634]	678 [557–734]	.64
Device placement to delivery (minutes)	1291 [1203–1408]	1441 [1343–1521]	.14
Hospital stay (hours)	63 [59–67]	66 [64–69]	.67
Total time device in place (minutes)	666 ± 319	774.1 ± 295	.0005
Indications for cesarean delivery			
Nonreassuring fetal heart rate	13 (6.2)	16 (7.7)	.55
Failure to progress	30 (14.4)	20 (9.6)	.13
Maternal request	7 (3.3)	1 (0.5)	.03
Other	4 (1.9)	6 (2.9)	.51
Regional anesthesia	188 (90.0)	174 (83.7)	.05
Analgesia during cervical ripening	38 (18.2)	34 (16.7)	.70

Data are represented as n (percentage), median [range], or mean ± SD.

DS, Dilapan-S; *FB*, Foley balloon.

[a] χ^2 or Mann-Whitney rank sum as appropriate; [b] Defined as cervical dilation >5 cm.

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Clinical implications

Both devices were safe. Neither mechanical device had any malfunction, such as balloon rupture, retraction, retention, or fragmentation. In the DS group, the most common maternal adverse event was bleeding at insertion or extraction, while in the FB group, it was nonreassuring fetal heart rate tracing. None of the adverse events were severe enough to require intervention.

The safety profile for DS was not significantly different from the FB. Maternal infection comorbidity was similar in both groups. However, patients were more satisfied with the Dilapan-S compared with the Foley balloon. This is likely due to the difference in how the devices are handled after insertion. While the Foley protrudes from the introitus and is kept under tension, the Dilapan-S remains mostly in the cervical canal, allowing more patients to continue with daily activities.

Roughly up to one fourth of women undergo induction of labor in the United States every year.[1] Mechanical dilators are one of the most commonly used methods for cervical ripening.[5] Their low cost, effectiveness, and safety profile make them ideal preinduction agents. The Foley balloon has been the gold standard method for decades.[16-18] After the findings of the A Randomized Trial of Induction Versus Expectant Management (ARRIVE) trial,[2] an increasing rate of labor induction is anticipated, emphasizing the importance of choosing induction methods that are safe, practical, and cost effective.

Dilapan-S was recently approved by the FDA for preinduction cervical ripening in late gestation. While

TABLE 5
Safety outcomes[a]

Outcome[b]	Treatment group	
	FB (n = 214)	DS (n = 196)
Vaginal bleeding[c]	2 (0.9)	6 (3.1)
Cervical laceration[c]	1 (0.5)	2 (1)
Rupture of membranes[c]	2 (0.9)	1 (0.9)
Tachysystole[c]	0 (0)	0 (0)
Nonreassuring fetal status[c]	3 (1.4)	1 (0.5)
5 minute Apgar score <7	1 (0.5)	1 (0.5)
Cord arterial pH <7.1	3 (1.9)	3 (1.2)
High level of neonatal care[d]	15 (7)	11 (5.6)
Maternal infectious comorbidity[e]	28 (13.1)	28 (14.3)

Data are represented as n (percentage), median [range], or mean ± SD.

DS, Dilapan-S; *FB*, Foley balloon.

[a] Safety population: set of all study subjects who used either DS or FB. If both treatments were used in the study for a subject, the randomized study treatment was used. No retraction, fragmentation, or entrapment occurred in either device; [b] No statistical difference was found between groups ($P > .05$; χ^2); [c] During cervical ripening interval; [d] Admission to higher level than normal neonatal care; [e] Occurring within 2 weeks of delivery. Not attributable to device used.

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Dilapan-S use in early pregnancy cervical ripening is well established, the clinical experience with DS at term is limited.

Prior studies involved the older version of the device, Dilapan, instead of Dilapan-S. Gilson et al[19] compared Dilapan with oxytocin alone for induction of labor. Outcomes studied were change in Bishop score, length of labor, mode of delivery, and maternal and neonatal outcomes. The Dilapan group had a statistically significant increase in Bishop score after treatment. There were no differences in the overall length of labor or the cesarean delivery rate.

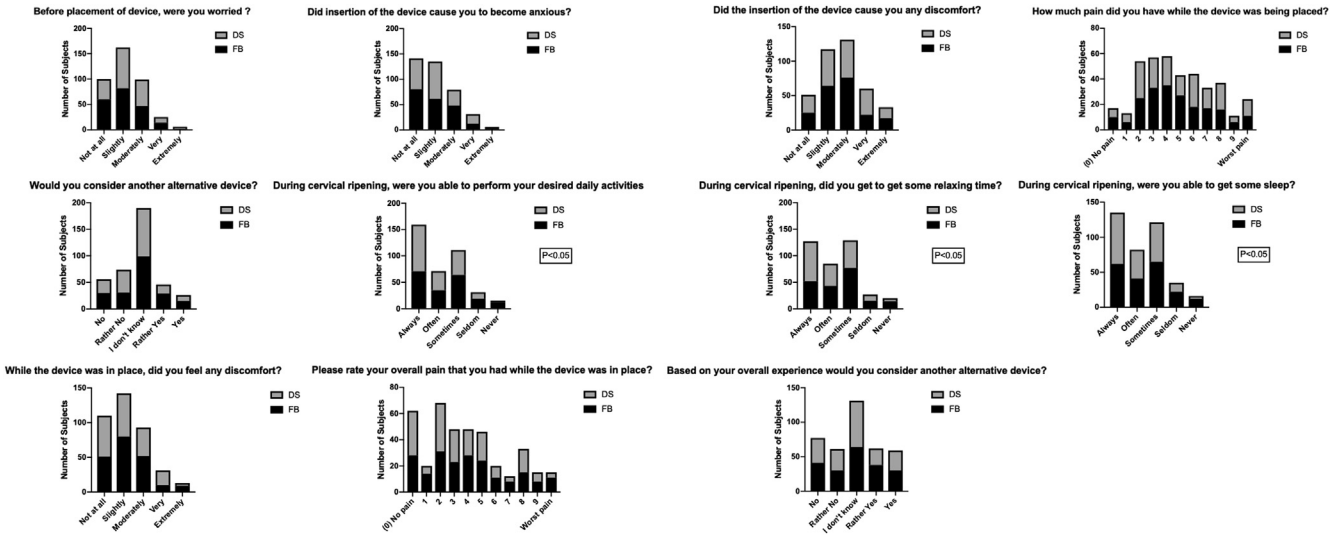
Another trial by Blumenthal and Ramanauskas[20] compared Dilapan with laminaria for preinduction cervical ripening and found a shorter induction-to-delivery interval with Dilapan but no statistically significant differences in cesarean delivery rates between the 2 groups.

Strengths and weaknesses

The strengths of our study include a large sample size, prespecified outcomes and analyses, and management of labor induction that is consistent within a single institution.

Our study also has some limitations. Given the nature of the intervention, masking was not an option. We believe the impact of this potential bias is minimal because the outcomes were prespecified and were not subject to subjective interpretation (eg, route of delivery). In addition, the patients were managed independently from the investigators. Finally, the data set and the decisions regarding the ITT and PP populations were locked prior to the analysis, which was performed by an

FIGURE 3
Satisfaction survey results



The survey was completed by the patient immediately after mechanical dilator placement and after device extraction. The analysis was performed using a Cochran-Armitage test for trend method. $P < .05$ was considered significant.

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independent biostatistician who was blinded to the group assignment.

Given that designation of the comparator and the noninferior groups is required for a noninferiority analysis, the independent biostatistician performed the analysis both ways and the applicable analysis revealed after completion.

Another limitation is that a study in a single center may have lower variability in management and therefore may be less generalizable to other centers. However, determining whether the results of a trial are applicable to other patient populations is not unique to ours.

Conclusion with future research implications

In summary, we present level 1 evidence that Dilapan-S is not inferior to the Foley for preinduction cervical ripening at term. While both Dilapan-S and Foley had minimal adverse events, the advantages of Dilapan-S over Foley include FDA approval, no protrusion from the introitus, no need to keep under tension, and improved patient satisfaction.

As for the cost in our hospital, Dilapan-S is cheaper than the only other FDA-approved mechanical dilator. Depending on the number of rods inserted, Dilapan-S may be the same or slightly more expensive than the Foley.

Given the anticipated rise in induction of labor at term following the ARRIVE trial results, these advantages may prove useful if outpatient cervical ripening becomes an option. This option may provide a solution to the strain on the clinical infrastructure that is anticipated following the ARRIVE trial publication. Clinical studies evaluating Dilapan-S in the outpatient vs inpatient settings would be needed to determine the risk and benefits of such an approach. ■

Acknowledgment

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SUPPLEMENTAL FIGURE

Survey consisted of 11 questions scored on a 5-point Likert scale

After Insertion of Device for Cervical Ripening:

1. Before placement of the cervical ripening device, were you worried about the insertion procedure itself?
   0. Not at all 1. Slightly 2. Moderately 3. Very 4. Extremely
2. Did insertion of the device cause you to become anxious?
   0. Not at all 1. Slightly 2. Moderately 3. Very 4. Extremely
3. Did the insertion of the device cause you any discomfort?
   0. Not at all 1. Slightly 2. Moderately 3. Very 4. Extremely
4. How much pain did you have while the device was being placed in the cervix?
   VAS score 1-10.
5. Based on your overall experience from device insertion, would you consider another alternative mechanical cervical dilator?
   0. No 1 Rather No. 2 I don't know 3 Rather yes 4 yes

After Extraction of Device for Cervical Ripening (before hospital discharge):

6. While the device was in place, did you feel any discomfort?
   0. Not at all 1. Slightly 2. Moderately 3. Very 4. Extremely
7. Throughout the period that the device was inside your cervix, were you able to perform your desired daily activities such as walking, dressing, hygiene, shower?
   0. Always 1. Often 2. Sometimes 3. Seldom 4. Never
8. During the time the device was in place, were you able to get some relaxing time?
   0. Always 1. Often 2. Sometimes 3. Seldom 4. Never
9. During the time the device was in place, were you able to get some sleeping time?
   0. Always 1. Often 2. Sometimes 3. Seldom 4. Never
10. Please rate your overall pain that you had while the device was in place.
    VAS score 1-10.
11. Based on your overall experience of pre-induction cervical ripening, would you consider another alternative mechanical cervical dilator?
    0. No 1 Rather No. 2 I don't know 3 Rather yes 4 yes

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