Study Protocol and Statistical Analysis Plan

Title: Cook Balloon vs Dilapan-S for Outpatient Cervical Ripening

NCT05062343

Document date 10/24/2022

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator: Sarah Little, MD MPH

Project Title: A Randomized Controlled Trial Comparing Cook Balloon and Dilapan-S for Outpatient Cervical Ripening

Version Date: 10/24/2022

For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.

1. Background and Significance

In August 2018, the ARRIVE trial was published in the New England Journal of Medicine. This large, multicenter, randomized, controlled trial showed that elective induction of labor (IOL) at 39 weeks' gestation reduced the c-section rate, when compared to expectant management (awaiting labor until 41 weeks or other medical indication for induction arose) with a decrease in hypertensive disorders of pregnancy and no increase in neonatal or maternal morbidity or mortality[1]. Since then, demand for elective IOL has been increasing nationwide[2]; however, while IOL was shown to have many positive benefits, it does lead to longer admission on labor and delivery when compared to spontaneous labor, and many labor and delivery units do not have the physical resources (rooms, nurses) to accommodate this surge in induction[2-3].

Given this strain on resources, research has turned to identifying safe, effective outpatient methods for the initial steps of IOL, termed "cervical ripening"[3-5]. Cervical ripening prepares the cervix for induction of labor with Pitocin, a synthetic oxytocin. Pitocin is most effective after the cervix has already started to dilate and thin out, or efface, as Pitocin receptors are upregulated during this "ripening" phase.

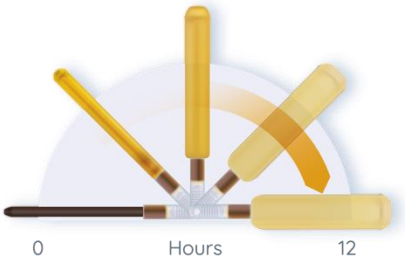
Both the Cook Balloon (Figure 1), a dual balloon mechanical cervical dilator, and Dilapan-S (Figure 2), a synthetic osmotic cervical dilator, are FDA approved for cervical ripening. Both have been shown to be effective inpatient agents of cervical ripening[6]. Most outpatient cervical ripening to date has been studied in mechanical balloon devices, either Foley catheter or Cook balloon [4-5]. Dilapan-S has been more commonly used for outpatient cervical dilation prior to dilation and evacuation or other gynecologic procedures[7] and patients and providers are less familiar with it for pre-induction of labor cervical ripening. Both the Cook catheter and Dilapan-S are already approved agents of outpatient cervical ripening at Brigham and Women's Hospital. This study will be the first to compare Dilapan-S and the Cook catheter directly in the outpatient setting. Currently, the choice of outpatient ripening agent (mechanical ripening with a Cook balloon or Dilapan-S or pharmacologic ripening with misoprostol) is at the provider's discretion at Brigham and Women's Hospital. Our study will help providers and patients make informed choice about the optimal mechanical ripening agent in the outpatient setting.

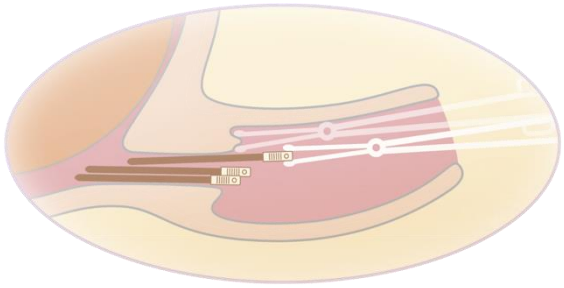
Figure 1. Cook Balloon for cervical ripening. A. Catheter with both uterine and vaginal Balloon Inflated. B. Cook Balloon in place with uterine balloon and vaginal balloon inflated and "ripening" the cervix.

A. 

B. 

Figure 2. Dilapan-S. A. Demonstration of the increase in diameter Dilapan-S undergoes due to osmotic dilation. B. Dilapan-S in place in the cervix.

A. 

B. 

2. Specific Aims and Objectives

Specific Aim 1: To determine if Dilapan-S is not inferior to Cook balloon for outpatient cervical ripening. ***We hypothesize that Dilapan-S is non-inferior to Cook balloon for cervical ripening, as measured by change of Bishop score.***

Specific Aim 2: To determine with which method of outpatient cervical ripening patients are more satisfied. ***We hypothesize that patients will be more satisfied with their experience with Dilapan-S when compared to the Cook Catheter.***

3. General Description of Study Design

This study will be a randomized controlled trial with 1:1 randomization.

Clinic visit for term (37-41 6/7 week) pregnant patients 18-50 years old with decision by primary obstetrics provider for induction of labor and patient is deemed candidate for outpatient cervical ripening per BWH Cervical Ripening Protocol by their primary obstetrics provider

- Inclusion:
  - Vertex presentation
  - Induction of labor indicated for maternal or neonatal reasons
- Exclusion
  - Prior cesarean section
  - Non-English-speaking participants
  - No need for cervical ripening (Bishop score >6, >2cm dilated)

Patient is scheduled for outpatient cervical ripening per BWH protocol. Her outpatient obstetrical provider informs her of the study. Study staff will attempt to contact patient once appointment is made and discusses study with patient and answer any questions she may have. If patient is unable to be contacted they will still be approached for the study when they arrive for outpatient cervical ripening after study has been introduced by a clinician/provider at their visit.

At time of her cervical ripening appointment on CWN 3, CWN 5 labor and delivery, or at 850 Boylston street if patient remains interested, she is consented by physician investigators. Questions answered.

RANDOMIZATION: 1:1 Cook catheter Vs Dilapan-S per outpatient protocol.

Cervical ripening with either agent per randomization.

If unable to place cervical ripening device, further cervical ripening per provider preference by one of options already approved per BWH outpatient cervical ripening protocol

Return to L&D within 24hrs of device placement (return visit will be scheduled through hospital EMR as is current BWH outpatient cervical ripening protocol) or earlier with any concerning symptoms (vaginal bleeding, fever, rupture of membranes, labor, decreased fetal movement, etc), as detailed in existing BWH outpatient cervical ripening protocol

When returned to L&D, device removed or confirmed expelled. Sterile vaginal exam performed by blinded examiner (3rd year, chief resident, or further in training- i.e. Fellow or Attending), blinded to study arm.

Paper patient satisfaction survey to be given to patient at this time by study staff for written completion by subject

Further induction of labor per primary labor and delivery team.

4. Subject Selection

Our study population will include women 18-50 years of age at term (37-41 6/7 weeks gestational age) who are low risk (i.e. without any maternal or fetal co-morbidity) and with a singleton gestation in cephalic presentation who are candidates for outpatient cervical ripening per the Brigham and Women's outpatient cervical ripening protocol (Appendix A). Both nulliparous and multiparous women will be included. Women will need to have a bishop score <6 or cervical dilation <2cm with intact membranes to be included, as these are the women currently being offered outpatient cervical ripening prior to labor induction. Women will be excluded if there is a contraindication to outpatient cervical ripening per Brigham and Women's outpatient cervical ripening protocol (Appendix A) or contraindication to vaginal delivery. Women with history of a prior cesarean section will be excluded given their management may differ after cervical ripening. Non-English-speaking women will also be excluded given lack of study staff ability to communicate in languages other than English and lack of guaranteed 24/7 interpreters. Women who are patients of study investigators will be eligible for enrollment. This vulnerable population will be protected from coercion by giving patients a consent form to review at home prior to actual study enrollment and by encouraging patients to discuss the study with other healthcare professionals.

Women will be recruited from all practices that delivery at the Brigham, including Maternal Fetal Medicine, general Obstetrics clinics, private practice groups, and midwifery groups at Brigham and Women's Hospital. By recruiting from all of the delivering groups at BWH, we should be enrolling a diverse patient population.

5. Subject Enrollment

Women will be booked for outpatient cervical ripening per their primary obstetrics provider. Typically, cervical ripening is scheduled by the primary provider within the week prior. Outpatient ripening is currently performed by a variety of methods (Cook balloon, Dilapan-S and misoprostol) at the primary provider's discretion. The eligibility for each of these methods is the same, thus all patients scheduled for outpatient ripening in current clinical practice are potentially eligible for this study. At the time patients are scheduled, the scheduling provider (nurse or MD) may inform the patient about the study. The scheduling provider will then let the study staff know if patients are interested and if they would like to be contacted for further information or if they are not interested and would prefer not to be further contacted by study stuff. Study staff will attempt to contact interested patients to answer any questions they have about the study. This will not be a pre-screening call as anyone who is scheduled for outpatient cervical ripening is eligible for the study. Study staff will also monitor the outpatient ripening appointments booked through the EPIC schedule. Study staff will contact patients who are scheduled for outpatient cervical ripening appointments within 48 hours of their appointment via telephone to discuss the study and answer any questions and assess interest. If the patient is unable to be contacted, a clinician/provider at their cervical ripening visit will introduce the study to the patient and if they agree to be approached, study staff will then approach them for possible enrollment. Once the patient arrives for their scheduled outpatient cervical ripening appointment on CWN3, CWN5 Labor and Delivery triage, or 850 Boylston study staff will review the study, answer any questions and informed consent will be obtained. If the patient had not heard about the study previously, a provider/clinician will introduce the study to the patient when patient arrives and ask if study staff can approach them. If the patient agrees,

study staff will then discuss the study in more detail, answer any questions, then will step away while NST is being performed (20-30 minutes) to allow for contemplation then will re-approach the subject to confirm if they are or are not interested in the study after NST is complete. After it is confirmed that the patient is still candidate for outpatient cervical ripening per standard practice at Brigham and Women's, which requires the non-stress test fetal heart tracing to be reactive, an exam to confirm the cervix needs ripening (Bishop score < 6 and cervix < 2cm dilated) and an ultrasound to confirm cephalic presentation, they will be randomized to either Dilapan-S or Cook balloon in a 1:1 ratio.

At the time of enrollment, patients will be assured that they will receive standard of care treatments whether or not they are in the study and enrollment will not affect their care.

Only adults will be included in the study. Study will be limited to English speaking patients as enrollment may happen day or night and on weekends (given outpatient cervical ripening schedule on labor and delivery) when interpreters may not be available. No surrogate decision makers will be allowed to consent for patients.

A random number generator will be used to randomize women in blocks of 6 with stratification based on parity (patients who have had a vaginal delivery before or not).

As randomization will occur after sterile vaginal exam, the examiner obtaining the initial exam will be blinded to which arm of the study the patient will be in as the exam will be recorded prior to randomization. The patient will not be blinded as the devices are different in placement and post-placement.

6. STUDY PROCEDURES

Upon presentation for cervical ripening, a non-stress test will be performed per BWH outpatient ripening protocol. Then a sterile vaginal exam will be completed to assign Bishop score, as per standard routine. A bedside ultrasound will be completed to confirm fetus is still in the vertex presentation. The patient will then be consented if they have a reactive non-stress test, a Bishop score <6 and cervical exam <3cm dilated with confirmed vertex fetus. Once the patient has been consented and randomized, the participant will have a Cook catheter or Dilapan-S by direct visualization with a speculum, For the Cook catheter, the uterine component of the balloon will be inflated to maximum 60mL, the vaginal balloon will not be inflated per standard practice at BWH and per the literature that shows slightly increased pain and negligible improvement in cervical ripening. The catheter will be taped to the inner thigh with gentle traction. For Dilapan-S, 3-5 dilators will be placed per BWH protocol.

After placement, the patient will be discharged home with strict return precautions per the BWH outpatient cervical ripening protocol. With written instructions of who to call/page, with phone number listed, list of concerns that should prompt calling / return to hospital: Fever > 100.4 Fahrenheit, labor, rupture of membranes, reduced fetal movement vaginal bleeding, what to do if the balloon/rods fall out, exact time and place to return. Patients must return to labor and delivery within 24 hours of cervical ripening agent placement at their scheduled inpatient induction time.

Upon return to labor and delivery, if not already expelled, the mechanical ripening device will be removed, and an examiner ***blinded to the cervical ripening method*** will complete a sterile vaginal exam to assign a Bishop score.

The patient satisfaction survey will be completed by the patient at this time in paper form and collected by study staff.

At that point health care providers will manage active labor per usual practice. Labor interventions are at the discretion of the healthcare provider. The need for operative delivery or cesarean section will be at the discretion of the healthcare provider.

Secondary outcome information will be obtained from the Epic record including delivery, maternal and neonatal outcomes as defined in the statistical analysis below.

If the patient satisfaction survey is not completed during the delivery admission, it may be collected anytime the patient returns to the hospital for routine prenatal care until the 6 week postpartum visit.

7. Risks and Discomforts

Women may experience discomfort with either Cook catheter or Dilapan-S insertion, though there is no increased risk from the standard BWH outpatient cervical ripening protocol.

Because both the Cook catheter and Dilapan-S are both routinely used for outpatient cervical ripening, we think that there is minimal increased risk from the study versus routine standard of care for outpatient cervical ripening.

8. Benefits

There is no direct benefit to individuals. There are however many benefits for the healthcare system in the future. By determining that Dilapan-S is noninferior to Cook catheter for outpatient cervical ripening we will be increasing provider awareness of an effective method of cervical ripening. Healthcare cost would benefit from the information gained in this study by potentially increasing outpatient cervical ripening which could decrease hospital stays. Currently, the most effective method of inducing labor remains unknown.

9. Statistical Analysis

The main outcome will be change in Bishop score. We will collect any information about outcomes regarding maternal or neonatal morbidity until four weeks from delivery. The patient satisfaction survey may be administered until the 6-week postpartum visit. Once these items are collected, patient participation will end.

Bishop score is defined by 5 components (Figure 3) all assessed during a sterile vaginal exam. These individual scores are then combined into a single score (0-13) to determine the Bishop score. Our

outcome of interest is change in Bishop score to be calculated as Bishop score after cervical ripening minus Bishop score prior to cervical ripening.

Figure 3. Bishop score. Final score is a sum of the 5 individual scores.

Score	Dilation (cm)	Position of Cervix	Effacement (%)	Station (-3 to +3)	Cervical Consistency
0	Closed	Posterior	0-30	-3	Firm
1	1-2	Mid-position	40-50	-2	Medium
2	3-4	Anterior	60-70	-1,0	Soft
3	5-6	--	80-100	+1 to +3	--

Secondary maternal outcomes will be measured including patient satisfaction with cervical ripening method via a survey administered after return to labor and delivery (Appendix B), cesarean delivery rate, time from admission on labor and delivery to delivery, maternal length of stay, and indication for cesarean delivery. We will also calculate a composite cervical ripening success score. Success will be defined by a lack of any of the following: failure of placement of cervical ripening agent, unscheduled return to medical care, rupture of membranes, vaginal bleeding, or need for further cervical ripening after the initial agent is removed. We will also calculate a composite maternal morbidity outcome. Morbidity will be defined by any of the following: higher-order laceration, blood transfusion, endometritis, wound infection, venous thromboembolism, hysterectomy, ICU admission or death. These outcomes will also be stratified by parity. We will also evaluate rates of regional analgesia use in both groups.

A composite neonatal morbidity will be calculated including any one of the following: culture-proven neonatal sepsis, neonatal blood transfusion, hypoxic-ischemic encephalopathy, intraventricular hemorrhage grade 3 or 4, or therapeutic hypothermia. We will also analyze NICU admission, NICU admission for greater than 48 hours, and neonatal length of stay.

This study design is a non-inferiority randomized control trial with 1:1 randomization comparing Dilapan-S to Cook Catheter with the primary outcome of change in Bishop score. We have defined a non-inferiority margin of 2 with a standard deviation of 3 consistent with prior literature. A Type I α error of 0.05 was selected. Assuming 80% power and a two-sided P value we would need 39 patients in each arm for a total of 78 patients; however, prior studies[6] reported a 10% failure of placement rate (due to patient intolerance of exam or provider failure) to account for this and the small risk of loss to follow-up, we will increase the sample size by 15% and will include 45 participants in each group for a total of 90 participants.

For statistical purposes, intent to treat analysis will be performed. Non-parametric measures will be used for statistical analysis. These models will also be adjusted for parity.

10. Monitoring and Quality Assurance

The principal investigator will review the entries for each participant to ensure they are complete. We will not perform any interim analysis, as we feel there is minimal risk from the study protocol and would not stop the study early. When adverse events occur, they will be reported to the Partners' IRB within 5 days with a detailed description of the event as described in the guidelines for

adverse events reporting. Serious adverse events (severe hemorrhage, maternal death, neonatal death, neonatal hypoxemic encephalopathy) will be reviewed by the head of labor and delivery and the study staff to ensure the outcome is not related to the study protocol.

11. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)- **No specimens collected**
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☐ All electronic communication with participants will comply with Mass General Brigham secure communication policies**- No electronic communication will occur**
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☐ Additional privacy and/or confidentiality protections

12. References

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APPENDIX A: Brigham and Women's Outpatient Cervical Ripening Protocol

Medical Staff Note...

OBSTETRICS AND GYNECOLOGY
BRIGHAM AND WOMEN'S HOSPITAL

DATE: **12/21/2020** **Updated June 17, 2021** **# 2313**

TO: Medical Staff
FROM: Rebecca Reimers, Sarah Little, Sarah Lassey, Barbara Stabile, Nora Scharf, Wendy Moan, Yael Hoffman-Sage, Louise Wilkins-Haug
RE: **Office-Based Ambulatory Cervical Ripening Protocols**

Updates June 17, 2021

GBS positivity is no longer an exclusion for office-based ambulatory cervical ripening using a mechanical method of cervical ripening, including Foley or Cook balloons, Dilapan or laminaria cervical dilators.

Mild polyhydramnios is not an exclusion for office-based ambulatory cervical ripening.

Well-controlled GDM, with or without medications, is not an exclusion for ambulatory office-based cervical ripening.

Background: As noted in a recent Medical Staff note from Dr. Robinson (**Cervical Ripening and Induction of Labor in Nulliparous Patients before Forty Weeks' Gestational Age, #2304)** clinical practice

is evolving to increase the use of office-based ambulatory cervical ripening as the **initial step** for induction of labor in low-risk women from 39 weeks and 0 days gestation through 39 weeks and 6 days gestation. **One day of office-based ambulatory cervical ripening is an important part of a multi-step process that is followed by additional ambulatory (CWN5 Triage) or inpatient cervical ripening, if needed, and oxytocin induction of labor.**

At BWH we have years of experience with office-based ambulatory cervical ripening using oral misoprostol. Office-based ambulatory mechanical cervical ripening with a balloon catheter (Foley or Cook catheters) or Dilapan (hygroscopic cervical dilator) are also effective and safe methods (Alfirevic 2020, Dong 2020, Yang 2018, Saade 2019). Mechanical methods are particularly suitable for the office-based ambulatory setting as they are not generally associated with an increased risk of tachysystole.

The choice of office-based ambulatory cervical ripening agent is at the provider's discretion. However, we encourage the following:

(1) First line: Balloon cervical ripening (30 cc Foley or Cook balloon)
(2) Second line: Dilapan-hygroscopic cervical dilator
(3) Third line: Oral misoprostol

At this time, we are not endorsing the use of dual agents in the office-based ambulatory setting (e.g. balloon or Dilapan plus misoprostol).

Exclusions (all office-based ambulatory methods of cervical ripening):

Fetal conditions:
Contraindication to vaginal delivery (non-vertex presentation, complete placenta previa, etc.)
IUGR: Growth < 5th percentile
Abnormal umbilical artery dopplers
Oligohydramnios or polyhydramnios (mild polyhydramnios is not an exclusion to ambulatory office-based cervical ripening)
Multiple gestation
Major fetal anomalies
Induction for the indication of non-reassuring fetal assessment
Any history of decreased fetal movement
Any history of non-reassuring fetal assessment

Maternal conditions:
Prior Caesarean delivery or uterine surgery involving removal of a full thickness of uterine tissue
Clinically significant vaginal bleeding.
Type1 or Type 2 diabetes mellitus. (Well-controlled GDM with or without medication is not a contraindication to ambulatory office-based cervical ripening.)
Significant hypertension: preeclampsia, or taking antihypertensive medications instituted or recently up-titrated in this pregnancy to control blood pressure.
A patient who is unable to understand instructions or return easily should symptoms arise

Exclusion specific to mechanical methods (Foley/Cook/Dilapan):
GBS positivity is no longer an exclusion to office-based ambulatory cervical ripening using a mechanical method of cervical ripening, including Foley or Cook balloons, Dilapan or laminaria cervical dilators.

Protocol: Overall, office-based ambulatory cervical ripening by any method should be followed by additional CWN5 triage cervical ripening, if needed, or by inpatient induction of labor if the cervix is favorable within 6 to 24 hours.

Important guidance: An inpatient induction of labor slot should be booked for 6 to 24 hours following the initiation of office-based ambulatory cervical ripening.

Prior to ripening (all methods):

1) Confirm eligibility. Review exclusion criteria above.

2) **Confirm that an inpatient induction slot is booked at 6 to 24 hours following the initiation of office-based ambulatory cervical ripening.**

3) Confirm that clinical testing such as NST or BPP is performed within the appropriate time frame (i.e. if weekly fetal testing is indicated, this should be performed within the week prior to the induction or if an ultrasound estimate of fetal weight is indicated this should be performed within 2 weeks of the induction).

4) Confirm cephalic presentation and normal fluid volume. This can be done via formal or bedside ultrasound. If a formal ultrasound is performed within the week but not on the day of induction, cephalic presentation should be confirmed by physical exam or bedside ultrasound.

Prior to ripening (misoprostol only):

1) NST must be performed and must be reactive without excessive uterine activity (no more than 2 contractions in 10 minutes).

Foley Balloon Placement:

1) This can be placed in any setting, though ideally in the office-based ambulatory setting in the afternoon.

2) Either a 30 cc Foley (inflated up to 35 cc) or a Cook catheter can be used.

3) Balloons can be placed digitally or with a speculum (at provider discretion). If a speculum is used, the cervix should be cleansed with betadine prior to placement.

4) Only 2 attempts at a balloon should be performed. If placement fails after 2 attempts, the provider can place Dilapan instead or abandon office-based ambulatory mechanical ripening.

5) After placement, the Foley catheter tail can be taped to the thigh, tucked into the vagina or tied off and trimmed.

6) No monitoring is needed after placement.

7) If the Foley catheter falls out before the scheduled inpatient appointment, the patient should be instructed to throw out the Foley catheter. She can stay home until her scheduled appointment (unless labor, rupture of membranes or other concerns require an office or hospital visit).

Dilapan Placement:

1) Cervix is visualized with a speculum and cleansed with betadine.

2) Dilapan rods are placed using a ring forceps. Ideally 3-5 rods should be placed. No more than 5 rods should be used. Rods can be moistened with saline or sterile water to aid in placement.

3) A moistened gauze can be placed in the vagina to help keep the Dilapan in place if desired (though not necessary).

4) The number of Dilapan and gauzes left in the patient should be clearly documented in the EPIC record.
5) No monitoring is needed after placement.
6) If the Dilapan(s) or sponge(s) fall out before the scheduled inpatient appointment, the patient should be instructed to collect all the rods/sponges in a plastic bag or take a picture of the rods/sponges and throw them away. She can stay home until her scheduled appointment (unless labor/rupture of membranes or other concerns arise).

Misoprostol Placement:
1) 50 mcg of oral misoprostol is administered
2) Patient is monitored by NST for 1 hour after medication administration.

After Ripening (all methods):
1) Patient must be given clear instructions, ideally in writing, including:
a) A number to call / page overnight if any concerns arise.
b) Concerns that should prompt calling / return to hospital: Fever > 100.4 Fahrenheit, labor, rupture of membranes, reduced fetal movement vaginal bleeding
c) What to do if the balloon/rods fall out (as above)
d) When to return

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Appendix B: Patient Satisfaction Survey

Patients: Please consider your experience with cervical ripening, from when the device was placed until now. The answers to your questions will not affect any aspect of your care.

1. Before placement of the cervical ripening device were you anxious? (Please circle one)
1- Not at all 2- Slightly 3- Moderately 4- Very 5- Extremely

2. Did the insertion of the device cause you any discomfort? (Please circle one)
1- Not at all 2- Slightly 3- Moderately 4- Very 5- Extremely

3. What number would you rate the pain you had while the device was being placed? (scale 0-10, 0= no pain, 10= worse pain imaginable, please circle one number)
0 1 2 3 4 5 6 7 8 9 10

4. Once you went home with cervical ripening device (please circle one for each question):
A) Did you feel any discomfort?
1- Not at all 2- Slight Discomfort 3- Moderate Discomfort 4- Very Uncomfortable 5- Extremely Uncomfortable

B) Were you able to complete your routine daily activities?
1- Not at all 2- Slightly 3- Moderately 4- Very 5- Extremely

C) How able were you to get some sleep?
1- Not at all 2- Slightly 3- Moderately 4- Very 5- Extremely

5. Please rate your overall discomfort during the entire cervical ripening experience (scale 0-10, 0= no pain, 10= worse pain imaginable, please circle one number).

0 1 2 3 4 5 6 7 8 9 10

6. Please rate your overall satisfaction with the entire cervical ripening experience(scale 0-10, 0= completely dissatisfied, 10= completely satisfied, please circle one number).

0 1 2 3 4 5 6 7 8 9 10