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P E R S P E C T I V E S O N

Outpatient Cervical Ripening Across Borders



Panelists

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and specializes in blood, kidney, and immune disorders in pregnancy. He is an expert in cervical cerclage and pessary to prevent premature delivery.

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Disclosures

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INDUCTION OF LABOR IS A common process, occurring in approximately 25% of all term pregnancies.^{1,2} Cervical ripening is often the first component of labor induction in women with an unfavorable cervix, and is used to facilitate the softening and thinning of the cervix.

While cervical ripening was primarily initially confined to the inpatient setting, outpatient cervical ripening has now become the standard of care in many countries. It has, however, been more slowly adopted in the United States. In this supplement, four ob/gyn experts—two in Canada and two in the United States—discuss the reasons for the divergent perspective and offer insight into why outpatient cervical ripening may or may not be appropriate for today's pregnant women. >>



■ Cultural differences in the approach to cervical ripening

Moderator: *How do perspectives on outpatient cervical ripening differ between the United States and Canada?*

Mara Sobel, BScH, MSc, MD, FRCSC: At both Mount Sinai Hospital and St. Michael's Hospital in Toronto Canada, the default is outpatient cervical ripening.

Eliane Shore, MD, MSc, FRCSC: Based upon our experiences at other hospitals within Ontario, I think it's fair to assume that most Canadian sites are using a combination of outpatient and inpatient cervical ripening.

Richard M. Burwick, MD: Certainly, outpatient cervical ripening is not as common in the United States as it is in Canada. Over the years, I've worked at a number of hospitals that did not offer outpatient cervical ripening to patients.

Moderator: *Why is outpatient cervical ripening looked upon more favorably in Canada than in the United States?*

Dr. Burwick: There are a variety of reasons. Some physicians

are worried about medical and legal issues that may be involved, but I think a lot of it simply has to do with changing our mindset. Many hospitals have historically only offered inpatient induction, so convincing both physicians and patients that outpatient induction is a safe and reasonable option is challenging. Raising awareness has been the first step for us at Cedars-Sinai as we've worked on adopting an outpatient induction protocol.

Rodney K. Edwards, MD: There are a lot of physicians in the United States who are not yet convinced that the advantages of outpatient cervical ripening are proven, and when there is an absence of such evidence, people are going to be slow to change their practice. I would also agree that the medicolegal climate in the United States plays a role. In a setting where there is even a tiny likelihood of increased risk of complication with an unproven clinical benefit, the risk tolerance is very low.

■ Choosing the right patient

Moderator: *How do you determine when a patient is a suitable candidate for outpatient cervical ripening?*

Dr. Shore: At St. Michael's, we schedule three inductions a day, but it's not divided into inpatient or outpatient slots. Generally, the decision about keeping the patient in the hospital versus sending them home is up to the most responsible physician on that day. When the patient first arrives, they have a nonstress test (NST). We assess them, check their history, the fetal indication, maternal indications, and do a bimanual examination to determine the Bishop score. We then either determine what method of cervical ripening we are going to use (ie, progesterone gel, dinoprostone, Foley catheter) or, if their cervix is already ripe, admit the patient for artificial rupture of membranes and oxytocin as needed. For those patients who do qualify for cervical ripening, generally they are discharged home unless there is a maternal or fetal indication for admission. We also take into account the distance the patient has to travel to and from our hospital as well as social circumstances that may affect outpatient induction (eg, patients who are underhoused).

Dr. Edwards: Our group at the University of Oklahoma doesn't generally support outpatient cervical ripening and certainly would not advocate an outpatient induction. There is an important difference between those two that I would like to highlight.

There are some people who advocate the administration of a dose of misoprostol as an outpatient procedure and consider it a procedure to "avoid" a labor induction. In my mind, however, misoprostol is both an induction and cervical

ripening agent. If one is considering outpatient cervical ripening, I think that it would be preferable to choose an agent that will change the cervix but won't necessarily induce labor. Although our hospital does not prohibit outpatient cervical ripening, it's not something our physicians perform in a widespread fashion.

Moderator: *Do any of you have a formal protocol in place at your institution for outpatient induction?*

Dr. Burwick: I helped write our facility's outpatient induction protocol with the Foley catheter. It's been in place for less than 2 years. Because we didn't previously have the option for outpatient induction, we started conservatively, developing a protocol for low-risk women, between 39 and 41 6/7 weeks' gestation, with singleton pregnancies. Eligible women are those opting for an elective induction of labor. We are not yet permitting outpatient inductions for medical indications, such as hypertension or fetal growth restriction.

Dr. Sobel: At our institution, most patients are selected for outpatient induction unless there is an indication that the patient will require maternal or fetal surveillance throughout the process. As long as maternal and fetal well-being are reassuring, the patient will receive outpatient cervical ripening. Patients with maternal or fetal concerns, or those whose cervix is already favorable, are designated for an inpatient induction spot.

Moderator: *How do you define a "favorable cervix"?*

Dr. Sobel: We primarily look at the Bishop score, with a score

greater than 6 as favorable. A cervix with a Bishop score of >6 is typically amenable to artificial rupture of membranes.

Moderator: What is the benefit of outpatient cervical ripening?

Dr. Shore: The typical induction process is lengthy, so as long as patients are located close enough to the hospital that it's easy for them to get back to us in a short amount of time, we find they are more comfortable in the early stages

of induction at their own home. They know they can come back in at any time. They don't need to wait for us to tell them it is time to return. We make sure they are reassured when we send them home that if anything comes up, they can call and speak to one of the nurses on labor and delivery or they can just come in. I think knowing that they are not abandoned at home makes outpatient induction an acceptable option for patients.

■ Outpatient cervical ripening: efficacy and safety

Moderator: What does the current medical literature say about the general efficacy of outpatient cervical ripening?

Dr. Shore: In 2013, a Cochrane review was published looking at the efficacy and safety of the three most common methods used for cervical ripening: prostaglandin gel, dinoprostone, and Foley balloon catheter. It compared results in the inpatient versus outpatient setting. The authors found equivalent results regardless of the induction method. They did, however, note that there were limited data in the outpatient setting and that it was not yet possible to determine whether induction of labor was safe and effective in the outpatient setting.³

One important feature was noted in the OPRA study, a 2015 trial comparing inpatient versus outpatient results following the use of prostaglandin E2 gel. That trial attempted to randomize patients to one of the two groups, but several of the patients randomized to the outpatient group either couldn't proceed as outpatients due to maternal or fetal concerns or simply because they didn't want to go home.⁴ That speaks to the importance of setting up appropriate expectations prior to the initial induction visit, so patients know what to expect.

Dr. Edwards: I would classify the data surrounding outpatient cervical ripening as mixed. I was a coauthor of a recent paper that looked at whether outpatient cervical ripening with a transcervical Foley catheter in parous women undergoing elective induction of labor shortens the total duration of time from admission to the labor ward until delivery. We did not find a significant difference.⁵ There have been other papers, however, that did show a time benefit.⁶ So from my perspective, mixed results.

I'm certainly more conservative about this topic than other members of this panel, and maybe that is because I'm the only one here with gray hair, but I don't think we are ready to roll out outpatient induction at my center based on the current evidence. That said, there certainly are opportunities to investigate methods of care in terms of resource utilization. For example, what if we started evaluating beginning labor inductions that required cervical ripening in hospital units other than labor and delivery, since resources there are often strained? That could be interesting.

Moderator: What about any safety issues related to outpatient cervical ripening?

Dr. Shore: Very few safety concerns have been identified in clinical trials. One 2001 study looked at the use of dinoprostone in a simulated outpatient setting and found that more than 25% of patients required removal of the insert within 12 hours, usually due to regular contractions. The authors concluded that it therefore was not a good idea to send patients home with the dinoprostone insert, but I'm not sure I agree with that conclusion.⁷ The whole point of the procedure is to induce labor. It didn't sound like the insert was removed for any concerning features, only because the women in the study were uncomfortable. I would not consider that a safety concern.

The OPRA study did note one adverse event about which the ob/gyn community should be mindful. In that study, one patient treated with prostaglandin gel had a baby with an undiagnosed growth restriction that necessitated delivery in a compromised state. The trial was actually temporarily halted while that case was reviewed, and eligibility criteria were tightened to exclude women from the outpatient induction group who had a baby with gestational age <10th percentile in the third trimester.⁴ But that was the only notable adverse event in the entire trial of 827 women.

Dr. Sobel: The general theme in most papers about this topic that I have read is that outpatient cervical ripening is safe in the appropriately selected patient.

Moderator: What questions or concerns do patients raise when you are talking to them about outpatient induction?

Dr. Sobel: We spend a lot of time explaining what our outpatient induction process will look like. Our outpatient induction slots are scheduled between 4:30 and 5:30 pm, and we send patients home overnight after an assessment of maternal/fetal well-being as long as there are no contraindications to doing so. It's important to explain to patients that they might experience some uterine cramping and that, in the case of a Foley catheter, it might fall out.

Patients are given careful instructions on when to come back. If they are having painful contractions or their water

breaks, they should return to the hospital. We have a nurse-staffed phone line 24 hours a day for patients if they have any questions or concerns.

Dr. Shore: Especially for women in their second or third pregnancy who have kids at home, not having to be away from them for potentially several days during the labor and

delivery process is also appealing. The biggest pushback I get from patients comes from those who might not have their own method of transportation. For instance, they may not have a car, so they're looking at taxis or public transportation. We do take this into account when deciding about inpatient versus outpatient induction.

■ Current standards of care

Moderator: *In patients that you do send home for outpatient induction, which of the three common cervical ripening methods do you prefer?*

Dr. Sobel: At Mount Sinai, our default approach for inductions is the Foley catheter. It tends to cause less uterine contractions and is economical, which is always a concern in a publicly-funded health care environment. One downside to the Foley catheter is that it can be uncomfortable to insert and, in some cases, the patient won't tolerate it. In these patients, we use prostaglandins in an outpatient setting.

Dr. Shore: Our approach at St. Michael's is similar. The nice thing about Foley catheters and dinoprostone inserts are that they are removable methods. The Foley catheter will fall out. Dinoprostone inserts can be removed by the patient if they are suffering excessive pain or if they start having regular contractions. Another benefit is that neither method requires frequent

reassessment, unlike prostaglandin gel, which requires patients to come back every 6 hours for reassessment.

Dr. Burwick: We have not yet started offering prostaglandins as part of our outpatient induction protocol and solely rely on Foley catheters, although prostaglandins do seem like a reasonable option. I did work at one center that offered misoprostol as part of an outpatient induction protocol, and I found it to be safe and effective in low-risk pregnancies.

In the past few years, I have seen a big change in our mindset regarding elective inductions at 39 weeks. Traditionally, the mindset was to avoid elective inductions in nulliparous women with an unfavorable cervix, but that's beginning to change. As our inpatient labor floors are becoming fuller, there has been increased attention to outpatient induction protocols.

■ Impact of the ARRIVE trial

Moderator: *In 2018, the ARRIVE trial was published showing that induction of low-risk, nulliparous women at 39 weeks was linked to a lower rate of cesarean section compared to those assigned to expectant management and a reduced chance of developing pregnancy-induced high blood pressure.⁸ What effect, if any, have the results of that trial had on your practice?*

Dr. Edwards: To me, the ARRIVE trial results gave us a clear indication that induction of low-risk, nulliparous women is a viable option. However, we have not seen as brisk a rise in elective inductions in the last 2 years as I might have expected. Some patients simply don't want to deliver at the 39-week stage via induction and want to carry the pregnancy for as long as necessary until spontaneous labor.

Dr. Burwick: We've noticed a big change at our hospital. Prior to the ARRIVE trial, we did not routinely offer elective induction in nulliparous women with an unfavorable cervix due to a variety of factors, including unclear benefit and a high demand for medically indicated induction of labor. We have a large unit with 20 active labor rooms and 7 induction slots per day, but most are prioritized for women with a medical indication. That said, we have seen an uptake in 39-week elective inductions based on the results of the

ARRIVE trial, which encouraged us to develop an outpatient option for our patients.

Dr. Shore: We've certainly had a number of women come in with questions about the ARRIVE trial and what it means for them. Unfortunately, it's a matter of resources. We only have three induction slots available each day, so if there are patients with medical indications for an induction such as post-term, preeclampsia, or intrauterine growth restriction, they will trump any woman who asks for an elective induction.

Moderator: *One thing several of you have said is that the current demand for elective induction outstrips the number of available slots in your institutions. Have there been discussions about increasing the number of slots available for induction to accommodate the rising demand?*

Dr. Shore: Not really. The reason why we don't have more spots is because we can't safely accommodate more patients on any given day. We don't have the financial resources to hire more nurses and other staff right now. What I suspect will happen is that there will be a shift over time as fewer patients need to be induced post term. We just have not seen that shift yet.

■ Future perspectives

Moderator: *What advice would you give to centers in the United States that are interested in developing an outpatient induction protocol or expanding opportunities for elective inductions? What are some of the pitfalls to avoid?*

Dr. Sobel: Certainly, the adoption of protocols from other centers that have succeeded previously can be helpful. Getting buy-in from the various parties who will be affected—including ob/gyns, nurses, midwives, patients and others—is key. Everyone needs to understand the primary components of the new protocol and be allowed to offer their input.

It can be helpful to start your outpatient induction protocol by only including the healthiest, lowest-risk patients until your team gets comfortable with the process. We initially only included healthy, post-term women as outpatients, but now, as we have gained experience, we're even including women with stable high blood pressure or other medical concerns as outpatients if they have reassuring findings in the pre-induction assessment.

Dr. Burwick: I agree that staff buy-in is key. We have numerous provider groups that deliver at Cedars Sinai, and thus we tried to reach out to stakeholders from all groups as we developed our protocol.

The hardest part comes during actual rollout of the new protocol and seeing, “OK, we’ve talked about this and put the protocol down on paper, but when push comes to shove, will people be willing to recommend it to their patients?” We’re currently tracking and analyzing our post-implementation data to see how we are doing.

It’s also important to allow providers some flexibility within the boundaries of the protocol. For example, we have some providers who prefer to place the Foley catheter in the office as opposed to in the labor-and-delivery triage setting within the hospital. We also noticed that providers had different preferences specific to the Foley catheter. In our initial protocol, we called for a 16-French Foley catheter, but we learned that there were many providers in the hospital setting who used a 22 or 24 French. You need to allow for some flexibility so that your protocol works for the entire team.

Moderator: *This has been a terrific discussion. We want to thank you all for your insights. I hope that our audience can take away some helpful information from our discussion to inform their practice’s approach to outpatient cervical ripening and induction of labor.* ■

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