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OB/GYN Clinical [ALERT]

Evidence-based commentaries on women's reproductive health

ABSTRACT & COMMENTARY

Prenatal Care Visits During COVID-19

By Rebecca H. Allen, MD, MPH, Editor

SYNOPSIS: In this nested case-control study in the Boston area, there was no association between testing positive for COVID-19 during pregnancy or on admission to labor and delivery and the number of in-person prenatal care visits.

SOURCE: Reale SC, Fields KG, Lumbreras-Marquez MI, et al. Association between number of in-person health care visits and SARS-CoV-2 infection in obstetrical patients. *JAMA* 2020; Aug. 14. doi: 10.1001/jama.2020.15242. [Online ahead of print].

When the COVID-19 pandemic began in the United States, there was little evidence to guide prenatal care providers on how to continue to provide necessary obstetric care. Some providers opted to space out prenatal care visits and use telehealth; some did not. A concern that resulted during and after the quarantine was that patients did not seek and are still not seeking necessary medical attention because of fear of contracting COVID-19 in outpatient offices, emergency departments, and hospitals. The authors of this study wanted to examine the association between office visits and the risk of SARS-CoV-2 infection in the obstetric population, since this is a group of patients who require frequent visits.

The study population included all women delivering at four hospitals in Boston between April 19 and June 27, 2020. During this time period, all obstetrical patients were tested for COVID-19 using nasopharyngeal swabs on admission to labor and delivery. Cases were patients who tested positive during this time period either during pregnancy or on admission to labor and delivery. Cases were matched with up to five control patients on gestational age, race/ethnicity, insurance type, and SARS-CoV-2 infection rate in the patient's ZIP code. The electronic medical record was queried to determine the number of in-person visits from March 10, 2020, (two weeks prior to the closure of nonessential businesses in Massachusetts) to the date of the SARs-CoV-2 infection diagnosis. The association between the number of in-person visits and the odds of infection was assessed, controlling for age, body mass index, and essential worker occupation.

During the study time period, 2,968 patients delivered and 111 (3.7%) tested positive for COVID-19. Of these patients, 45 tested positive antenatally and 66 tested positive on admission to labor and delivery.

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After excluding patients who lived outside of Massachusetts and those who had missing data, 93 cases were matched with 372 controls. The mean number of in-person visits was 3.1 (standard deviation [SD], 2.2) for cases and 3.3 (SD, 2.3) for controls. The odds ratio was 0.93 (95% confidence interval, 0.80-1.08) for the association between in-person visits and a positive coronavirus diagnosis. Results were similar when excluding patients who had a household member with a known SARS-CoV-2 infection.

■ COMMENTARY

Reassuringly, this study found no association between the number of in-person prenatal care visits and the risk of COVID-19 infection. At the time, Massachusetts was affected greatly by the coronavirus pandemic, with Boston being a hotspot. The American College of Obstetricians and Gynecologists (ACOG) provided guidance to its members on how to conduct prenatal care during the pandemic. This guidance included the following:[1]

- Spacing out appointments;
- Choosing to continue in-person prenatal care appointments for patients who are not sick, if staffing is available, but spacing out in-person appointment times where appropriate to reduce the number of patients in the office or facility at one time;
- Postponing some nonemergent gynecologic or well-woman appointments to facilitate social distancing and to maintain availability to accommodate medically necessary appointments (but not postponing appointments for which a delay will negatively affect patient health and safety);
- Alternating or reducing prenatal care schedules;
- Grouping components of care together (e.g., vaccinations, glucose screenings, etc.) to reduce the number of in-person visits;
- Conducting telehealth appointments.

Notably, ACOG emphasizes that these decisions need to be made at the local level, considering the risk of coronavirus transmission in the community at the time. Nevertheless, based on this study, ACOG has updated its guidance to say, "Emerging evidence suggests that with the appropriate precautions, in-person obstetric healthcare can be safely performed and is not likely to be an important risk factor for infection."[1] Certainly, with appropriate precautions, in-person medical visits can be continued. There are many aspects of prenatal care that should not be delayed and need an in-person visit. On the other hand, many providers who began to implement prenatal care visits by telehealth were satisfied with the experience as long as they had the appropriate administrative, staff, and computer support.[2] At one New York City hospital, from March 9 to April 12, 2020, approximately one-third of prenatal care visits were conducted via telehealth. Patient barriers to telehealth, especially using video technology, were noted, such as the need for continuous WiFi connection and home monitoring devices as well as the technology being cumbersome when interpreters were needed.

In general, the COVID-19 pandemic has provided an opportunity to revisit the concept of prenatal care. There have been several calls to revise the frequency of prenatal care visits from the current 12 to 14 individual patient visits to a more flexible schedule of eight to nine visits.[3] Furthermore, some advocate for models that include telemedicine routinely, not just during a pandemic. It is unclear, however, if payment models would support these changes and whether telemedicine reimbursement will continue after the pandemic. The delivery of prenatal care does have value, but likely can be individualized to a particular patient's needs to make the system more efficient for the provider, patient, and healthcare system overall. Although my practice in Rhode Island did space out prenatal care visits during the height of the COVID-19 pandemic and employed limited telemedicine (telephone only), we are now back to routine practice as rates of infection have subsided. ■

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ABSTRACT & COMMENTARY

Maternal Sepsis: Risk Factors that Could Lead to Postpartum Readmission

By Jeanine Mikek, MSN, RN, CEN, RNC-NIC

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Ms. Mikek reports no financial relationships relevant to this field of study.

SYNOPSIS: In this analysis of California deliveries between 2008 and 2011, risk factors for maternal readmission for sepsis were found to include preterm birth, hemorrhage, obesity, and a primary cesarean delivery.

SOURCE: Foeller ME, Sie L, Foeller TM, et al. Risk factors for maternal readmission with sepsis. *Am J Perinatol* 2020;37:453-460.

Data from the California Department of Public Health were collected from birth certificates and hospital discharge records to better understand what factors may precipitate maternal readmission for sepsis up to nine months after delivery. In alignment with the World Health Organization definition of sepsis from 2017, the presence of organ dysfunction was required for those cases to be included in the study. More than 1.88 million deliveries over the gestational age of 20 weeks were reviewed, and a total of 494 (0.03%) women were readmitted. Out of the 494 readmissions, 192 patients (39%) were hospitalized with sepsis less than six weeks after delivery (early sepsis) and the remaining 61% (n = 302) were readmitted between six weeks and nine months post-delivery (late sepsis. Multiple variables were investigated, including sociodemographic differences such as maternal age, ethnicity, comorbidities, body mass index (BMI), and mode of delivery. In addition, specific complications related to pregnancy also were reviewed, such as infection or sepsis during delivery admission, unplanned cesarean deliveries, or postpartum hemorrhage.

Women who were readmitted for sepsis were more likely to have an increased BMI and a younger gestational age at delivery ($P < 0.001$). Readmission with sepsis was found more commonly in those who had government-issued insurance and underwent a primary cesarean delivery ($P < 0.001$). Surprisingly, the statistical significance reflecting chorioamnionitis as a potential risk factor is not profound ($P = 0.047$). In fact, hemorrhage and preeclampsia were found to be of greater risk and had higher incidences in the readmission group ($P = 0.038$ and $P < 0.001$, respectively).

More than three-fourths of the readmissions within nine months post-delivery had infectious processes identified, primarily a urinary tract infection, pyelonephritis, or pneumonia. The majority of infecting organisms were found to be *Escherichia coli* (10%), *Staphylococcus* (8%), and *Streptococcus* (5%).

■ COMMENTARY

There are many factors that can place a postpartum patient at increased risk for sepsis. Interestingly, women in the study who experienced a birth with a gestational age less than 28 weeks demonstrated a sevenfold increase in risk for sepsis readmission within six weeks postpartum. Several factors may contribute to this, including underlying infection that could precipitate the preterm birth, maternal immune dysregulation, or variants of tumor necrosis factor. However, the direct reasoning behind the correlation remains unclear.

With nearly 49 million cases worldwide and 11 million associated deaths, sepsis is a leading cause of mortality for all patients and should not be taken lightly.[1] Because of the high mortality rate, healthcare providers must be observant and suspicious for sepsis when the patient reports feeling ill or has vague complaints. At the six-week postpartum visit, providers should be cognizant of questioning patients about any physical symptoms that could reflect a potential infection and overall physical health.

Although the majority of pregnant patients who are readmitted for sepsis do so within the first nine months postpartum, infection also can be present during pregnancy/labor and may be difficult to identify. Typically, vital signs that raise suspicion for sepsis include an elevated temperature, increased heart rate, and/or increased respiratory rate.[2] However, pathophysiological changes of pregnancy can mimic signs of an infection and can hinder recognition, testing, and treatment. For example, an elevated heart rate caused by increased cardiac output, as well as shallow breaths and decreased functional residual capacity of the lungs, can be justified by either labor progression or a potential infectious process.[3]

Screening tools exist to help guide provider questions and assessments with an emphasis on feelings of fatigue or pain, elevated temperature, increased heart rate or weakness, and shortness of breath. Such

examples include the quick Sequential Organ Failure Assessment (qSOFA) score, Modified Early Warning Score (MEWS), and Systemic Inflammatory Response Syndrome (SIRS) criteria.[4] Although the screening tools can increase knowledge, awareness, and prompt treatment, the majority of mothers do not present as septic while in labor or in the immediate postpartum period of two to three days.[5] Therefore, patients need to be well educated to watch for these symptoms at home and to call their provider when feeling ill.

Sepsis is a topic discussed much more commonly in the emergency department when compared to labor and delivery or postpartum units in the hospital setting. Best practices related to decreasing infection rates are used in the labor and delivery process, including sterile insertion of a urinary catheter and proper application of a surgical skin cleanser prior to a cesarean delivery. However, infectious processes can begin at any time, and the study found that most mothers present with sepsis weeks to months after delivery, not in the day or two they still are hospitalized. Discharge education related to sepsis should be discussed on the postpartum unit, and instructions on when to call a provider (such as presence of a fever, body aches, fast heart rate, dizziness, etc.) should be provided for all deliveries, not just cesarean deliveries. At the postpartum visit in the office or clinic, providers should question any new symptoms the mother has experienced, and patients should not hesitate to call telephone triage for medical advice if they are feeling ill. ■

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ABSTRACT & COMMENTARY

Outpatient Foley Catheter for Induction of Labor in Nulliparous Women

By Mitchell Linder, MD

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Dr. Linder reports no financial relationships relevant to this field of study.

SYNOPSIS: In this randomized controlled trial among nulliparous patients with low Bishop scores, outpatient placement of a Foley catheter the day prior to scheduled admission, when compared to inpatient placement, showed a decreased mean time from admission to delivery.

SOURCE: Ausbeck EB, Jauk VC, Xue Y, et al. Outpatient Foley catheter for induction of labor in nulliparous women: A randomized controlled trial. *Obstet Gynecol* 2020;136:597-606.

This randomized controlled trial compared outpatient placement of a Foley catheter on the day prior to scheduled admission to scheduled induction patients who received the catheter on admission to the hospital. Women were eligible for the study if they were nulliparous, 18 years of age or older with singleton pregnancies between 39.0 to 41.6 weeks gestation (as determined by a dating ultrasound prior to 20.6 weeks) with planned inductions scheduled, and had modified Bishop scores less than 5 with a maximum cervical dilation of 2 cm.

In addition, participants had to have access to reliable transportation and a telephone and live within 30 minutes of the study hospital. Exclusion criteria included fetal death, fetal anomalies (as defined by the presence of a major anomaly of any organ system), fetal growth restriction, suspected fetal macrosomia, oligohydramnios, polyhydramnios, non-reassuring fetal status (biophysical profile of 6/10 or less on testing done just prior to randomization), prior uterine surgery involving the myometrium, uncontrolled hypertension, uncontrolled pregestational diabetes, White classification type C diabetes or higher, infection with hepatitis B or C or human immunodeficiency virus, latex allergy, or other conditions deemed by the attending physician to be unsuitable for outpatient cervical ripening.

Once enrolled, patients were seen in the office at 39.0 weeks or greater and underwent a biophysical profile, blood pressure evaluation, and a cervical examination. Randomization occurred in a 1:1 fashion. Women randomized to outpatient ripening had a 16 French

Foley catheter placed immediately after randomization. The Foley was filled with 30 mL of sterile water and the catheter was placed on tension, taped to the patient's inner thigh. The women then underwent electronic fetal and contraction monitoring for at least 20 minutes. If the patient was not found to have regular, painful contractions, or bleeding, and if the tracing showed reassuring status, she was discharged home with labor precautions. The patients randomized to inpatient placement were sent home immediately after randomization. All women were admitted the next day for scheduled induction regardless of the group to which they were randomized. Patients randomized to inpatient placement had their catheters inserted on admission. The primary outcome was the total duration of time from hospital admission to delivery.

One hundred twenty-six women were enrolled between May 2018 and October 2019 at the University of Alabama at Birmingham Hospital. One hundred eighteen (94%) of enrolled patients underwent successful catheter placement. The average age for both groups was 22 years. The mean starting gestation was 39.3 weeks. The group demographics were balanced regarding race, education level, public vs. private insurance, tobacco use, and starting modified Bishop score. The only differences were a lower average body mass index and Group B *Streptococcus* colonization rate in the outpatient cohort.

In reference to the primary outcome, the outpatient catheter group spent less time in the hospital before delivery (17.4 ± 7.4 hours vs. 21.7 ± 9.1 hours), with a mean difference of 4.3 hours ($P < 0.01$). The proportion of patients delivering within 24 hours of hospital admission also was higher in the outpatient group (81% vs. 65%, $P = 0.4$). The overall length of stay did not differ between the groups (3.3 days vs. 3.5 days, $P = 0.27$). Patients in the outpatient group also were more likely to show up in labor prior to their scheduled induction time (22% vs. 5%, $P < 0.01$). Despite this, the rate of spontaneous rupture of membranes prior to admission was not significantly different between the groups (11% vs. 16%, $P = 0.43$).

Regarding secondary outcomes, patients who had outpatient placement were found to have higher modified Bishop scores on arrival to the hospital, with values of 3 vs. 1 ($P < 0.01$) as a result of changes in components of cervical dilation and effacement (3 cm vs. 1 cm, $P < 0.1$, and 50% effacement vs. 25%, $P < 0.01$). Women who had outpatient ripening also were found to require lower doses of oxytocin (17.5 vs. 22.6 mU/min, $P < 0.01$) as well as a shorter time of oxytocin infusion (15.8 h vs. 19.4 h, $P < 0.01$) and a shorter duration of neuraxial anesthesia use (11.4 h vs. 15 h, $P < 0.01$). No difference was found in the rates of cesarean delivery, operative delivery, meconium-stained amniotic fluid, duration of rupture of membranes, postpartum hemorrhage, or endometritis. The rate of chorioamnionitis was 22% in the outpatient group and 13% in the inpatient group, but this was not statistically significant ($P = 0.16$). Outpatient ripening also was found not to be associated with an increase in adverse neonatal outcomes. Patients in both groups were found to be satisfied overall with their care, with no significant differences between scores on patient surveys.

■ COMMENTARY

According to the Centers for Disease Control and Prevention, in 2018, 31.9% of all babies in the United States were born via cesarean delivery.[1] In that same year, the ARRIVE trial showed that induction of nulliparous women with unfavorable Bishop scores at 39 weeks resulted in lower rates of cesarean surgeries and hypertensive disorders of pregnancy.[2] Given these findings, there is a potential for a paradigm shift away from expectant management of these patients. The issue then becomes one of timing, resources, and physical space to care for a potential increased amount of inductions. This study looked at a possible outpatient intervention that could help decrease the use of inpatient hospital resources by way of a safe, relatively inexpensive method.

The authors found positives in the fact that the outpatient ripening decreased the total time from admission to delivery by more than four hours and increased the rate of unscheduled hospital admission without significantly increasing adverse neonatal outcomes, rates of infection, or operative deliveries. They acknowledged that even though an outpatient visit for catheter placement would increase the amount of time and care given to the patient, in the context of healthcare costs, the reduction in hospital use signified that their results were meaningful. They also pointed to the fact that both patient groups scored similarly on their satisfaction surveys to demonstrate that patients ultimately did not seem to mind the extra visit.

In my institution, we have not yet fully embraced the ARRIVE trial's findings and, thus, many of our groups still are managing patients at or post-term expectantly. If we were to move to actively promote most of our inductions at 39 weeks gestation, I think this research would be a good initial step to help reduce the burden that would come with an increase in potentially lengthy nulliparous inductions. Ideally, I would like to see this research repeated in multiparous patients to see how generalizable it would be to a full practice setting. ■

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ABSTRACT & COMMENTARY

Understanding the Utility of Hemoglobin A1c in Diagnosing Gestational Diabetes in Early Pregnancy

By Ahizechukwu C. Eke, MD, MPH

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Dr. Eke reports no financial relationships relevant to this study.

SYNOPSIS: In this retrospective cohort study of 243 pregnant women who had combined hemoglobin A1c (HbA1c) and a two-step oral glucose tolerance testing at less than 21 weeks of gestation, median values of HbA1c were higher in women with gestational diabetes compared to nondiabetics (5.8% compared to 5.3%; $P < 0.001$). The predictive probability of using HbA1c in diagnosing diabetes in early pregnancy was high compared to two-step testing (area under the curve, 0.8), with an optimal diagnostic threshold of 5.6%. Although a HbA1c level of > 6.5% is diagnostic of early gestational diabetes, a lower diagnostic threshold might be justified during pregnancy.

SOURCE: Battarbee AN, Grant JH, Vladutiu CJ, et al. Hemoglobin A1c and early gestational diabetes. *J Womens Health (Larchmt)* 2020; July 15. [Online ahead of print].

Gestational diabetes is a common medical complication during pregnancy, and a major cause of neonatal morbidity and mortality.[1,2] Although the 50-g, one-hour oral glucose tolerance testing (if > 140 mg/dL, but < 200 mg/dL), followed by a 100-g, three-hour oral glucose testing (two-step testing) is the preferred algorithm for diagnosing gestational diabetes in the United States, the utility of the two-step diabetic test is greater during the second trimester of pregnancy (24 to 28 weeks) because of worsening insulin resistance from placental hormones with advancing gestation.[3] Hence, investigators have considered other alternatives to the two-step testing for earlier diagnosis of gestational diabetes.[4]

Increasingly, hemoglobin A1c (HbA1c) is being used to diagnose diabetes in early pregnancy.[5,6] The ease of obtaining a single blood draw and not subjecting pregnant women to glucose loads (50 grams, then 100 grams) makes HbA1c an attractive option to the two-step oral glucose tolerance testing in diagnosing diabetes in pregnant women. Although a HbA1c concentration of ≥ 6.5% is diagnostic of diabetes outside of pregnancy, its utility in diagnosing diabetes during pregnancy is still a subject of debate.

In this retrospective cohort study in Chapel Hill, NC, Battarbee and colleagues reported their findings in pregnant women at high risk for gestational diabetes who were screened by either using oral glucose tolerance testing or HbA1c at < 21 weeks of gestation between July 2016 and July 2017. Women were eligible for inclusion if they were considered high risk for gestational diabetes, including women with a prior history of gestational diabetes or obese women (body mass index of ≥ 30 kg/m^2) at < 21 weeks of gestation. Pregnant women were excluded if they were pregestational diabetics, on metformin therapy, anemic (hematocrit of < 27 mg/dL), and homozygous for hemoglobinopathy.[7]

To estimate the predictive probability of using HbA1c or the two-step test in the diagnosis of early gestational diabetes at < 21 weeks of gestation, the area under the receiver operative curve (ROC) was used, and the concordance probability method that maximized sensitivity and specificity for defining the optimal HbA1c cut-off value in the ROC area under the curve was used. Other HbA1c diagnostic cut-offs were assessed using alternate sensitivity, specificity, and diagnostic accuracy.[7]

Among 426 high-risk women initially identified for inclusion, 243 women were selected after excluding all ineligible women. Seventy-seven (32%) of the women were non-Hispanic Black, 89 (36%) were non-Hispanic white, 55 (23%) were Hispanic, and 22 (9%) were from other ethnicities.[7] Women diagnosed with gestational diabetes at < 21 weeks of gestation were more likely to be obese and/or had a history of gestational diabetes in a previous pregnancy. Median values of HbA1c were higher in women with gestational diabetes compared to nondiabetics (5.8% compared to 5.3%; $P < 0.001$). The ROC area under the curve for HbA1c when compared to two-step oral glucose tolerance testing was 0.8 (95% confidence interval, 0.69-0.91), with an optimal threshold of 5.6% (64% sensitivity and 84% specificity).[7] Fourteen (5.8%) of the 243 were diagnosed with diabetes based on the two-step oral glucose tolerance testing, while nine women were diagnosed with gestational diabetes using an optimal threshold of 5.6%.

■ COMMENTARY

HbA1c is a glycated hemoglobin resulting from sustained exposure of red blood cells to glucose in the setting of hyperglycemia.[8] Although a level of ≥ 6.5% is recommended for diagnosing diabetes in nonpregnant women, no consensus has been reached in the utility of HbA1c for diagnosing diabetes during pregnancy. However, levels of HbA1c ≥ 6.5% have been used in diagnosing diabetes in early pregnancy on the basis that HbA1c levels in early pregnancy are similar to those to in nonpregnant women (4.5% to 5.7% in early pregnancy vs. 4.7% to 6.3% in non-pregnant women).[5,6] Therefore, HbA1c levels of ≥ 6.5% in early pregnancy implies undiagnosed pregestational diabetes. The study by Batterbee and colleagues was unique compared to other HbA1c studies in early pregnancy because they studied an ethnically and racially diverse group of pregnant women. In addition, they analyzed their samples with modern technology, and used a single site, thereby increasing precision of HbA1c reported values. Their optimal threshold for diagnosing diabetes was 5.6% and is consistent with the values reported by other studies.[5,6] The lower HbA1c thresholds reported in these studies might be related to the physiological changes that occur during normal pregnancy — for example, the red blood cell lifespan shortens to approximately 90 days, with HbA1c declining from rapid red blood cell turnover,[9] physiologic anemia of pregnancy, and increased intestinal transit times that occur during pregnancy.[4] In addition, there are racial differences in HbA1c normal values.[4] Because of these factors, using lower HbA1c levels (< 6.5%) in early pregnancy for making a diagnosis of diabetes, while reasonable, remain a subject of debate.

In conclusion, the HbA1c threshold of 5.6% for diagnosing diabetes in early pregnancy, although modest, is not currently recommended. Until well-designed studies are completed, a HbA1c of ≥ 6.5% could remain useful as a screening test in early pregnancy as an alternative to the two-step oral glucose tolerance testing in women intolerant to large glucose loads (for example, patients with a history of Roux-en-Y gastric bypass surgery). This is important because making the diagnosis of gestational diabetes in early pregnancy and instituting early management improves outcomes and decreases the future risk of cardiovascular disease, obesity, type 2 diabetes, and metabolic syndrome. ■

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CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- Explain the latest data regarding diagnosis and treatment of various diseases affecting women;
- Discuss new data concerning prenatal care, neonatal health, and complications arising in pregnancy and the perinatal period; and
- Discuss the advantages, disadvantages, and cost-effectiveness of new testing procedures in women's health.

CME/CE INSTRUCTIONS

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4. After completing the test, a credit letter will be emailed to you instantly.
5. Twice yearly after the test, your browser will be directed to an activity evaluation form, which must be completed to receive your credit letter.

CME/CE QUESTIONS

1. **Based on the study by Reale et al, which of the following is true about in-person prenatal care visits during the COVID-19 pandemic?**
   a. In-person visits increase the risk of COVID-19 infection.
   b. In-person visits decrease the risk of COVID-19 infection.
   c. In-person visits did not affect the risk of COVID-19 infection.
   d. In-person visits increase immunity against COVID-19.
2. **Which of the following was found to increase the risk of postpartum sepsis?**
   a. Chorioamnionitis
   b. Preeclampsia
   c. Lower body mass index
   d. Delivery after 40 weeks
3. **When compared to traditional inpatient cervical ripening, outpatient cervical ripening with Foley catheters in nulliparous patients leads to findings of:**
   a. increased rate of cesarean deliveries.
   b. more adverse neonatal outcomes.
   c. longer duration of neuraxial anesthesia use.
   d. decreased time from admission to delivery.
4. **Currently, which of the following is recommended by the American College of Obstetricians and Gynecologists for gestational diabetes screening during pregnancy in high-risk women?**
   a. Two-step oral glucose tolerance testing
   b. Hemoglobin A1c levels of ≥ 6.5%
   c. Hemoglobin A1c levels of ≥ 5.6%
   d. Fructosamine

[IN FUTURE ISSUES]

Female Caregivers May Delay Seeking Care for Pelvic Floor Disorders