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Evidence-based commentaries on women's reproductive health

ABSTRACT & COMMENTARY

Fetal Fibronectin: Its Role in Threatened Preterm Labor

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

SYNOPSIS: A recent letter to the editor disputes the conclusion of an earlier study that fetal fibronectin is of little value in threatened preterm labor, despite other studies suggesting that when used in conjunction with cervical length measurements, it can diminish unnecessary hospitalizations appreciably.

SOURCE: van Baaren GJ, Bruijn MMC, Mol BW, et al. Randomized trials are not always the best way to assess diagnostic tests: The case of fetal fibronectin testing. *Am J Obstet Gynecol* 2017; Nov. 21. pii: S0002-9378(17)31230-9. doi: 10.1016/j.ajog.2017.10.037. [Epub ahead of print].

The featured letter to the editor, along with two responses,[1,2] were published in the January issue of the *American Journal of Obstetrics and Gynecology*, all pertaining to a 2016 article by Berghella et al[3] about the use of fetal fibronectin (fFN) in patients with threatened preterm labor (PTL). This interplay provided very interesting commentary regarding the interpretation of the original study results and the benefits/shortcomings of randomized, controlled trials (RCTs) and observational studies. First, the index study: Berghella et al trolled the Cochrane database for RCTs involving fFN alone as a predictor of preterm delivery < 37 weeks.[3] They found six studies that satisfied their inclusion requirements. These studies all involved patients being evaluated for threatened PTL. Half of 546 patients, who were between 23 and 35 weeks' gestation, were randomized to having fFN testing available to their managing providers shortly after the patients presented. In the other half, the test results were not available. None of the studies dealt with cervical length (CL) measurements. In three studies, a common protocol for management and/or therapy was used, but in the remaining three studies, the management was ad lib.

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The authors found no statistically significant differences in the rates of delivery < 37 weeks (their primary outcome measure), delivery < 32 weeks, length of hospitalization, use of steroids or tocolytics, neonatal respiratory distress syndrome, or length of neonatal stays. The only difference was an average increased cost of $153 per patient in the fFN group. The authors' concluded that use of fFN was not associated with a decrease in preterm birth or any improvement in perinatal outcome.

In a companion editorial in the same issue, Macones went one step further in suggesting that the use of fFN in threatened preterm labor cannot be justified.[4]

■ COMMENTARY

The above study and editorial sparked the featured letter to the editor in this month's issue of the *American Journal of Obstetrics and Gynecology* from van Baaren and colleagues, who pointed out that most patients with threatened PTL are not in labor and the benefit of selectively used fFN is in its high negative predictive value (NPV). Their own observational study showed that a negative fFN, used in conjunction with CL in this setting, would allow most patients to be discharged safely without the need for tocolysis or steroids.[5] They believed that before concluding that fFN was worthless in threatened PTL, the study should include a uniform management protocol regarding how to deal with the results of the fFN test.

In response to this letter to the editor, both Berghella and Macones seemed to agree with van Baaren that a predictive test such as fFN alone cannot change an outcome unless it segues into some type of action that works. Steroids do not stop PTL and even the overall benefit of tocolysis in PTL has been questioned over the years. However, Macones noted that the investigative power of RCTs was superior to observational studies, since they show what "does" happen with a particular test or action, rather than what "could" happen (with observational studies).

After wading through the entertaining collegial jousting, it should be clear that fFN does not have significant benefit in a vacuum. However, when used selectively in conjunction with CL in a regimented protocol — as suggested by van Baaren in the letter to the editor, Berghella in his response to the letter to the editor,[1] and in a 2007 RCT for which Berghella was an author[6] — it "will" decrease unnecessary hospitalizations, interventions, and healthcare costs.

If using fFN, the following is a re-formatted evaluation of threatened PTL initially suggested by van Baaren et al:[5] On initial evaluation, patients with painful preterm contractions can have a sample taken with a swab from the posterior fornix of the vagina, which will be held in abeyance until the rest of the initial evaluation has been completed. This would include transvaginal sonography, in conjunction with a pelvic exam, to assess the status of the cervix. A CL < 1.5 cm would suggest the need for hospital admission (and the swab would be discarded since fFN would offer no additional benefit). If CL > 3 cm, the high NPV of this measurement alone would not be enhanced by fFN and the patient could be discharged. However, if the cervical length is between 1.5 cm and 3.0 cm, a positive fFN result would trigger admission and a negative result would mean that the patient would simply be followed carefully with outpatient visits.

Although both RCTs and observational studies have strong merit alone, they are, in fact, linked symbiotically. Often, an evidence-based evaluation of a concept or method can be accomplished only through an RCT. However, without observational studies there would be no concepts to test. Also, at times, the data from an observational study are so compelling — and the likelihood is so low of getting the results tested through a timely, flawlessly designed RCT — that management could be guided legitimately by the results of the observational study. The focus should not necessarily be on whether fFN decreases the rate of preterm birth, but should be on whether it can keep patients from having an unnecessary (and disruptive) hospitalization at a time when healthcare costs are out of control. ■

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ABSTRACT & COMMENTARY

Which Antibiotics Are Safe in the First Trimester of Pregnancy?

By Rebecca H. Allen, MD, MPH

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SYNOPSIS: A total of 7.2% of pregnant women were diagnosed with a urinary tract infection, and of these, 69% filled an antibiotic prescription. The most common antibiotics prescribed in the first trimester were nitrofurantoin, ciprofloxacin, cephalexin, and trimethoprim-sulfamethoxazole.

SOURCE: Ailes EC, Summers AD, Tran EL, et al. Antibiotics dispensed to privately insured pregnant women with urinary tract infections — United States, 2014. *MMWR Morb Mortal Wkly Rep* 2018;67:18-22.

This cross-sectional study by the Centers for Disease Control and Prevention (CDC) was designed to identify antibiotics prescribed to pregnant women with urinary tract infections (UTIs). The Truven Health MarketScan Commercial Database contains a convenience sample of women with employer-sponsored private health insurance. This database was queried to identify women who were pregnant in 2014 (pregnancies had to include at least one day in 2014). To be included, pregnant women had to be enrolled continuously in insurance with prescription drug coverage, or missing only one month of enrollment from 90 days prior to the last menstrual period to the end of pregnancy. Claims from physician offices, emergency departments, and urgent care centers were searched to identify those with a diagnosis of UTI using ICD-9 diagnosis codes. Inpatient hospitalizations and women who had recurrent UTIs (three or more during the study period) were excluded. Prescription records then were searched to identify antibiotic medications dispensed on the day of and up to seven days after the outpatient UTI claim.

The researchers identified 482,917 pregnant women who met the study criteria. Among these, 34,864 (7.2%) were diagnosed with UTIs, 41% in the first trimester, 22% in the second trimester, and 11.8% in the third trimester. Overall, 69% of women diagnosed with UTIs filled prescriptions within seven days of the outpatient visit. The antibiotics most commonly prescribed in pregnancy were nitrofurantoin, cephalosporins, and penicillins. The most frequently dispensed medications in the first trimester were nitrofurantoin (37.5%), ciprofloxacin (10.5%), cephalexin (10.3%), and trimethoprim-sulfamethoxazole (TMP-SMX; 7.6%).

■ COMMENTARY

The CDC performed this study to ascertain which antibiotics were being prescribed to pregnant women in the first trimester for UTIs based on a concern for teratogenicity with nitrofurantoin and TMP-SMX. As confirmed in this study, UTI/asymptomatic bacteriuria occurs in about 8% of pregnant women. In pregnant women, untreated UTIs/asymptomatic bacteriuria can lead to pyelonephritis, sepsis, and preterm delivery, resulting in severe maternal and fetal morbidity and possibly mortality.[1] Therefore, pregnant women are screened in the first trimester for bacteriuria and treated if the culture result is positive to prevent pyelonephritis.[2]

Study limitations included reliance on diagnosis and procedure codes to identify pregnancies and UTIs, which can be subject to misclassification. Last menstrual period dates, delivery dates, and UTI diagnoses were not validated by examining the clinical record. Furthermore, the pregnancy may not yet have been diagnosed in some cases when the provider was prescribing treatment. In addition, the specific and appropriate use of nitrofurantoin or TMP-SMX based on culture sensitivity reports were not ascertained. Finally, the database is not

generalizable to the U.S. population, and antibiotic prescriptions paid out of pocket were not captured. Although penicillins, cephalosporins, metronidazole, and erythromycin/azithromycin are regarded as safe during embryonic organogenesis, questions remain about nitrofurantoin and TMP-SMX. Fluoroquinolones usually are not prescribed during pregnancy because of concerns about toxicity to developing cartilage in animal studies. I suspect that the use of ciprofloxacin documented in this study during the first trimester occurred mostly in cases in which the pregnancy had not yet been diagnosed clinically.

The American College of Obstetricians and Gynecologists (ACOG) published a committee opinion in 2011, updated in 2017, that addressed concerns regarding nitrofurantoin and TMP-SMX.[3] In essence, case-control studies using the National Birth Defects Prevention Study database have shown a relationship between nitrofurantoin and TMP-SMX use during pregnancy and birth defects.[4,5] However, these studies have major limitations, such as relying on mothers to recall postpartum if they had even been diagnosed with a UTI during pregnancy and which antibiotic they had been prescribed. The diagnosis and prescription of antibiotics were not confirmed in the medical record, and many mothers could not recall the specific name of the antibiotic prescribed. Other studies have not shown any association.[6] Therefore, the data are mixed, and ACOG recommended that use of nitrofurantoin and TMP-SMX in the first trimester is still appropriate when no other suitable alternative exists (e.g., a penicillin or cephalosporin cannot be used).

We should all practice antibiotic stewardship when treating patients and select antibiotics carefully. Often, despite the clean-catch technique, urine cultures are contaminated in pregnancy, and we should be sure only to treat women with recognized uropathogens. The urine culture can always be repeated to confirm the diagnosis. Nevertheless, pregnant women should not be denied treatment for UTI/asymptomatic bacteriuria based on theoretical concerns regarding birth defects. Failure to treat can lead to more devastating adverse outcomes for both mother and fetus such as sepsis, preterm delivery, and death. ■

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ABSTRACT & COMMENTARY

Oxytocin Discontinuation

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SYNOPSIS: A recent meta-analysis of randomized, clinical trials has shown that discontinuing oxytocin infusion once active labor has been attained in inductions and augmentations of labor will result in a reduction of cesarean delivery and tachysystole, but an increase in the length of labor.

SOURCE: Saccone G, Ciardulli A, Baxter JK, et al. Discontinuing oxytocin infusion in the active phase of labor: A systematic review and meta-analysis. *Obstet Gynecol* 2017;130:1090-1096.

The rate of induction of labor in the United States is about 23%.[1] Since the uterus and cervix often are not ready for labor, it is not surprising that induction of labor is associated with an increased rate of cesarean delivery, which is now about 30%. Most often, the rationale for using oxytocin has been to initiate contractions and to assist in the transition into active phase. Oxytocin-driven tachysystole is not an uncommon (or innocuous) byproduct and can result in abnormal fetal heart rate patterns. This leaves one to wonder whether the labor medication is really needed once the uterus is on its own during the active stage of labor.

Saccone et al undertook a meta-analysis of randomized, clinical trials (RCTs) comparing a

protocol of a "business-as-usual" approach of continuing oxytocin through delivery against one in which the infusion was stopped once the active phase was attained. They analyzed data from nine RCTs involving 1,538 pregnancies, all of which had inductions of labor or augmentations with oxytocin. In one group, the infusion was discontinued once active labor was achieved, but if labor arrested (as defined by a plateauing of cervical dilatation over two hours) then it was restarted. In the other group (controls), the oxytocin was continued, generally at the same dosage, until delivery. Only three of the studies employed placebo control. In all studies, the definition of active labor was cervical dilatation of 5 cm of greater.

The meta-analysis included 764 patients in the discontinuation group and 774 patients in the control (continuation) group. An average of 30% in the discontinuation group had to have oxytocin restarted because of an arrest in dilatation, and the oxytocin infusion was stopped because of "fetal distress" in 7.7% of the control group. The authors were aware of the potential biases in this type of study, and they addressed the seven domains of bias described in the *Cochrane Handbook for Systematic Reviews of Interventions*.[2]

The primary outcome measure was the cesarean delivery rate. The rate in the discontinuation group was 9.3% vs. 14.7% in the control group (relative risk [RR], 0.64; 95% confidence interval [CI], 0.48-0.87). Secondary outcomes included the rate of tachysystole, which was 6.2% vs. 13.1% (RR, 0.53; 95% CI, 0.33-0.38). The discontinuation group had an average active phase of labor that was 27.6 minutes longer than the control group (95% CI, 3.94-51.36 minutes). There were no significant differences in any of the other secondary variables evaluated.

■ COMMENTARY

In view of the high cesarean delivery rate, many common labor protocols have undergone re-evaluation. This has led to more liberal thresholds of tolerance for the lengths of active first and second stages of labor. Friedman's original data suggested that the active phase started when patients had attained 4 cm of dilatation. In their recent labor guidelines,[3] the American College of Obstetrics and Gynecology and the Society of Maternal Fetal Medicine increased the dividing line between the early and active phases of labor to 6 cm. Also, these guidelines indicate that providers should be more patient before considering intervention when progress in labor is sluggish. In fact, it was suggested that the label "arrest of labor" in the latent phase should not be used unless adequate contractions are attained for 12 to 18 hours following rupture of membranes and augmentation with oxytocin, if needed. Also, arrest of labor in the active phase now has been defined as no progress in dilatation after at least four hours of adequate contractions, thereby doubling the original threshold of two hours.

The concept of stopping oxytocin once adequate contractions have been attained in strength and frequency not only appeals to patients who wish to experience a more natural labor, but it also may have some scientific merit. Two studies have suggested that after about 10 hours of induction, the oxytocin receptors may not respond, and further infusion even could have the opposite effect on contractions.[4,5]

This meta-analysis has shown that the possible benefits from oxytocin discontinuation are lower rates of cesarean delivery and tachysystole. The downside is a longer length of labor, by an average of 27 minutes (or an addition of about eight to nine more contractions). Since the authors applied intention-to-treat methodology, the above data included the 30% in the discontinuation group whose infusion needed to be restarted.

Is there a drawback to this practice? Prolonged labor has been associated, in general, with a higher rate of amnionitis and shoulder dystocia.[6] Authors of one of the RCTs found a nonsignificant trend toward a higher rate of amnionitis. However, this and shoulder dystocia were not addressed in the other papers in the meta-analysis. That concern will need further study.

The meta-analysis showed a 35% decrease in the cesarean delivery rate. When weighing the downside of an extra half hour of labor against a substantially lower chance of having a cesarean delivery, I would guess most patients would vote for stopping the oxytocin. ■

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SPECIAL FEATURE

Prevalence of Cognitive Impairment in Older Women With Pelvic Floor Disorders

By Chiara Ghetti, MD

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

SYNOPSIS: Mild cognitive impairment and early dementia are prevalent in women seeking care for pelvic floor disorders.

SOURCE: Kunkle CM, Abernethy MG, Van Tongeren LR, et al. Prevalence of cognitive impairment in older women with pelvic floor disorders. *Int Urogynecol J* 2017;28:1645-1650.

Kunkle et al conducted this study to determine the overall prevalence of mild cognitive impairment (MCI) and early dementia in women who sought care for pelvic floor disorders (PFDs) and to identify associations between cognitive impairment and condition-specific quality of life (QoL). This was a cross-sectional study of women 55 years of age or older. They excluded women who had existing diagnoses of dementia. The primary outcome was the prevalence of MCI and early dementia as measured by Short Test of Mental Status (STMS), a validated screening tool used in dementia assessment. The authors defined MCI having an STMS score of ≤ 31 and early dementia as having a score ≤ 29. Other outcome measures included pelvic organ prolapse measured by the Pelvic Organ Prolapse Quantification (POP-Q), urinary incontinence severity measured by the Sandvik Severity Index (SSI), and depression assessed by the Patient Health Questionnaire (PHQ-9). PHQ-9 scores of 10 to 14 correspond to moderate depressive symptoms, scores of 15 to 19 correspond to moderately severe depressive symptoms, and scores of 20 to 27 correspond to severe depressive symptoms. Condition-specific QoL was assessed with the Pelvic Floor Distress Inventory Short Form (PFDI-20) and the Pelvic Floor Impact Questionnaire Short Form (PFIQ-7). Higher scores on these measures indicated greater symptom severity and effect on condition-specific QoL.

Two hundred eleven women were eligible for the study. The baseline prevalence of MCI and early dementia were 15% (95% confidence interval [CI], 10.9-20.6; n = 32) and 17% (95% CI, 11.9-22.1; n = 36), respectively. Upon univariate analysis when patients with MCI and early dementia were compared to those with normal cognition, those with impaired cognition were older, had lower educational levels, had lower rates of alcohol use, and were less likely to have had prior PFD treatment. Patients with abnormal cognition also had higher depressive symptom scores. POP-Q stage, PFDI-20, and SSI scores were similar between groups; however, patients with cognitive impairments had higher PFIQ-7 scores. The authors reported results of a multivariate linear regression, with PFIQ-7 score as the main outcome and cognitive impairment (MCI plus early dementia) as the main exposure of interest. The final model only included variables that most significantly affected the cognitive impairment/PFIQ-7 association, which included education, prior treatment for PFDs, alcohol use, and depression. In this model, only prior treatment for PFDs and depression were independently associated with higher PFIQ-7 scores. However, in a second model excluding depression, cognitive impairment was independently associated with higher PFIQ-7 scores.

■ COMMENTARY

PFDs are known to affect many women, and the proportion of women who report at least one PFD increases with age.[1] Mild cognitive impairment affects 22% of the general population older than 55 years of age. The U.S. Census Bureau has estimated that by 2030, one-fifth of women will be 65 years of age or older. As the population of older women increases, the burden related to PFDs and cognitive impairment will increase.

Although this study had several limitations, it is only the second study of which I am aware that investigated cognitive impairment and pelvic floor disorders. Erekson et al studied the occurrence of frailty, cognitive impairment, and functional disability in older women seeking treatment for PFD and found that 16% of women 65 years or older seeking care for a PFD met the criteria for frailty and that 21.3% of women screened positive for dementia, using the Saint Louis University Mental Status score.[2] One-third of women reported functional difficulty or dependence in performing at least one activity of daily living. Together these studies highlight the unique needs of our older gynecologic patients.

Cognitive impairment is difficult to diagnose from one screening tool. In addition, there are very

complex relationships between depression and cognitive impairment. Depression is common in patients with cognitive impairment or dementia, and cognitive decline seems to affect older patients with depression frequently.[3] The interrelationship of cognitive impairment and depression needs to be explored more fully, as does the complex relationship of these factors with condition-specific QoL. These are limitations of this study.

In a prior issue, we discussed cognitive impairment and the use of anticholinergic medications. The identification of cognitive impairment also has significant ramifications in the care of older women, and it is especially important in the perioperative period. Cognitive impairment may significantly affect the informed consent process, a patient's decision-making ability, and a patient's true ability to understand the risks and benefits of treatment options. Cognitive impairment and associated frailty also affect a woman's individual risk of complications. The most common postoperative complications for older patients include falls, delirium, surgical site infections, and electrolyte imbalance.[4]

In a small group of healthy older women undergoing elective gynecologic pelvic floor surgery, Richter et al found no difference in postoperative QoL outcome (measured by the Short Form 36) in subjects in whom a preoperative geriatric assessment was performed.[5] However, the authors cautioned that further studies are required to better understand which patients might benefit from preoperative geriatric assessment. In a study of older women undergoing surgery for pelvic organ prolapse, Oliphant et al found that most older women with baseline functional status independence undergoing pelvic organ prolapse surgery can expect to regain independence by three months postoperatively.[6]

According to the American College of Obstetricians and Gynecologists Guidelines for Women's Health Care, "Evaluation of functional assessment findings, coupled with appropriate management, referrals, or both, can assist the elderly woman to live independently and maintain her health. A functional assessment also should be carried out before any medical intervention or surgery."[7] Malani advocates strongly for incorporating preoperative assessment of mobility, functional status, and cognition into preoperative care of older adults.[8] However, most of us were not trained in these evaluations. In a study of physicians that included general internal medicine, family medicine, cardiology, pulmonary medicine, endocrinology, rheumatology, gynecology, and neurology, Chodosh et al found that physicians were unaware of cognitive impairment in more than 40% of their cognitively impaired patients.[9] Mildly impaired patients are more difficult to identify. This begs the question, how best can we assess mobility, functional status, and cognition in a busy clinical gynecologic practice?

Several simple and efficient screening tools can be used. The Get Up and Go test is an easy way to assess mobility. Have patients wear their regular footwear and any walking aid they normally use for this test. Instruct the patients to sit back in a standard arm chair, and when given the signal go, they should stand up from the chair, walk to a line on the floor 10 feet away, turn around, and walk back to the chair and sit down. Begin recording time at the word go and stop timing after patients sit back down. Patients who take 12 seconds or longer are considered to be at significant risk for falling.[10]

Reviewing the difficulty or need for assistance for basic activities of daily living is an easy way to assess functional status. Activities of daily living include walking one block, walking across a room, putting on shoes and socks, bathing or showering, cutting food, getting in and out of bed, and using the toilet. Instrumental activities of daily living include being able to perform tasks such as balancing a checkbook, paying bills, and grocery shopping.

A simple test to screen for cognitive impairment is the Mini-Cog test, which takes about three minutes to administer and is composed of a three-word recall and a clock drawing exercise. Instructions for administration and scoring can be found at https://www.alz.org/documents_custom/minicog.pdf.

These tests can help providers identify underlying deficits that can affect perioperative care and discharge planning. For example, a patient with preoperative mobility issues may be at risk for falls and may benefit from perioperative physical or occupational therapy visits postoperatively. Patients requiring assistance with activities of daily living preoperatively may need postoperative rehabilitation or in-home assistance. Knowing that a patient has cognitive deficits will help the care team be on the lookout for delirium or postoperative confusion.

The number of older women undergoing gynecologic surgical procedures and surgeries for prolapse is estimated to increase. Studies using comprehensive geriatric assessments show promise in identifying elderly patients at greater risk for morbidity and mortality following elective surgery. While instituting extensive geriatric testing may be beyond the ability of our individual practices, the use of simple measures to assess mobility, functional status, and cognitive impairment in our older patients may have a significant effect on our patients' quality of life and on our own ability to care for them. ■

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CME/CE QUESTIONS

1. The 2016 meta-analysis of randomized clinical trials showed that all but one of the following outcomes were not significantly affected by the use of fetal fibronectin.
a. Preterm birth < 37 weeks
b. Preterm birth < 32 weeks
c. Neonatal length of stay
d. Maternal hospital length of stay
e. Cost of the workup

2. Fetal fibronectin is of dubious benefit, even when used in conjunction with cervical length.
a. True
b. False

3. In the study by Ailes et al, UTIs were diagnosed most commonly in which trimester of pregnancy?
a. First
b. Second
c. Third

4. By the newest standards, active labor is achieved only when the patient has progressed to 4 cm.
a. True
b. False

5. In meta-analysis by Saccone et al, 30% of patients in the "discontinuation" group needed to have the oxytocin restarted.
a. True
b. False

6. Cognitive impairment in patients undergoing elective gynecologic surgery:
a. has no effect on perioperative outcomes.
b. can be easily screened for using the Mini-Cog test.
c. is easily recognized by practitioners.
d. should not be of concern to surgeons.

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.

[IN FUTURE ISSUES]

The Latest in Genetic Screening for Gynecologic Malignancies