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Some Ob.Gyns. and Other Providers Misuse Low-Risk HPV Tests

BY HEIDI SPLETE

FROM OBSTETRICS & GYNECOLOGY

Approximately one-third of health care providers conduct unnecessary low-risk HPV testing, based on results of a survey of 376 office-based health care providers and 216 outpatient clinics.

A high-risk human papillomavirus (HPV) DNA test, which detects cancer-causing HPV types, is generally used for screening and managing women with abnormal Pap test results, but there are no clinical recommendations for use of a low-risk HPV DNA test that detects five nononcogenic HPV types, said Jennifer Wai-Yin Lee, R.N., and her colleagues at the Centers for Disease Control and Prevention (Obstet. Gynecol. 2011;118:4-13).

To assess the use of different types of HPV testing, the researchers reviewed data from the 2006 Cervical Cancer Screening Supplement, a survey conducted by the CDC.

Overall, 76% of the office-based providers and 77% of the outpatient clinics reported ever ordering an HPV



Dr. Mona Saraiya of the CDC, said, "Over one-third of providers in our study who used HPV testing reported using the low-risk HPV test, which is a large number and sheds light on a practice that we didn't know much about before."

test, and 35% of health care providers and 32% of clinics said they used low-risk HPV testing.

Ob.gyns. were significantly more likely to report using the HPV test than family physicians and internists (99% compared

with 77% and 45%, respectively).

The finding on the use of low-risk HPV testing "is surprising," the researchers wrote.

"The low-risk HPV DNA test screens

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Dose Selection Key in Picking Antiepileptic Drug in Pregnancy

BY ROBERT FINN

FROM THE LANCET NEUROLOGY

Dose selection is as critical as is the choice of antiepileptic drug for avoiding birth defects in women with epilepsy, according to a large observational cohort study.

In a comparison of the four most commonly prescribed antiepileptic drugs, lamotrigine at a dose of less than 300 mg/day at the time of conception was the least likely to be associated with birth defects. Valproic acid at 1,500 mg/day or more was 16 times more likely to be

associated with birth defects, according to the results of the multivariate analysis. Carbamazepine and phenobarbital carried intermediate levels of risk, depending on the dose.

The results came from an observational cohort study of 3,909 pregnancies representing 3,521 women in 42 countries between 1999 and 2010. All the women had epilepsy and were taking one of the four drugs at conception.

The investigators, led by Dr. Torbjörn Tomson of the Karolinska Institute, Stockholm, excluded pregnancies in women whose antiepilepsy prescription was

changed during the first trimester, those who were exposed to antiepileptic polytherapy or to other potentially teratogenic medications, and women with comorbidities such as diabetes, toxoplasmosis, and HIV that are known to increase the risk of congenital malformations (Lancet Neurology 2011 [doi:10.1016/S1474-4422(11)70107-7]).

In their multivariate analysis, the investigators controlled for a host of potential confounders. These included maternal age, sex of child, parental history of major congenital malformations, geographical

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Screens for Nononcogenic HPV

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for infection with nononcogenic HPV types and thus serves no purpose in the context of cervical cancer screening," they noted.

The use of low-risk HPV testing in the United States may be driven by a combination of factors including financial gain, test marketing, and health care provider confusion on the difference between the low-risk and high-risk tests, the researchers said.

"We discovered that the low-risk HPV test – which has no clinical indications and is not recommended by any guidelines – was actually part of an older version of the HPV test, which tested for both low- and high-risk HPV types," lead author Dr. Mona Saraiya, also of the CDC, said in an interview.

"Despite newer HPV tests that screen only for high-risk types, the combined test remains in active use. Over one-third of providers in our study who used HPV testing reported using the low-risk HPV test, which is a large number and sheds light on a practice that we didn't know much about before," she said.

Overall, office-based providers and clinics were more likely to use HPV testing to manage an abnormal Pap test (reflex or recall testing) than to augment routine cervical cancer screening (cotesting). Of the office-based providers who ordered any HPV test, 89% said they used it for managing an abnormal test result, while 47% said that they used it with the Pap test for routine cervical cancer screening. Clinics also were more likely to perform reflex or recall testing than HPV cotesting.

However, approximately 60% of the respondents (60% of office-based providers and 66% of clinics) also said they used HPV cotesting with a Pap test for routine cervical cancer screening in women younger than 30 years, although such testing is recommended only for women aged 30 years and older.

And more than half of health care providers (56% of office-based providers

and 55% of clinics) reported doing reflex HPV testing in women younger than 30 years.

"The concern over testing in this age group arises from the follow-up colposcopies and excisional treatments, which carry their own risks and side effects that may occur as a result of HPV testing that should not have been performed to begin with," Dr. Saraiya said.

"Clinicians may need to explain to a patient under 30 years old who is requesting the HPV test with her Pap smear why HPV testing is, at best, not useful in her situation and potentially harmful, at worst," she said.

The frequent use of HPV tests in younger women in both health care settings is cause for concern, because most HPV infections in women younger than 30 years are transient, and these infections will resolve without further intervention and health care costs, the researchers noted.

"Avoiding unnecessary work-up or treatment of transient HPV infections in younger women is an important goal ... because studies have found associations between certain procedures used to treat cervical dysplasia and adverse birth outcomes," including preterm delivery and perinatal mortality, the investigators noted.

In addition, 71% of office-based providers and 63% of clinics performed reflex HPV testing after Pap test results of ASC-H (atypical squamous cells, cannot rule out high-grade squamous intraepithelial lesions), although HPV testing is not recommended in these instances.

Guidelines from the American Cancer Society, the American College of Obstetricians and Gynecologists, and the American Society for Colposcopy and Cervical Pathology state that HPV DNA testing is not recommended for certain situations, including low-risk HPV types, routine cervical cancer screening in women younger than 30 years, routine screening more often than 3 years in

Be Wary of Unnecessary Testing

This study emphasizes the need for continued education for practitioners and the public about cancer screening and prevention that includes the value-added tests we order to preserve the lives of our patients and the health of our community, in addition to their absolute cost and potential downsides of unnecessary further testing.

We do not use, or teach our residents and students to use, low-risk testing. There may be some confusion concerning the test's benefits in the clinics and practices that are ordering it. Many clinics have algorithms for testing, and the practitioners may not even be aware that their algorithm is incorrect. There is no financial benefit for the ob.gyn. physician to do the low-risk HPV test.

The opinions published by the American College of Obstetricians and Gynecologists are the most widely read and most frequently used by ob.gyn. physicians as well as by women's health practitioners worldwide. In addition, well-respected organizations, such as the ASCCP (a society for the study of management

of lower-tract genital disease), regularly publish evidence-based guidelines that help practitioners practice the most up-to-date medicine. Following these evidence-based guidelines is the best way to decide when to do HPV testing.

Research into the knowledge of the practitioners who report ordering the tests in a way not consistent with the guidelines would help leaders understand where additional educational efforts are needed.

As the science of cervical-cancer prevention continues to grow and evolve, we may see a time when we only do Pap smears as a reflex to HPV testing, and the testing may be every 3-5 years. The long-term health of our patients and our community, as well as the costs and value of medical testing, needs additional research in a time of limited resources and increasing population.

OWEN MONTGOMERY, M.D., is chairman of obstetrics and gynecology at Drexel University in Philadelphia. Dr. Montgomery said he had no relevant financial disclosures.

'Clinicians may need to explain to a patient under 30 years old who is requesting the HPV test with her Pap smear why HPV testing is, at best, not useful in her situation and potentially harmful, at worst.'

women older than 30 years, routine sexually transmitted disease screenings, sexual assault work-ups, and initial triage of women with Pap test results of high-grade squamous intraepithelial lesions or of ASC-H, the researchers said.

The unnecessary and improper use of HPV testing suggests that actions such as limiting test reimbursement and educating health care providers are needed to eliminate unnecessary low-risk testing, the researchers said.

"When it comes to low-risk HPV testing, the take-home message to clinicians is simple: Women should stop being tested for low-risk HPV," Ms. Lee said in an interview. "We already know that low-risk HPV types are nononcogenic, so testing for low-risk HPV is not useful in determining a woman's risk for developing cervical cancer.

"We also want to make clear that although low-risk HPV types are associated with genital warts, having a positive low-risk HPV test does not mean a woman will develop genital warts, nor does it provide any prognosis for women who have genital warts," she said.

"By knowing this information, clinicians will hopefully feel empowered to request their laboratories to provide high-risk-HPV-only testing, instead of a combined low- and high-risk HPV test," Ms. Lee added.

More work is needed to improve the clinical value of HPV testing, the researchers said. "Eliminating the low-risk HPV test and making the high-risk HPV test the only option would help minimize confusion for providers when ordering the HPV test.

Removing incentives for this practice like insurance reimbursement is another method that may be effective," Ms. Lee said.

"Interventions that can help providers use HPV tests appropriately include changing laboratory requisition forms to reflect guideline-consistent HPV testing and point-of-care decision support algorithms that are designed to give patient-specific recommendations," she said.

In an accompanying editorial, Philip E. Castle, Ph.D., of the American Society for Clinical Pathology in Chicago, noted that the overuse and improper use of HPV testing has negative effects on patients: "A patient who tests HPV positive has a wide range of negative psychosocial and psychosexual outcomes, including anxiety, distress, and a decreased sense of sexual well-being."

Dr. Castle also emphasized the impact of unnecessary HPV testing on the health care system.

"With an estimated \$4 billion spent on cervical cancer prevention screening alone in 2004, we can no longer afford to perform tests that do not benefit our patients" (Obstet. Gynecol. 2011;118:1-3).

Dr. Castle supported the study authors' call for better education of clinicians, because they have the final responsibility for HPV testing.

He said it also would be helpful if payers stopped reimbursing for these unnecessary HPV tests, for that would quickly put a halt to such practices.

Dr. Castle emphasized, "Overuse of HPV testing not only seriously wastes government, payer, and patient dollars, but also potentially harms patients, therefore violating the first tenet of the Hippocratic Oath: Do no harm."

Neither the study authors nor Dr. Castle said they had any relevant financial disclosures. ■

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