Molecular Tests Overused for Genital Infections

BY DOUG BRUNK

FROM THE ANNUAL MEETING OF THE INFECTIOUS DISEASES SOCIETY FOR OBSTETRICS AND GYNECOLOGY

SANTA FE, N.M. — Molecular diagnostic tests appear to be overused for the diagnosis of lower genital tract infections in women, results from an analysis of national practice patterns showed.

VITALS

Major Finding: The use of unrecommended molecular tests for lower genital tract infections increased total molecular test spending by 29%, compared with the cost of recommended molecular tests alone.

Data Source: Laboratory claims from 82,443 patients in a large national insurance database from the year 2008.

Disclosures: Dr. Eckert said that she had no relevant financial conflicts to disclose.

In fact, use of unrecommended tests increased total molecular test spending by 29%, compared with the cost of recommended molecular tests alone.

Vaginitis is a common clinical problem in which accurate diagnosis "can be challenging," Dr. Linda O'Neal Eckert said during the meeting. "In fact, many of us make a living by trying to accurately diagnose challenging cases of vaginitis. The availability of molecular testing for female genital tract infections is definitely increasing. Their use may offer appeal, partly because there's a perception of accuracy when you can get the result back and hope that that might determine the etiology of the symptoms, and also because using these tests does not require a microscope."

Dr. Eckert of the University of Washington, Seattle, and her associates conducted a cross-sectional study of laboratory claims within a large national insurance database for the year 2008. "This database represents 3.5 million commercially insured patients," she said. "More than 500 laboratories are in this database, including both commercial and hospital laboratories."

The researchers used ICD-9 codes to select women who presented for a first evaluation of vaginal and cervical infections, and then identified molecular tests performed to detect infections from laboratory CPT codes billed on the same visit. They used published guidelines (N. Engl. J. Med 2006;355:1244-52; ACOG Practice Bulletin No. 72, May 2006, reaffirmed 2008) to classify molecular tests as either recommended (*Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis*, herpes simplex virus) or not recommended (*Candida* species and subspecies, *Gardnerella vaginalis*, staphylococcus, streptococcus, enterococcus, cytomegalovirus, and others) for use in this setting.

Of 211,933 women in the database, 82,443 met criteria for inclusion in the study. Of these patients, 61,132 (74%) had recommended tests, 17,934 (22%) had both recommended and nonrecommended tests, and 3,377 (4%) had only nonrecommended tests performed at their initial visits.

The use of unrecommended tests increased total molecular test spending by 29%.

DR. ECKERT

The most common molecular test classified as not recommended that was ordered was for the detection of an agent not otherwise specified by amplified DNA probe method. Dr. Eckert reported that this test was performed 15,526 times at an average cost of $21.60 per test, for a total amount spent of $335,290.

The second most common test performed, a direct DNA probe to search for *G. vaginalis,* was performed 14,698 times at an average cost of $21.30 per test, for a total amount spent of $313,298. The third most common test performed, a direct DNA probe for *Candida* species and subspecies, was performed 14,630 times at an average cost of $21.37 per test, for a total amount spent of $312,707.

Overall, a total of $6,328,168 was spent on molecular testing, Dr. Eckert said. Of this total, the cost of recommended tests amounted to $4,816,407 (76.1%), whereas the cost of nonrecommended tests amounted to $1,408,270 million (22.3%). The use of nonspecified molecular tests accounted for the remaining 1.6%, or $103,491.

The researchers determined that the average cost of recommended testing was $61 per patient visit, whereas the average cost of additional unrecommended testing was $66 per visit. In the aggregate, use of unrecommended tests increased total molecular test spending by 29%, compared with the cost of recommend testing alone.

One of the meeting attendees, Dr. Harold C. Wiesenfeld, director of the division of reproductive infectious diseases in the University of Pittsburgh, said that some of his patients who aren't covered by insurance are getting bills approaching $1,400 for vaginitis panels. "There is no data that any clinical outcome is improved based on these tests," he commented.

Dr. Eckert noted that one of the labs studied accounted for the vast majority of nonrecommended molecular testing. "There is a significant variation that occurs between laboratories for the use of recommended vs. nonrecommended molecular tests," she said. ■

Tinidazole Treatment Appears Equal to Metronidazole for Bacterial Vaginitis

BY DOUG BRUNK

FROM THE ANNUAL MEETING OF THE INFECTIOUS DISEASES SOCIETY FOR OBSTETRICS AND GYNECOLOGY

SANTA FE, N.M. — Treatment of bacterial vaginitis with tinidazole at 500 mg twice a day for 7 days was not significantly more efficacious than the standard dose of metronidazole, results from a single-center study demonstrated.

"BV is extremely common and has associated complications, but the therapeutic options that we have are limited and I think we all get frustrated in trying to treat women with BV," Dr. Jane R. Schwebke said at the meeting. "Tinidazole was licensed in the U.S. for BV based on a placebo-controlled study, so we really have no data to compare the efficacy of tinidazole for the treatment of BV … with metronidazole."

In what she described as the first study of its kind, Dr. Schwebke and her associates randomized 593 women with symptomatic BV who attended an STD clinic in Birmingham, Ala., over 4 years to one of three regimens: metronidazole 500 mg b.i.d. for 7 days, tinidazole 500 mg b.i.d. for 7 days, or tinidazole 1 g b.i.d. for 7 days. The researchers conducted follow-up visits at 14 and 28 days and then monthly for two additional visits. Cure was defined as a Nugent score of less than 7 among any of the treatment groups.

'The therapeutic options that we have are limited and I think we all get frustrated in trying to treat women with BV.'

DR. SCHWEBKE

The mean age of the study participants was 28 years and most (92%) were black. Dr. Schwebke, professor of medicine at the University of Alabama, Birmingham, reported that there were no statistically significant differences between the cure rates at the day-14 visit or at the day-28 visit among any of the treatment groups.

Cure rates at the day 14 visit for the metronidazole, tinidazole 1 g b.i.d., and tinidazole 500 mg b.i.d. were 82%, 73%, and 73%, respectively, while the cure rates at the day 28 visit were 64%, 68%, and 62%.

"Interestingly, neither baseline Nugent score, consistent use of condoms, sex with a new partner, nor sex with multiple partners were associated with treatment outcome," Dr. Schwebke said. "However, women who engaged in sex during the study were more likely to have BV at follow-up, which has been a consistent finding among most studies of late."

The side effect profiles were similar among treatment groups, with the most common side effects being yeast infections, nausea/vomiting, and a bad taste in the mouth.

The study was funded by the National Institute of Allergy and Infectious Diseases. Mission Pharmacal Co. provided the tinidazole.

Dr. Schwebke said that she had no relevant financial conflicts. ■

Hypofractionated Irradiation Endorsed

FROM THE INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY*BIOLOGY*PHYSICS

A shorter course of hypofractionated whole-breast irradiation may be substituted for treatment with conventional fractions following breast-conserving surgery in selected patients with early-stage breast cancer.

The new recommendation comes from an evidence-based guideline published by the American Society for Radiation Oncology (Int. J. Radiat. Oncol. Biol. Phys. [doi:10.1016/j.ijrobp.2010.04.042]).

The guideline task force concluded that hypofractionated whole-breast irradiation is just as effective as conventional fractions for women who are at least 50 years old at diagnosis and meet *all* of the following criteria:

- The pathologic stage is T1-2N0, and the patient has been treated with breast-conserving surgery.
- The patient has not been treated with systemic chemotherapy.
- The minimum dose is no less than 93%, and the maximum is no greater than 107% of the prescription dose within the breast along the central axis.

Hypofractionated whole-breast irradiation uses a higher radiation dose for each treatment, but fewer total treatments are necessary. Typically, patients can finish treatment in 4 weeks or less with hypofractionated radiation therapy.

This can help to minimize some of the inconvenience and expense associated with conventionally fractioned whole-breast irradiation, which involves daily treatments for up to 7 weeks.

The guideline authors reported that they have no conflicts of interest.

—Kerri Wachter