Achieving Accurate, Timely Vaginitis Diagnosis

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“Even under research conditions that provided clinicians with sufficient time and materials to conduct a thorough and standardized clinical evaluation, the diagnosis and, therefore, subsequent treatment of these common vaginal problems remains difficult.”

**Background**

Vaginitis is the most common reason for visits to obstetricians and gynecologists, accounting for up to 10 million office visits a year in the U.S. However, clinicians often underestimate the challenges—and importance—of accurate diagnosis of vaginitis. Both published and anecdotal data, including our own experience at Planned Parenthood Southwest Ohio, point to the difficulty of accurate diagnosis based on history, examination, and the use of traditional methods including microscopy, pH, or amine (whiff) test. The availability of new technologies such as DNA probes presents an opportunity to redefine best practice in vaginitis diagnosis.

Accurate diagnosis is essential, first and foremost, because it is the foundation of good patient care. Just treating the patient for the correct pathogen is important in and of itself, not to mention the value it has in building trust and rapport with the patient. Vaginitis has many different etiologies. Three pathogens account for up to 90% of vaginitis cases. Bacterial vaginosis (BV) is associated with a decimation of normal lactobacilli and proliferation of facultative anaerobic bacteria with the sentinel organism being *Gardnerella vaginalis*. Candidiasis, or yeast infection, is most commonly associated with *Candida albicans*. Trichomoniasis is the result of infection by a protozoan, *Trichomonas vaginalis*. Mixed infections are not uncommon. One study found more than one of the three pathogens in 22% of the samples that tested positive for vaginitis. Treatment is available for each of these three diseases, so timely, accurate diagnosis is the first step to effective management.

A second consideration is cost to the patient and to the healthcare system. Persistent or recurrent infections that are often a result of inaccurate or incomplete diagnosis are costly, as is incorrect or unnecessary treatment. Every year, hundreds of millions of dollars are spent on over-the-counter treatments for self-diagnosed yeast infection. A study of women who purchased over-the-counter antifungal medications showed that only 33.7% of the participants actually had candidiasis, while 19% had bacterial vaginosis, 2% had trichomoniasis and 21% had mixed infections. The inaccuracy of self-diagnosis extends to diagnosis by the physician over the telephone, which has been shown to correlate poorly with actual in-office diagnosis.

Further underscoring the importance of accurate diagnosis is growing evidence that links vaginitis to pregnancy complications and other infections including HIV, HSV-2, and other STIs, as well as postoperative infections after gynecological procedures.

**Options for diagnosis of vaginitis**

Traditionally, vaginitis diagnosis is based on a combination of patient history, physical examination and the collection of vaginal samples for pH measurement, whiff test, and microscopy. The presence of clue cells (cells with unclear borders, dotted with bacteria) under the microscope is
indicative of BV. The diagnosis of candidiasis is based on the visualization of spores, pseudohyphae, or buds. Trichomoniasis is diagnosed by wet mount microscopy, where the presence of motile, flagellated trichomonads is diagnostic.10

Training and time constraints are significant limitations for microscopy. A full five minutes at high-field examination is recommended to uncover all potential pathogens present. In a busy office practice, five minutes is “forever” and a goal rarely realized in actual practice. One study found that 42% of physicians did not perform microscopy at all as part of any evaluation of vaginitis.11 If microscopy is performed in the laboratory, sample transport and workflow issues impose additional constraints.

Another limitation is sensitivity. Overall, the diagnosis of trichomoniasis using wet mount microscopy to visualize motile trichomonads has a sensitivity rate of only 55-60%.10 The diagnosis of yeast infection based on visualization lacks sensitivity and specificity.10

Culture is sometimes used when the initial clinical diagnosis is ambiguous. However, culture requires time, appropriate transport media, and additional cost. Further, as low numbers of Candida and anaerobic species (e.g., G. vaginalis) are part of the normal flora, culture colony counts are unreliable for pinpointing pathologic levels of organisms. Not surprisingly, CDC guidelines recommend against the use of culture for G. vaginalis as a diagnostic tool because it is not specific.2 Similarly, the presence of Candida in culture in the absence of symptoms is not an indication for treatment, since Candida species and other yeasts are present in 10-20% of women.2

Several tests designed for use in the physician’s office are available today. These include the OSOM® Trichomonas Rapid Test (Sekisui Diagnostics, Lexington, MA), which tests for T. vaginalis antigens, and the OSOM BVBLUE® Test (Sekisui Diagnostics), which measures vaginal sialidases associated with BV. With the growing awareness of the prevalence of trichomoniasis and its complications, including increased susceptibility to HIV infection,7 and CDC guidelines recommending screening for T. vaginalis in women considered at high risk for infection,2 a number of laboratory tests for T. vaginalis are becoming available.

DNA probe technology: the Planned Parenthood Southwest Ohio experience

In November 2012, we began a pilot project, initially at two of our health centers and expanding to all six health centers by early January, to evaluate the BD Affirm™ VPIII Microbial Identification Test (BD Diagnostics, Sparks, MD), which simultaneously detects the three pathogens associated with up to 90% of vaginitis cases in less than an hour.12 We looked at six evaluation criteria: change in diagnostic trends, decrease in “bouncebacks” or return visits due to unsatisfactory resolution of symptoms, improvement in patient satisfaction, improvement in clinician satisfaction, improvement in clinical flow, and reimbursement.

Comparing our experience during our first two months of using BD Affirm to the previous two months using microscopy pointed to some interesting trends. There was an overall increase in pickup of mixed infections (in particular, the combination of BV and T. vaginalis, as well as the presence of all three pathogens) and a decrease in the number of Candida infections. In the cases of returning patients who were previously tested using wet mount, 7 out of 11 received a different diagnosis when the BD Affirm test was used. Our initial observations also showed that clinician satisfaction and clinical workflow both improved. Reimbursement from all nine of our payers increased significantly.

A call to action

Many physicians approach vaginitis diagnosis with antiquated tools that are imprecise, subjective, and labor-intensive. The pathogens associated with the
vast majority of vaginitis cases are readily treated with topical and/or oral agents if the correct diagnosis (or, importantly, diagnoses) is made. Having a single test to readily detect all three of these pathogens in less than an hour allows for targeted treatment and preventive intervention such as counseling of sex partners. This not only benefits patients by reducing discomfort and complications, but also benefits the health-care system by freeing up resources and reducing the costs of return visits due to unresolved conditions, unnecessary drugs, and complications. The accuracy of diagnosis, together with early evidence of improved clinical workflow and clinician satisfaction at our clinics, holds promise for the use of DNA probe technology in general, and the BD Affirm™ VPIII Microbial Identification Test in particular, in improving vaginitis diagnosis and therefore elevating patient care and reducing costs.

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References