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# Trichomoniasis:

The "Neglected" Sexually Transmitted Disease

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#### INTRODUCTION

Trichomoniasis is a sexually transmitted disease (STD) caused by the parasite *Trichomonas vaginalis* (Fig. 1). Although this infection is common in the United States and worldwide, it has been considered a "neglected" parasitic infection, due to limited knowledge of its sequelae and associated costs.

## **EPIDEMIOLOGY**

T vaginalis infection is the most prevalent nonviral sexually transmitted infection:

- In the United States, an estimated 3.7 million people are infected with *T vaginalis*, more than chlamydia and gonorrhea combined.<sup>1</sup>
- There are an estimated 1.1 million new *T vaginalis* infections annually in the United States.<sup>1</sup>
- About 3% of the United States population is believed to carry T vaginalis infection.<sup>2</sup>

Health disparities by sex, age, and race are prominent in the epidemiology of T vaginalis:

- Infections are believed to be more common among women, with an estimated 16 infected women for every 10 infected men.<sup>3</sup>
- Infections are more common with increasing age, with prevalence peaking above 11% among women aged 40 years and older.<sup>2,4</sup>

Disclosures: None.

• Infections are more common among certain racial and ethnic groups, affecting an estimated 13.3% of black women and 1.8% of Hispanic women, compared with 1.3% of white women in the United States.<sup>2</sup>

Particularly high prevalences of T vaginalis infection have been detected among incarcerated men and women (up to 32%)<sup>5</sup> and patients at STD clinics (up to 17%).<sup>6</sup> In addition, incident T vaginalis infections are up to twice as common among individuals infected with the human immunodeficiency virus (HIV).<sup>7,8</sup> By contrast, studies among men who have sex with men have found low prevalences of T vaginalis infection.<sup>9,10</sup>

# **PATHOPHYSIOLOGY**

The *T vaginalis* parasite is a single-celled protozoan with 4 flagella at one end. Under a microscope, these flagella may be seen propelling the parasite. Infection may produce local inflammation as parasites adhere to mucosal tissue. *T vaginalis* parasites can infect both women and men, and are passed readily between sex partners, usually during penile-vaginal sex. <sup>11</sup>

T vaginalis thrives in certain moist areas of the body:

- Urethra, male or female
- Vagina
- Vulva

These parasites do not commonly infect the hands, mouth, or rectum. *T vaginalis* parasites require a human host and do not affect any other animals. Although these parasites might be able to survive for a few minutes in damp environments outside the human body, there have been no proven cases of transmission via shared baths, toilets, or towels.

Clinical signs and symptoms of trichomoniasis are variable and may include:

- Itching or irritation
- Local erythema
- Burning sensation during urination or ejaculation
- Vaginal or urethral frothy discharge that may be any color but is classically yellow/ green and malodorous
- None, because 70% to 85% of infected persons are asymptomatic<sup>2,12</sup>

Initial symptoms may develop within 5 to 28 days. However, untreated infections can last for months to years, and symptoms might occur at any time. 13

#### **DIAGNOSIS**

Several newly available diagnostic assays may improve the ability to identify *T vaginalis* infections in comparison with traditional methods. Available diagnostic methods include the following:

 APTIMA Trichomonas vaginalis assay, a highly sensitive nucleic acid amplification test (NAAT)

- OSOM Trichomonas Rapid Test, a dipstick that can be used at the point of care
- Affirm VPIII, a nucleic acid probe that assesses 3 microbial causes of vaginitis
- Wet mount microscopy, a common low-cost test with poor sensitivity
- Culture, the traditional gold-standard method

The first highly sensitive NAAT was cleared by the United States Food and Drug Administration (FDA) in 2011. The APTIMA Trichomonas vaginalis assay (Hologic Gen-Probe, San Diego, CA) can be used on vaginal, endocervical, or urine specimens. This assay uses transcription-mediated amplification with a clinical sensitivity of 95% to 100% and specificity of 95% to 100%, producing results within hours. <sup>14–16</sup> Although the assay has not been cleared by the FDA for use with penile swabs or urine from men, some laboratories have procedures in place to use the components as an in-house test. This test method may be particularly appealing for laboratories that use the same platform to conduct chlamydia and gonorrhea screening tests, as this assay can be run on the same specimen.

Same-day tests cleared by the FDA for the diagnosis of trichomoniasis include the OSOM Trichomonas Rapid Test (Sekisui Diagnostics, Framingham, MA), and the Affirm VPIII (Becton Dickinson, San Jose, CA). The OSOM is a CLIA (Clinical Laboratory Improvement Amendments)-waived dipstick assay that can provide results at the point of care within approximately 10 minutes. It is an antigen-detection test that uses immunochromatographic capillary flow technology on vaginal swabs with sensitivity of 82% to 95% and specificity of 97% to 100%. <sup>15,17</sup> The Affirm VPIII evaluates causes of vaginitis including *T vaginalis*, *Gardnerella vaginalis*, and *Candida albicans*. The probe for *T. vaginalis* uses nucleic acid probe-hybridization with sensitivity of 63% and specificity of 99.9%, and takes about 45 minutes in the laboratory. <sup>16</sup> Neither the OSOM nor the Affirm VPIII has been approved by the FDA for use on male specimens.

Traditionally, the most common method used to identify *T vaginalis* has been wet mount (saline) microscopy, whereby clinician or laboratory operator examines a mixture of saline and genital fluid (eg, vaginal discharge) on a glass slide under a microscope, attempting to identify the characteristic motile parasites of *T vaginalis*. Advantages of this method include low cost and immediate results, but major disadvantages are variability in skill and generally poor sensitivity, even with experienced observers (51%–65%), especially for specimens from males. <sup>15,18</sup> Wet mount specimens should be examined as soon as possible after collection for best results, as sensitivity declines rapidly after specimen preparation. <sup>19</sup>

The traditional gold standard is culture, a highly specific method for identifying *T vaginalis*, but disadvantages include the need for specialized equipment including transport and culture media, and a delayed time to result. Cultures may be inoculated with a variety of specimen types from men or women, including genital secretions, semen, or urine.

Neither traditional nor liquid-based Papanicolaou tests (Pap smears) are considered appropriate diagnostic or screening tests for trichomoniasis because of their poor

sensitivity.  $^{20,21}$  However, the specificity of liquid-based cytology for T vaginalis is high.  $^{22,23}$  When the parasite is an incidental finding, treatment is usually indicated, although at the discretion of the clinician for asymptomatic patients.  $^{24}$ 

The main reasons to check for *T vaginalis* are:

- To reduce symptoms by treating disease
- To reduce potential sequelae by curing infection

Diagnostic testing is recommended for all women presenting with symptoms of trichomoniasis (ie, vaginitis or vaginal discharge). For men with symptoms of trichomoniasis (ie, urethritis), trichomoniasis is less likely to be the cause, but testing could be considered if initial workup does not yield an alternative diagnosis. If diagnostic tests appropriate for use in males are not available, therapy for trichomoniasis can be considered as a second-line therapy for nongonococcal urethritis, recommended if the initial empiric regimens for nongonococcal urethritis (usually azithromycin or doxy-cycline) fail. <sup>25,26</sup>

Screening for *T vaginalis* infection is recommended for HIV-infected women at entry to care and at least annually thereafter.<sup>24</sup> Screening may be considered for asymptomatic persons receiving care in high-prevalence settings such as STD clinics and correctional facilities, as well as those at high risk of infection or disease (eg, persons with new or multiple sex partners or history of any STD). Decisions about screening may be informed by local, regional, or national epidemiology of *T vaginalis* infection.

The benefits and effectiveness of screening asymptomatic men are still unknown. In the absence of scientific evidence that symptoms or sequelae could be reduced by treatment of *T vaginalis*, testing and screening are not recommended for men.

#### CLINICAL MANAGEMENT

Infections usually can be cured with 5-nitroimidazole antimicrobials, which are the only class of medications approved by the FDA for treatment of trichomoniasis. First-line therapy consists of either metronidazole (Flagyl) or tinidazole (Tindamax), 2 g in a single dose, given either orally or intravenously (Box 1). These medications are widely available and fairly inexpensive, particularly metronidazole. Tinidazole has a longer half-life and achieves a higher genitourinary tract drug level than metronidazole, but it is more expensive. Topically applied antimicrobials such as metronidazole gel have high failure rates (>50%). Treating patients and all sex partners can cure infection, reduce symptoms, and reduce transmission.<sup>24</sup>

#### Box 1

Recommended regimens for treating trichomoniasis, according to the 2010 STD treatment guidelines of the Centers for Disease Control and Prevention

Recommended Regimens

Metronidazole: 2 g orally in a single dose

OR

Tinidazole: 2 g orally in a single dose

Alternative Regimen

Metronidazole: 500 mg orally twice a day for 7 days

*From* Workowski KA, Berman S, Centers for Disease Control and Prevention. Sexually transmitted disease treatment guidelines, 2010. MMWR 2010;59(RR-12):

1-110.

Allergy and antimicrobial resistance are of concern, given the lack of effective alternatives to nitroimidazoles.

Allergic reactions should be distinguished from potential side effects of nitroimidazole medication, which can include disulfiram-like reactions with flushing. True hypersensitivity reactions occur occasionally and may include urticaria, pruritus, facial edema, erythema, and gastrointestinal or other symptoms; true anaphylaxis is rare. Desensitization therapy according to a 14-step incremental dosing protocol can be effective in the management of trichomoniasis for patients with nitroimidazole hypersensitivity.<sup>27</sup>

When trichomoniasis does not respond to standard therapy, considerations include reinfection versus refractory disease. If reinfection from an untreated partner is excluded, patients can be treated with the alternative regimen of metronidazole, 500 mg orally twice daily for 7 days. For disease refractory to both recommended and alternative regimens, treatment with tinidazole or metronidazole, at least 2 g orally for 5 to 7 days, can be considered. If none of these regimens are effective, consultation with a specialist may be helpful, ideally including antimicrobial susceptibility testing to determine the resistance profile of the parasite.<sup>24</sup>

Antimicrobial resistance is an emerging issue of concern, given the lack of effective alternative treatments for trichomoniasis. In vitro, approximately 4% of *T vaginalis* parasites exhibit some degree of resistance to metronidazole, although correlation with clinical outcomes remains unclear. Tinidazole may be more active against *T vaginalis* isolates that demonstrate resistance. Susceptibility testing and consultation are available from the Centers for Disease Control and Prevention.<sup>28</sup>

## **ADVERSE OUTCOMES**

Traditionally there has been little appreciation of adverse outcomes associated with *T* vaginalis infection, as trichomoniasis rarely results in hospitalizations or deaths. An analysis of the direct medical costs of incident sexually transmitted infections in the United States estimated that 1.1 million new cases of trichomoniasis per year cost only US\$24 million.<sup>29</sup> In that analysis, the lifetime cost per case of trichomoniasis, at \$22, was the least expensive of any sexually transmitted infection, based on the assumption that persons with untreated *T* vaginalis infections do not incur any costs.<sup>29</sup> However, various recent studies have increased appreciation for the possibility that even asymptomatic *T* vaginalis infections can be linked

to a variety of other health problems. Conditions shown to be associated with *T vaginalis* infection include:

- Increased risk of HIV acquisition and transmission<sup>30</sup>
- Increased prevalence of other sexually transmitted infections<sup>31</sup>
- Adverse outcomes of pregnancy (eg, preterm delivery)<sup>32</sup>
- Pelvic inflammatory disease among HIV-infected women<sup>33</sup>

T vaginalis infection was an independent risk factor for HIV in several recent studies, which found it to significantly increase the risk of acquiring HIV by 2 to 3 times.  $^{30,34,35}$  Furthermore, maternal T vaginalis infection in an HIV-infected woman nearly doubles the risk of vertical transmission of HIV to the infant.  $^{36}$  Interestingly, HIV-infected women are less likely to shed HIV vaginally after receiving treatment for trichomoniasis.  $^{37,38}$  However, there are no data to show that treating T vaginalis can reverse the increased risks of HIV acquisition or transmission.

In a nationally representative study, 6 other sexually transmitted infections (chlamydia, gonorrhea, herpes simplex virus type 1, herpes simplex virus type 2, syphilis, and HIV) all were more common among women with a positive test for *T vaginalis*.<sup>31</sup>

Pregnant women who are infected with T vaginalis are more likely to deliver preterm infants, with correspondingly low birth weights. <sup>32,39</sup> In addition, ecological studies have suggested links between maternal trichomoniasis during pregnancy and having a child with intellectual disability or attention deficit/hyperactivity disorder, although the mechanism of association remains unclear. <sup>40,41</sup> Among HIV-infected women, those with concomitant T vaginalis infection are at a significantly increased risk for pelvic inflammatory disease. <sup>33</sup>

Researchers have also investigated possible associations between trichomoniasis and other conditions, such as male and female infertility<sup>42,43</sup> or prostate cancer,<sup>44,45</sup> but these relationships remain uncertain.

Additional studies considering the aforementioned sequelae would produce higher estimates of the costs of *T vaginalis* infections. For example, a mathematical model of HIV infections attributable to trichomoniasis in the United States estimated that each year, 746 new HIV cases among women could be attributed to trichomoniasis, at a lifetime cost of approximately \$167 million. 46

# **SPECIAL CONSIDERATIONS**

HIV

HIV-infected individuals should be screened at least annually for *T vaginalis* infections, given the high prevalence, <sup>7</sup> increased risk of pelvic inflammatory disease, <sup>33</sup> and ability of nitroimidazole treatment to reduce HIV viral shedding. <sup>37</sup> Those who are found to be infected with *T vaginalis* may benefit from an extended course of treatment. A study comparing the single-dose regimen with the 7-day alternative regimen of metronidazole

found that HIV-infected women receiving the longer treatment course had a reduced risk of remaining infected with *T vaginalis*, both at test of cure and 3 months later.<sup>47</sup>

### **Pregnancy and Breastfeeding**

Screening and treatment for T vaginalis infections can be considered for pregnant women, although it remains unclear whether such intervention improves outcomes for pregnant women and their infants. Metronidazole is safe for use during any stage of pregnancy or breastfeeding, although tinidazole should be avoided because of a theoretical risk to the infant.  $^{24,48}$ 

#### Children

*T vaginalis* colonization of the neonate has been known to occur during delivery and usually self-resolves within weeks without sequelae. Treatment is not usually necessary. In a child, *T vaginalis* infection is suspicious for sexual abuse.

#### **PREVENTION**

Approaches to preventing trichomoniasis include:

- Abstaining from sex
- Using condoms
- Ensuring that all sex partners receive adequate treatment
- Refraining from douching

STDs, including trichomoniasis, can be avoided by abstaining entirely from sex. Among sexually active individuals, however, a more realistic approach may be to use condoms consistently and correctly.<sup>49</sup>

All sex partners of a person diagnosed with T vaginalis infection should be notified promptly and treated appropriately before resuming sexual activity. Patient-delivered partner therapy has been found to be as effective as standard notification, and is an option in states where this strategy is permissible. $^{50,51}$ 

Douching is not effective in reducing trichomoniasis; on the contrary, this practice may be a risk factor for *T vaginalis* and other sexually transmitted infections.<sup>2,52</sup>

#### **CONTROVERSIES**

Neither trichomoniasis nor *T vaginalis* infection is a nationally notifiable condition in the United States. <sup>53</sup> Furthermore, neither the infection nor the disease is currently reportable to the health department of any state. Although the frequency, communicability, and associated health disparities have been clearly identified, consistent data are still lacking regarding severity of infection, preventability of associated adverse events, and costs. Finally, there has been little interest in this infection among members of the general public. <sup>53</sup>

# SUMMARY

Although *T vaginalis* infection is quite common, and usually curable with a widely available and fairly inexpensive medication, a lack of public awareness makes trichomoniasis a "neglected" STD. Disparities in the prevalence of infection by sex, age, race/ethnicity, and setting should be recognized. The emergence of antimicrobial resistance and lack of alternative treatments is of concern. Additional data regarding the severity and costs of infection, as well as evidence that treatment of *T vaginalis* can prevent associated conditions, could lead to wider recognition of this infection in the future.

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#### **KEY POINTS**

• Although *Trichomonas vaginalis* is the most prevalent curable sexually transmitted infection, it has been considered a "neglected" parasitic infection, due to limited knowledge of its sequelae and associated costs.

- Newly available diagnostic methods, including nucleic acid amplification tests, may improve the ability to identify trichomoniasis in the clinical setting.
- Infections usually can be cured with a single oral dose of a nitroimidazole antimicrobial (eg, metronidazole or tinidazole). Allergy and antimicrobial resistance are of concern, given the lack of effective treatment alternatives.
- Prevention approaches include condoms and treatment for all sex partners.



Fig. 1. *Trichomonas vaginalis* parasites.