

Don't Get Tricked by Trichomonas: A Neglected Sexually Transmitted Infection

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- Lupin Pharmaceuticals
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- Roche Molecular Diagnostics
- Becton Dickinson
- Abbott Molecular
- DynaMed

Learning Objectives

- Review the epidemiology of *T. vaginalis* infection
- Review clinical consequences of infection in women and men
- Provide an overview of why *T. vaginalis* is considered a neglected sexually transmitted infection (STI)
- Provides updates in diagnosis and treatment, as outlined in the 2021 CDC STI Treatment Guidelines
 - New molecular diagnostic tests
 - Changes in the recommended treatment in women
 - Treatment in the setting of 5-nitroimidazole hypersensitivity and drug resistance

Sexually Transmitted Infections Treatment Guidelines, 2021

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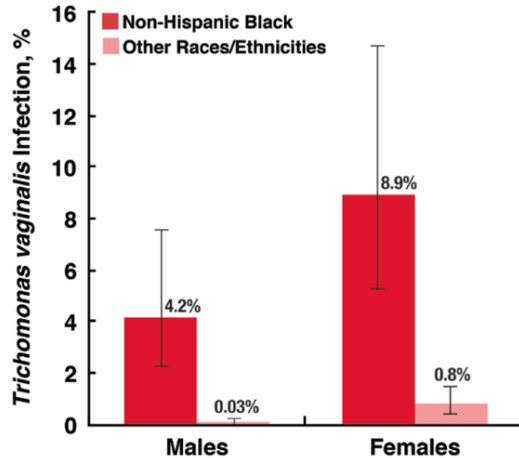


Trichomonas vaginalis – Summary of Changes in the Guidelines

- U.S. national prevalence data in women and men added
- Language added on *T. vaginalis* and an increased risk of cervical cancer
- Updated *T. vaginalis* molecular diagnostics section
- Change in treatment recommendations:
 - **Metronidazole 500 mg po bid X 7 days now the recommended treatment for ALL women**
 - Metronidazole 2 gram stat dose remains the recommended treatment for men
 - First time in the history of the guidelines that treatment for an STI is different based on gender

Epidemiology of *T. vaginalis* in U.S. Women and Men, NHANES 2013-2014¹

- Prevalence among U.S. women (1.8%) and men (0.5%) ages 18-59 (urine specimens tested with the Hologic Gen-Probe Aptima *T. vaginalis* NAAT)



- T. vaginalis* significantly associated with female sex, black race, older age, <high school education, being below the poverty level, and having ≥ 2 sexual partners in the past year
 - Racial disparity for *T. vaginalis* in the black population exceeds that for chlamydia, HSV-2, and HPV**
- Prevalence estimates exceed estimates of *T. vaginalis* burden in other high-income countries (i.e. UK)²

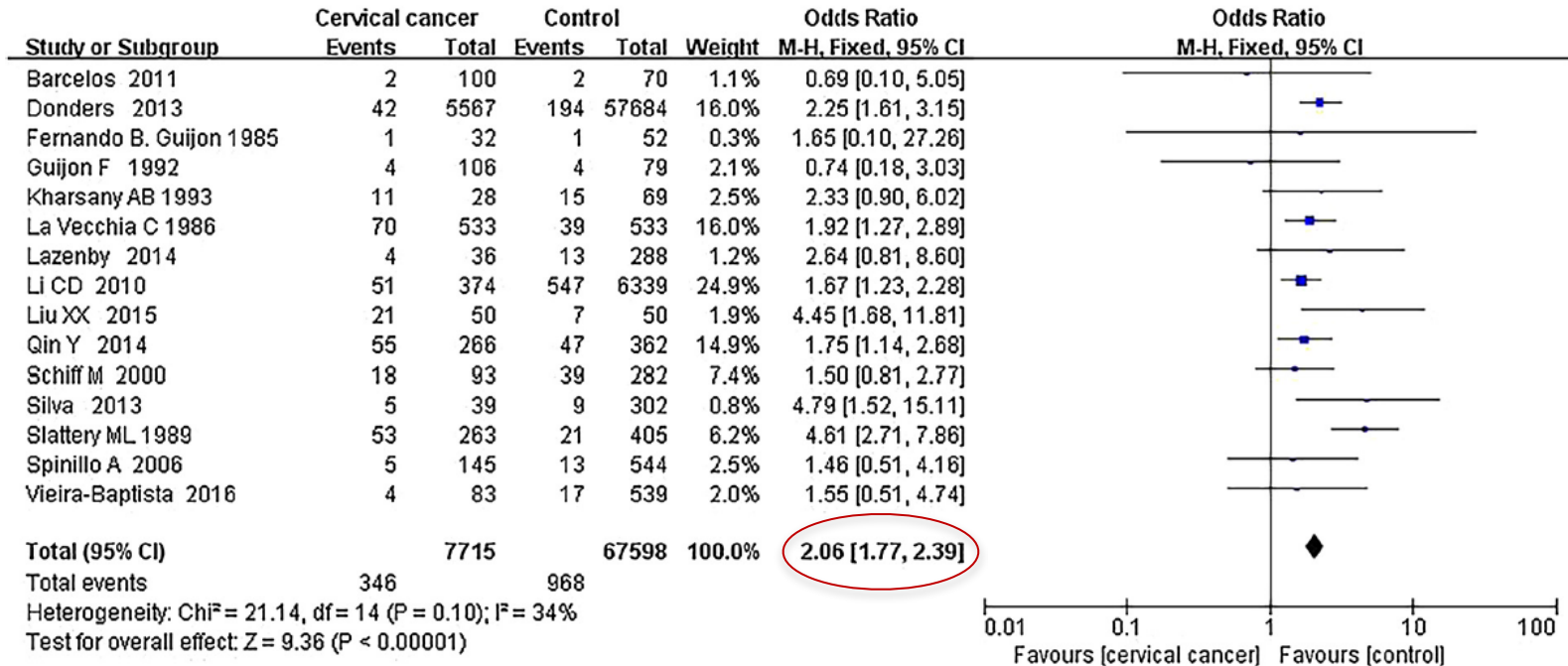
Epidemiology of *T. vaginalis* at the Jefferson County Health Department (JCDH) STD Clinic

Birmingham, AL

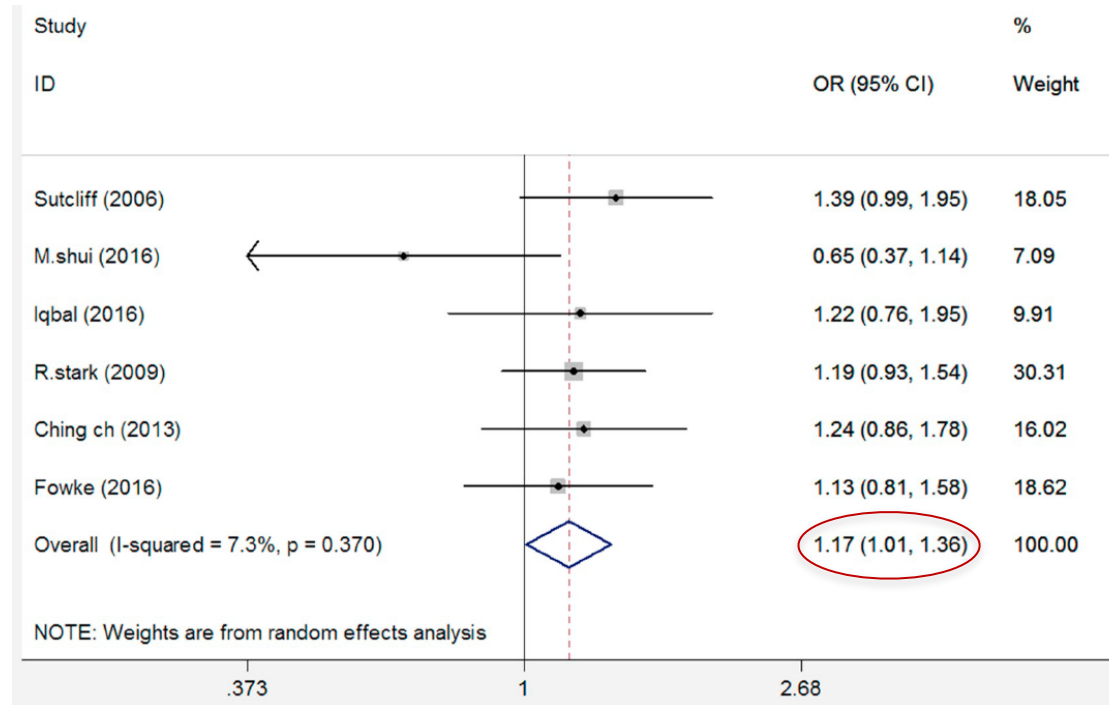


- In 2012, the JCDH STD clinic initiated *T. vaginalis* screening for all women and men presenting to the clinic using *T. vaginalis* NAAT
- Clinical and laboratory data of men (n=2,514) and women (n=3,821) receiving a *T. vaginalis* NAAT between 2012-2013 reviewed
- *T. vaginalis* prevalence: **20.2%; 27.0% in women and 9.8% in men**
- Correlates of *T. vaginalis* in women: age >40, African American race, WBC on wet mount, elevated vaginal pH, positive whiff test, co-infection with gonorrhea
- Correlates of *T. vaginalis* in men: age >40, African American race, ≥ 5 PMNs/HPF on urethral Gram stain
- *T. vaginalis* NAAT detected 1/3 more infections in women than wet mount alone

T. vaginalis and Risk of Cervical Cancer



T. vaginalis and Risk of Prostate Cancer



Additional Clinical Consequences of Untreated Trichomonas Infection



- Vaginitis, cervicitis, endometritis, increased risk of post-gyn surgical infection
- Premature rupture of membranes, low infant birth weight, long-term developmental problems
- Increased risk of HIV infection
- Fallopian tube damage, infertility

Despite it's High Prevalence and Clinical Consequences of Infection, *T. vaginalis* Is Considered a Neglected STI

- There are no established *T. vaginalis* screening, surveillance, or control programs for women or men in the U.S.¹
- Routine screening is only “recommended” in HIV-infected women, at entry to care and then annually²
- Screening is only “considered” for persons in high prevalence settings (STI clinics, correctional facilities) and asymptomatic persons at high risk (multiple sex partners, exchange of sex for money or drugs, illicit drug use, STI history)²

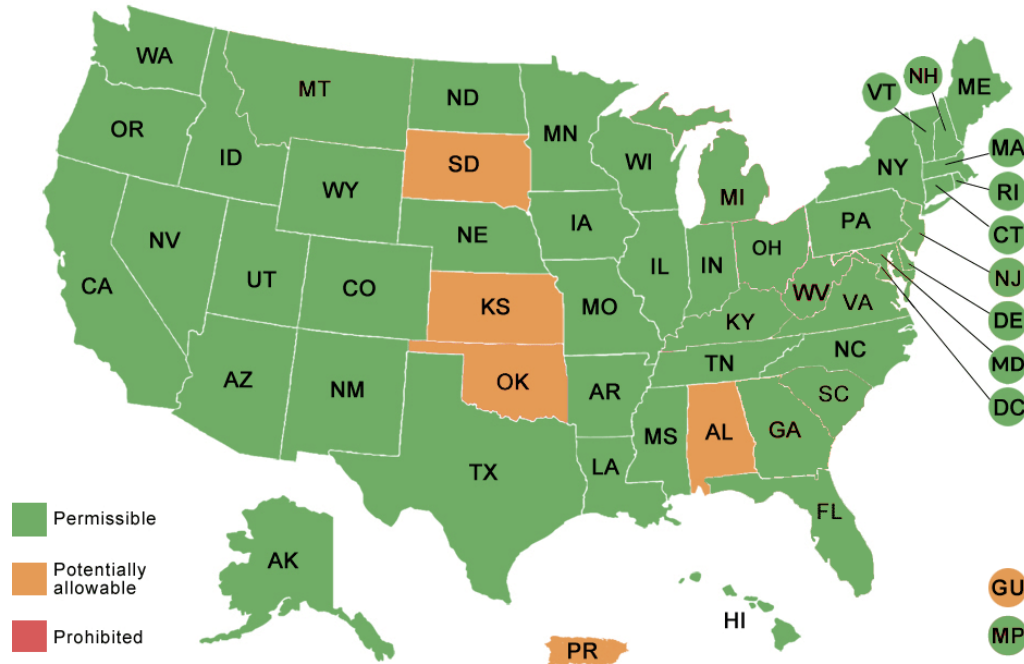
Lack of National Surveillance for *T. vaginalis*

- *T. vaginalis* previously said to meet only 3* out of 7 necessary criteria:
- Frequency*
- Associated disparities or inequities *
- Communicability – we know it is an STI *
- Severity – adverse outcomes said to be “uncommon” among mainly asymptomatic patients, although not studied in detail
- Associated costs – minimal data available on cost reduction from screening
- Preventability – no data on whether a national control program would reduce *T. vaginalis* prevalence
- Public Interest – however, a lack of public interest may reflect a lack of public knowledge

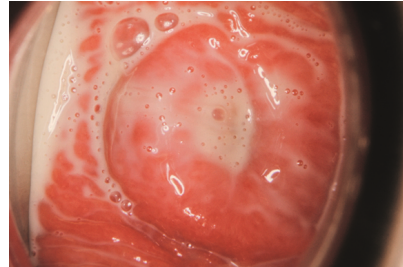
Not All Successful STI Control Measures are Being Used for Trichomoniasis¹

- Use of sensitive screening tests - *T. vaginalis* NAATs are available but not always widely used, particularly in men
- Availability of effective, affordable medications – MTZ (metronidazole) treatment of *T. vaginalis* is the most affordable treatment for any STI
- Accurate reporting of cases – not available for *T. vaginalis*
- Initiation of mandatory reporting to the CDC – not done for *T. vaginalis*
- Treatment of infected partners – EPT (expedited partner therapy) permissible in many but not all states and has mainly been used for treatment of male sexual partners of women with chlamydia or gonorrhea

Legal Status of Expedited Partner Therapy (EPT)



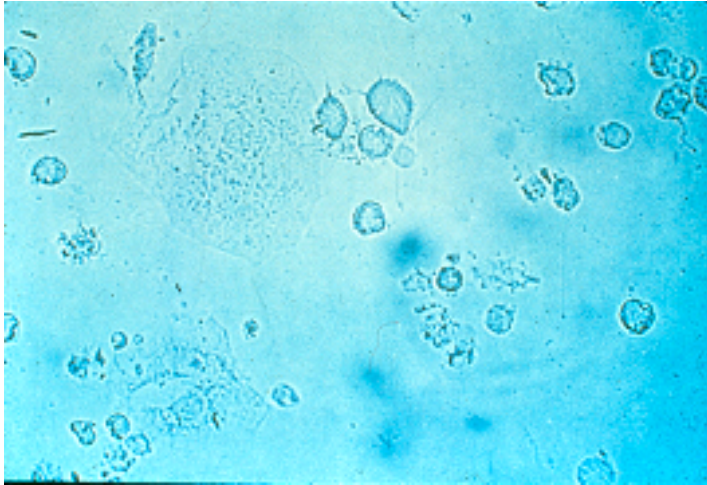
T. vaginalis Diagnosis



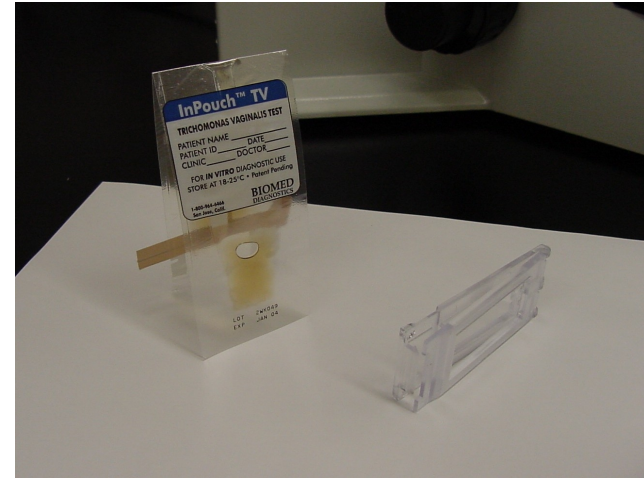
Case Presentation

- A 20-year-old woman with a history of trichomoniasis comes to the sexual health clinic with her new boyfriend to get an HIV test and be screened for chlamydia, gonorrhea, and trichomonas infection. She does not have any current genital symptoms.
- Which one of the following would you recommend as the preferred screening test for detecting *T. vaginalis* in this asymptomatic woman?
 - A) Wet-mount microscopy of vaginal secretions
 - B) Culture of a first-catch urine specimen
 - C) Culture of a mid-stream urine specimen
 - D) Nucleic acid amplification testing (NAAT) on a vaginal swab specimen
 - E) Culture of vaginal secretions

Traditional *T. vaginalis* Diagnosis: Wet Mount and Culture

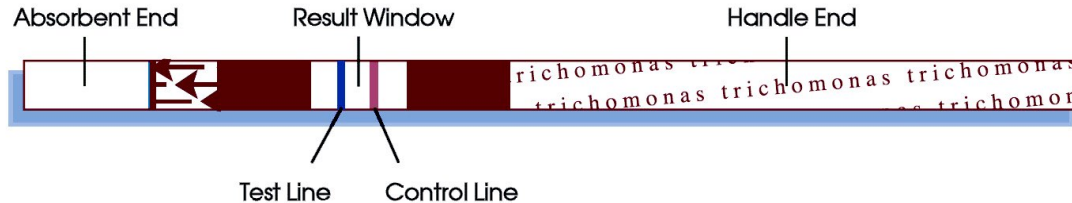


- Point-of-care test
- Must be performed in 10-20 minutes after specimen collection or trichomonads will lose viability
- **Sensitivity 44-68%**; Specificity 100%



- Need to inoculate InPouch within 1 hour of specimen collection (women: urine; men: urethral swab, urine sediment, semen)
- Requires incubation at 37°C
- **Sensitivity 44%–75%**; Specificity 100%

OSOM[®] Test Stick: Rapid Antigen Test for *T. vaginalis*



Performed on vaginal secretions: uses antibodies to detect trichomonas protein antigens
Sensitivity 83%, Specificity 97%; not validated in men

Positive test for detection of *T. vaginalis* antigen: blue test line and a red control line; results in 10 minutes
Cost can add up: test + have to buy a positive control kit

Hologic Aptima *T. vaginalis* NAAT - 2011

- The first *T. vaginalis* NAAT FDA-approved for use in women
 - Can be used on vaginal swab, endocervical swab, ThinPrep Pap, and urine specimens
- Sensitivity 95-100%; Specificity 98-100%
- Assay performance similar in asymptomatic and symptomatic women
- Requires central lab processing; results not available in real-time
- **Not FDA-approved for use in men; needs to be internally validated prior to being used in patient care**

BD ProbeTec Qx *T. vaginalis* NAAT¹ – 2014

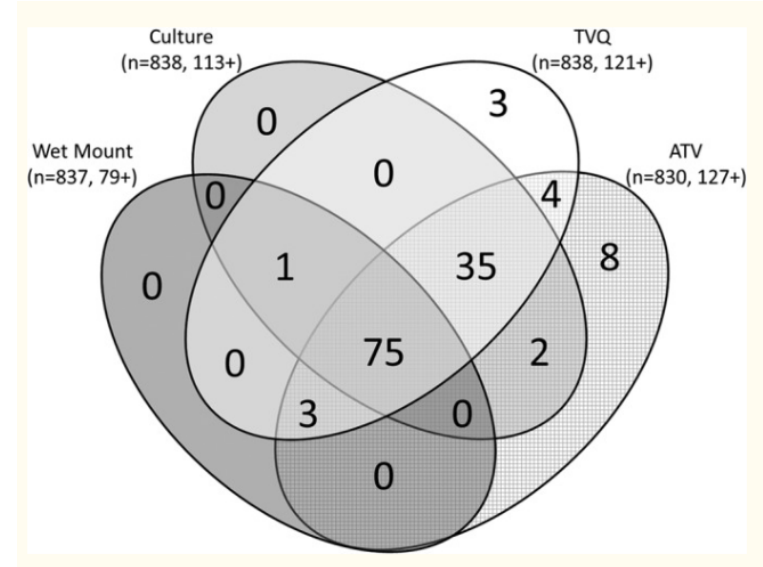
FDA-approved for use in women-vaginal specimens (patient or clinician-collected)

Requires central lab processing; results not available in real-time

Has superior performance vs. wet mount ($p < 0.001$); equivalent to the Aptima *T. vaginalis* NAAT ($p = 0.09$)

Not FDA-approved for use in men; needs to be internally validated

***BD CTGCTV2 assay - 2016** - approved for *T. vaginalis* diagnosis in men using urine samples, with 97.9% sensitivity and 99.7% specificity while also detecting chlamydia or gonorrhea coinfection simultaneously²



Cepheid Xpert® *T. vaginalis* NAAT - 2018



- **FDA-approved *T. vaginalis* NAAT for use in both women and men** that enables on-demand testing for same-day consultation and treatment
- Multi-center study using the Xpert® *T. vaginalis* Assay to test specimens from women and men
 - 1,867 women and 4,791 men
- In women, performance of the Xpert Assay compared to culture and Aptima *T. vaginalis* NAAT
- Sensitivity and specificity for combined female specimens (first catch urine, self-collected vaginal swabs, and clinician-collected endocervical swabs): 99.5-100% and 99.4–99.9%
- For male first catch urine, sensitivity and specificity were 97.2% and 99.9%, compared to culture
- Assay can provide on-demand results in 63 minutes or less, with early termination for positive results ~ 40 minutes → diagnosis in real time (uses smaller instrumentation)

Roche Cobas® TV/MG assay - 2019

- Performed on the Cobas® 6800/8800 platform
- FDA-approved for *T. vaginalis* diagnosis **in women and men (male urine)**
- Can also reliably detect the presence of *Mycoplasma genitalium* infection
- Samples used for chlamydia/gonorrhea testing can also be used for *T. vaginalis* and *M. genitalium* testing, when appropriate, in the same run
 - **Note:** Screening for *M. genitalium* is not currently recommended in any population (2021 CDC STI Treatment Guidelines); consider masking results

Visby Medical™ Sexual Health Testing Device - 2021

- First, single-use, rapid, point-of-care PCR device for the detection of chlamydia, gonorrhea, and trichomonas
- FDA-approved for use in self-collected vaginal specimens from women
- Results available in <30 minutes without complex instrumentation
- High sensitivity and specificity



Back to Our Case Presentation: Optimal Timing of *T. vaginalis* Test Results

- POC molecular STI diagnostic tests may be advantageous over traditional standard-of-care diagnostic tests as they can be performed rapidly while patients are in clinic, leading to an accurate diagnosis with the correct treatment provided.
- In the absence of this type of testing, patients may be treated in a syndromic fashion, taking into consideration whether they are a contact to a known STI
 - Inappropriate antibiotic use may occur in this setting as well as patient anxiety while waiting on their test results

Treatment of *T. vaginalis*



2021 Recommended and Alternative *T. vaginalis* Treatment Regimens



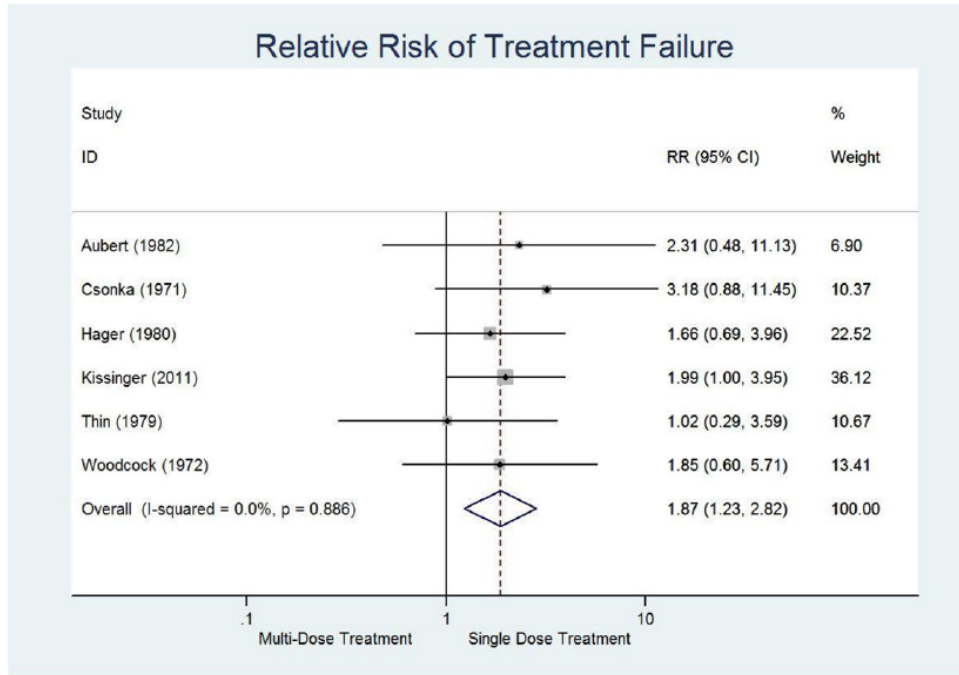
Recommended Regimen for Trichomoniasis Among Women
Metronidazole 500 mg orally 2 times/day for 7 days

Recommended Regimen for Trichomoniasis Among Men
Metronidazole 2 g orally in a single dose

Alternative Regimen for Women and Men
Tinidazole 2 g orally in a single dose



Single-dose compared to multi-dose metronidazole for the treatment of trichomoniasis in women: A meta-analysis



The pooled risk ratio indicated higher treatment failure for single dose MTZ compared to multi-dose MTZ: 1.87 (95% confidence interval, 1.23-2.82; $p < 0.01$)

Single-dose versus 7-day-dose metronidazole for the treatment of trichomoniasis in women: an open-label, randomised controlled trial

Patricia Kissinger, Christina A Muzny, Leandro A Mena, Rebecca A Lillis, Jane R Schwebke, Laura Beauchamps, Stephanie N Taylor, Norine Schmidt, Leann Myers, Peter Augostini, William E Secor, Martina Bradic, Jane M Carlton, David H Martin

- HIV-negative women recruited between October 2014 – April 2017 from 3 STD clinics: New Orleans, LA, Jackson, MS, and Birmingham, AL
- Randomized 1:1 to 2 gram oral MTZ vs. MTZ 500 mg po BID X 7 days
- Primary outcome: *T. vaginalis* infection by intent-to-treat at test of cure (TOC), 4 weeks after completion of treatment - diagnosed by NAAT and/or culture
- Analysis of primary outcome also stratified by BV status (defined by Nugent score)

--Of 1,028 patients assessed for eligibility, **623 were randomly assigned to treatment groups**

--Self-reported adherence was 99% in the single dose group and 96% in the 7-day dose group; side effects were similar by group; the most common being N/V, HA

	7-day-dose metronidazole group	Single-dose metronidazole group	7-day-dose vs single-dose difference (95% CI)	Relative risk (95% CI)	p value*
Primary outcome analyses by intention to treat†					
<i>Trichomonas vaginalis</i> infection at test-of-cure	34/312 (11%)	58/311 (19%)	-7.8 (-2.2 to -13.3)	0.55 (0.34 to 0.70)	<0.0001
Among patients with bacterial vaginosis at baseline	16/125 (13%)	26/125 (21%)	-8.0 (-12.8 to -20.8)	0.59 (0.43 to 0.80)	0.0002
Among patients without bacterial vaginosis at baseline	13/139 (9%)	24/140 (17%)	-7.8 (-0.2 to -15.8)	0.57 (0.45 to 0.71)	<0.0001
Sensitivity analyses of primary outcome					
All missing TOC results reclassified as negative	29/312 (9%)	51/311 (16%)	-7.1 (-1.9 to -12.4)	0.57 (0.45 to 0.71)	<0.0001
All missing TOC results reclassified as positive	71/312 (23%)	92/311 (30%)	-6.8 (-0.1 to -13.7)	0.77 (0.70 to 0.85)	<0.0001
<i>T vaginalis</i> culture results as outcome‡	22/269 (8%)	41/270 (15%)	-7.0 (-1.3 to -12.7)	0.54 (0.39 to 0.75)	0.0002
NAAT and <i>T vaginalis</i> culture results as outcome‡	29/270 (11%)	51/270 (19%)	-8.2 (-2.2 to -14.1)	0.57 (0.45 to 0.71)	0.008

TOC=test-of-cure. NAAT=nucleic acid amplification test. *Relative risks and p values were derived from generalised estimating equation (GEE) analysis. †Missing data imputed using the fully conditional method in SAS. ‡In the per-protocol population.

Table 2: Primary outcome and sensitivity analyses

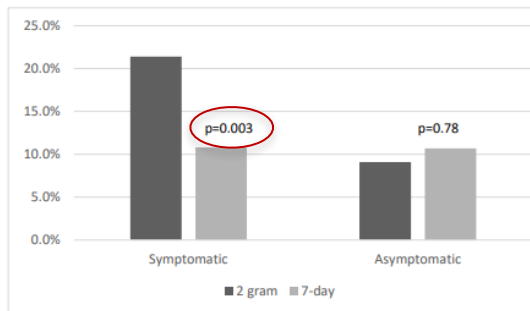
← BV status had no effect on the relative risk
←

Secondary Analysis of RCT Results

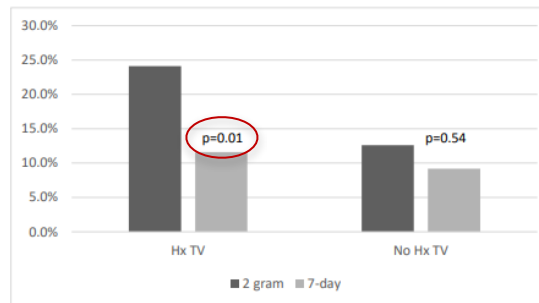
Sex Transm Dis 2022;49(3):231-236

Figure 1. *T. vaginalis* positivity at Test-of-Cure (TOC) by Selected Characteristics

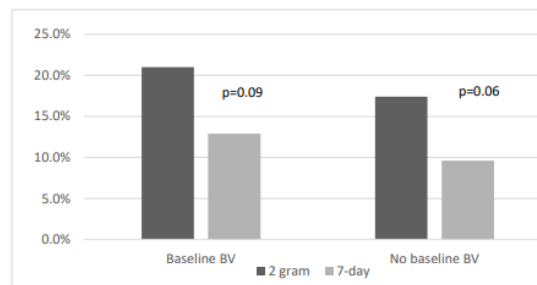
A. *T. vaginalis* positivity at TOC by Baseline Genital Symptoms (n=539)



B. *T. vaginalis* positivity at TOC by past history of *T. vaginalis* (n=538)



B. *T. vaginalis* positivity at TOC by Bacterial Vaginosis (BV) Status (n=522)



Alcohol and Metronidazole (MTZ) Use

- Several studies^{1,2} have found that alcohol use while taking MTZ or TDZ does not cause a disulfiram-like reaction
- 2014 review of the literature on MTZ and alcohol use³:
 - No *in-vitro* studies, animal models, reports of adverse effects, or clinical studies provide convincing evidence of a disulfiram-like interaction between alcohol and MTZ
 - The warning against simultaneous use of alcohol and MTZ appears to be based on lab experiments and individual case histories in which reported reactions were equally likely to have been caused by alcohol alone or by adverse effects of MTZ
 - MTZ does not inhibit acetaldehyde dehydrogenase as disulfiram does
 - Ethanol alone or ethanol-independent side effects of MTZ may explain the suspicion of disulfiram-like effects



Tidsskriftet

DEN NORSKE LEGEFORENING

Is it really dangerous to combine metronidazole and alcohol?

REVIEW ARTICLE

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9:20



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Ben Zonatate
@dRxuggist

Wait, what?? Most interesting line from the new @CDCgov STI guidelines right here.

Metronidazole does not inhibit acetaldehyde dehydrogenase, as occurs with disulfiram. Ethanol alone or ethanol-independent side effects of metronidazole might explain the suspicion of disulfiram-like effects. Thus, refraining from alcohol use while taking metronidazole (or tinidazole) is unnecessary. Clindamycin cream is oil based and might weaken latex condoms and diaphragms for 5 days after

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Knowledge that will change your world

Management of *T. vaginalis* in the Setting of 5-Nitroimidazole Hypersensitivity – Desensitization Preferred

TABLE 1. Protocols for Metronidazole Desensitization in the Setting of 5-Nitroimidazole Hypersensitivity

Modified Kurohara Protocol¹⁴ (PO)*	Pearlman Protocol³⁰ (IV, PO)
Dose 1, 0.0025 mg	Dose 1, 0.005 mg [†]
Dose 2, 0.025 mg	Dose 2, 0.015 mg
Dose 3, 0.25 mg	Dose 3, 0.05 mg
Dose 4, 2.5 mg	Dose 4, 0.15 mg
Dose 5, 5 mg	Dose 5, 0.5 mg
Dose 6, 10 mg	Dose 6, 1.5 mg
Dose 7, 25 mg	Dose 7, 5 mg
Dose 8, 50 mg	Dose 8, 15 mg
Dose 9, 100 mg	Dose 9, 30 mg
Dose 10, 250 mg	Dose 10, 60 mg
Dose 11, 500 mg	Dose 11, 125 mg
Dose 12, 1000 mg	Dose 12, 250 mg [‡]
	Dose 13, 500 mg
	Dose 14, 2000 mg

*PO doses in the Modified Kurohara Protocol are administered 30 minutes apart.

[†]Start of IV dosing, administered 15 to 20 minutes apart.

[‡]Start of PO dosing, administered 60 minutes apart.

IV indicates intravenous; PO, oral.

TABLE 2. Evidence for Alternative Treatment Regimens Outside of the 5-Nitroimidazole Drug Class for *T. vaginalis*-Infected Patients With 5-Nitroimidazole Hypersensitivity

Authors/Date Published	Case Presentation	Treatment (Duration)	Outcome	Follow-Up
Nyirjesy et al. ^{37s} (1998)	9 women total*, 5 with hypersensitivity to MTZ	Intravaginal paromomycin 250 mg per 4 g applicator QD (2 wk)	9 of 9 symptomatic cure [†]	4–6 wk after treatment
Aggarwal et al. ^{38s} (2008)	A woman aged 58 y with type I hypersensitivity to MTZ	Intravaginal clotrimazole daily alternating nightly with intravaginal boric acid 600 mg capsules (5 mo)	Symptomatic and microbiological (culture) cure	Time frame of TOC not specified
Helms et al. ^{39s} (2008)	17 women with 5-nitroimidazole hypersensitivity	Betadine douches [‡] Intravaginal paromomycin [‡] Intravaginal clotrimazole [‡] Intravaginal furazolidone Intravaginal acetarsol	Symptomatic and microbiological cure [§] in: 3 of 4 with betadine douches 1 of 4 with intravaginal paromomycin 1 of 3 with intravaginal clotrimazole 0 of 2 with intravaginal furazolidone [¶] 0 of 1 with intravaginal acetarsol	Time frame of TOC not specified
Muzny et al. ^{40s} (2012)	A Black woman aged 37 y with type I hypersensitivity to MTZ	Intravaginal boric acid 600 mg capsules BID (2 mo)	Symptomatic and microbiological (wet mount and culture) cure	TOC 60 d after end of treatment
Keating et al. ^{41s} (2015)	A woman with severe 5-nitroimidazole allergy	Intravaginal paromomycin 6.25% cream, 5 g daily (14 d)	Symptomatic and microbiological (OSOM rapid test, NAAT, or culture) cure	Time frame of TOC not specified
Backus et al. ^{42s} (2017)	A White woman aged 67 y with type I hypersensitivity to MTZ	Intravaginal boric acid 600 mg capsules BID (60 d)	Symptomatic and microbiological (NAAT) cure	Time frame of TOC not specified
Thomas et al. ^{43s} (2018)	A woman aged 27 y with type I hypersensitivity to MTZ	Intravaginal paromomycin 6.25% BID (8 d)	Symptomatic and microbiological (wet mount and culture) cure	26 d after end of treatment

* Results did not differentiate between MTZ-resistant and MTZ-hypersensitive patients.

[†]Eight of nine women had negative wet mounts, and 6 of those 8 had negative *T. vaginalis* cultures. One patient with a negative culture relapsed within 4 weeks of treatment.

[‡]Dose and duration of treatment were not specified and varied among patients.

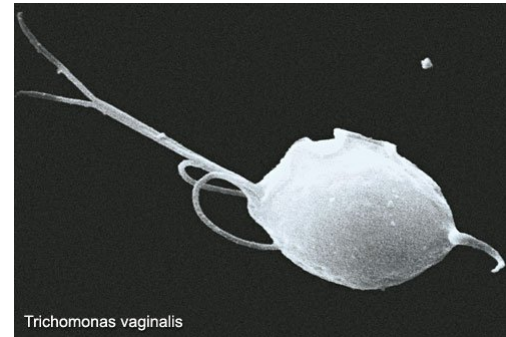
[§]Follow-up data available for 12 of 17 patients.

[¶]One of these 2 patients was subsequently cured with betadine douches (dose and duration not specified).

BID indicates twice daily; MTZ, metronidazole; NAAT, nucleic acid amplification test; PO, orally; QD, daily; TOC, test of cure.

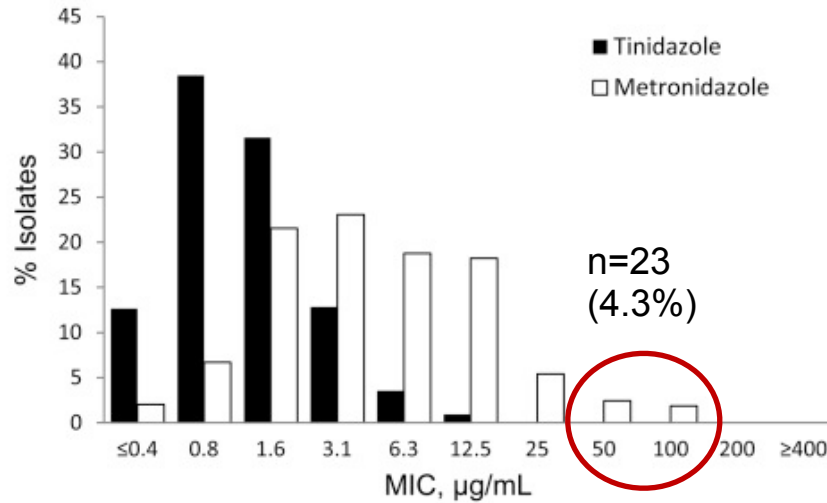
Treatment of Persistent *T. vaginalis* Infection

- Need to first distinguish persistent infection from re-infection from an untreated sexual partner
- If re-infection is excluded, consider 5-nitroimidazole drug resistance



Trichomonas vaginalis

Resistance to 5-Nitroimidazoles: Distribution of Minimum Lethal Concentrations (MLCs) of Tinidazole (TDZ) and Metronidazole (MTZ), STD Surveillance Network, 2009–2010 (n=538)¹



MLC <25 µg/mL = susceptible

MLC 50–100 µg/mL = low level resistance

MLC 200 µg/mL = moderate level resistance

MLC >400 µg/mL = high level resistance

Low-level MTZ resistance is more common than high-level resistance and can be overcome with high-dose TDZ

Dosing for Drug Resistance¹ (always avoid single-dose therapy)

- If patient fails multi-dose MTZ and re-infection cannot be excluded:
 - Re-treat with MTZ 500 mg po bid for 7 days
- If re-infection is excluded, consider:
 - MTZ or TIN 2 grams po daily for 7 days
 - Perform susceptibility testing on the *T. vaginalis* isolate -> CDC
 - High-dose oral TDZ 2–3g po daily in combination with vaginal TDZ 500 mg BID X 14 days
 - High-dose oral TDZ 2–3g po daily in combination with vaginal paromomycin (4 g of 6.25% cream nightly) X 14 days
 - **NOT Recommended:** intravaginal betadine douches, clotrimazole, acetic acid, furazolidone, gentian violet, nonoxynol-9, potassium permanganate, topic microbicides

Efficacy and Safety of Single Oral Dosing of Secnidazole for Trichomoniasis in Women: Results of a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Delayed-Treatment Study

Christina A Muzny¹, Jane R Schwebke¹, Paul Nyirjesy², Gregory Kaufman³, Leandro A Mena⁴, Gweneth B Lazenby⁵, Olivia T Van Gerwen¹, Keonte J Graves¹, Janeen Arbuckle¹, Belvia A Carter⁶, Connette P McMahon⁷, Scott Eder⁸, Jackie Shaw³, Brajesh Pandey³, Steven E Chavoustie⁹



Table 2. Microbiological Cure at TOC Visit (mITT)

	Secnidazole 2 g (n=64)	Placebo (n=67)
Microbiological cure ^a , n (%)	59 (92.2) ^b	1(1.5) ^b
95% exact binomial CI	82.70–97.41	0.04–8.04
P-value ^c		<.001

Abbreviations: CI, confidence interval; mITT, modified intent-to-treat population; TOC, test of cure.

^aInPouch™ *T. vaginalis* test negative for *T. vaginalis*.

^bPatients with no test results were assumed to be positive (numbers imputed: secnidazole = 1; placebo = 3).

^cP value vs. placebo from a Cochran-Mantel-Haenszel test adjusted for clinical symptoms (present/absent) of trichomoniasis at baseline.

SEC FDA-approved for treatment of trichomoniasis in U.S. women and men - June 30, 2021

Follow-Up of Infected Women

- Re-testing for *T. vaginalis* is recommended for all sexually active women <3 months after initial treatment regardless of whether they believe their sex partners were treated
- If re-testing at 3 months is not possible, clinicians should re-test whenever persons next seek medical care <12 months after treatment

Key Take Home Points

- *T. vaginalis* is a neglected STI with multiple adverse health outcomes in women and men
- Multiple diagnostic methods for *T. vaginalis* are available; time to test result and sensitivity of test result are important factors to consider
- Updated treatment recommendations have recently been made in women in the 2021 CDC STI Treatment Guidelines
- Advances in molecular diagnostic testing and treatment may help outsmart this parasite to improve outcomes for individual patients and the overall public health

Thank you!

Questions/Comments?