

Clinical Identification and Treatment of Trichomoniasis in Local Health Department Clinics

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Disclosures

- I have received grant funding from Cepheid, Melinta, NIH and CDC
- This presentation will include discussion of the following non-FDA-approved or investigational uses of products/devices:
- Testing for *T. vaginalis* utilizing:
 - Hologic Gen-Probe APTIMA Combo 2[®] (in men)
 - Roche COBAS[®] Amplicor PCR

Vaginitis

- **Most common reason for patient visit to OB/GYN. 10 million patient visits per year in the United States.**
- **Three primary infections in order of prevalence:**
 - **Bacterial vaginosis**
 - **Candidiasis**
 - **Trichomoniasis**

Vaginitis

- **Usually characterized by:**
 - **Vaginal discharge**
 - **Vulvar itching**
 - **Irritation**
 - **Odor**

Other Causes of Vaginitis

- **Mucopurulent cervicitis**
- **Herpes simplex virus**
- **Atrophic vaginitis**
- **Allergic reactions**
- **Desquamative Inflammatory Vaginitis (DIV)**
- **Vulvar vestibulitis**
- **Foreign bodies**

Diagnosis of Vaginitis

- **Patient history**
- **Visual inspection of internal/external genitalia**
- **Appearance of discharge**
- **Collection of specimen**
- **pH (avoid cervico-vaginal pool!)**
- **Preparation and examination of specimen slide**

SHAMPOO, CONDITIONERS, TREATMENTS AND HAIR GELS

TRICHOMANIA

OTHERWISE KNOWN AS 'THAT GORGEOUS COCONUT SHAMPOO'.



47⁰⁰ LB
11⁷⁵/₁₄ LB

Coconut (Cocos nucifera),
Sodium Lauryl Sulfate (SLS),
Sodium Chloride (Salt),
Sodium Hydroxide (Lye),
Sodium Benzoate (Preservative),
Sodium Citrate (pH Adjuster),
Sodium Hexametaphosphate (Water Softener),
Sodium Polyacrylate (Thickener),
Sodium Stearoyl Glucoside (Surfactant),
Sodium Sulfate (Filler),
Sodium Tricarballylate (Chelator),
Sodium Xanthate (Surfactant),
Sulfuric Acid (pH Adjuster),
Water





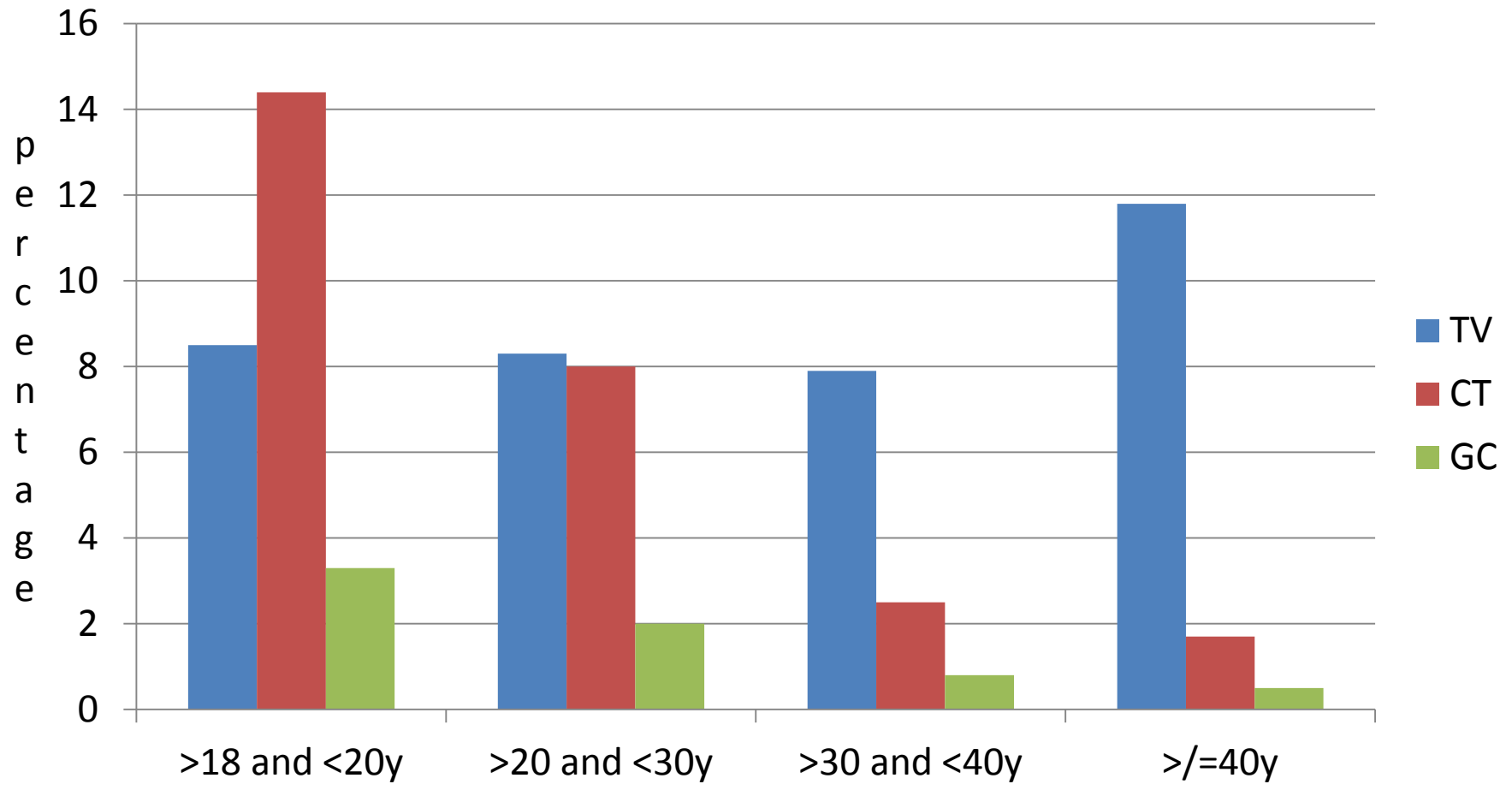
TV Incidence and Prevalence

- Sexually transmitted parasite
- 248 million new cases world-wide in 2005 (WHO 2011)
- Estimated prevalence in US:
 - 3.1% in the general female population (2001-4)
 - Prevalence increases with age
 - Highest rates in AA (13.3%; 95%CI 10-17.7%)
 - Symptoms not predictive
 - 8.7% women from 21 states undergoing testing for GC/CT (N=7593)
 - 2.5-23.2% of adolescents
 - 8.6-38% of drug users

Sutton et al. Clin Infect Dis 2007; Van der Pol et al JID 2005; Miller et al Sex Transm Dis 2005; Plitt et al Sex Transm Dis 2005; Forhan et al Pediatrics 2009; Miller et al JID 2008; Ginocchio et al Jclin Microbiol 2012

Prevalence Rates by Pathogen and Age

Ginocchio et al. J Clin Microbiol 2012, 50(8):2601



Trichomonas vaginalis and HIV

- **Most common curable STD in HIV+ women**
 - 6-44% prevalence
 - 18-36% repeat infection rate (8% in HIV-neg)
- **Multiple studies support the epidemiological association between TV and HIV**
- **HIV-infected women with TV had higher prevalence of HIV RNA in vaginal secretions than those without TV and TV treatment reduced vaginal HIV shedding over a 1-3 month period**

TV/HIV Interactions: Potential Mechanisms

- **Mechanical disruption of epithelial barrier**
- **Inflammation (cellular immune response)**
- **Impaired immune response**
 - TV decreases SLPI (secretory leukoprotease inhibitor) and other innate immune factors
- **Impact on vaginal flora**
 - Increased susceptibility to BV
 - Persistence of abnormal vaginal flora

TV and HIV Shedding

- 14 original studies examined, 8 found an increased risk.
- Meta-analysis and review papers were mixed
 - Small sample sizes in many studies
 - Confounding

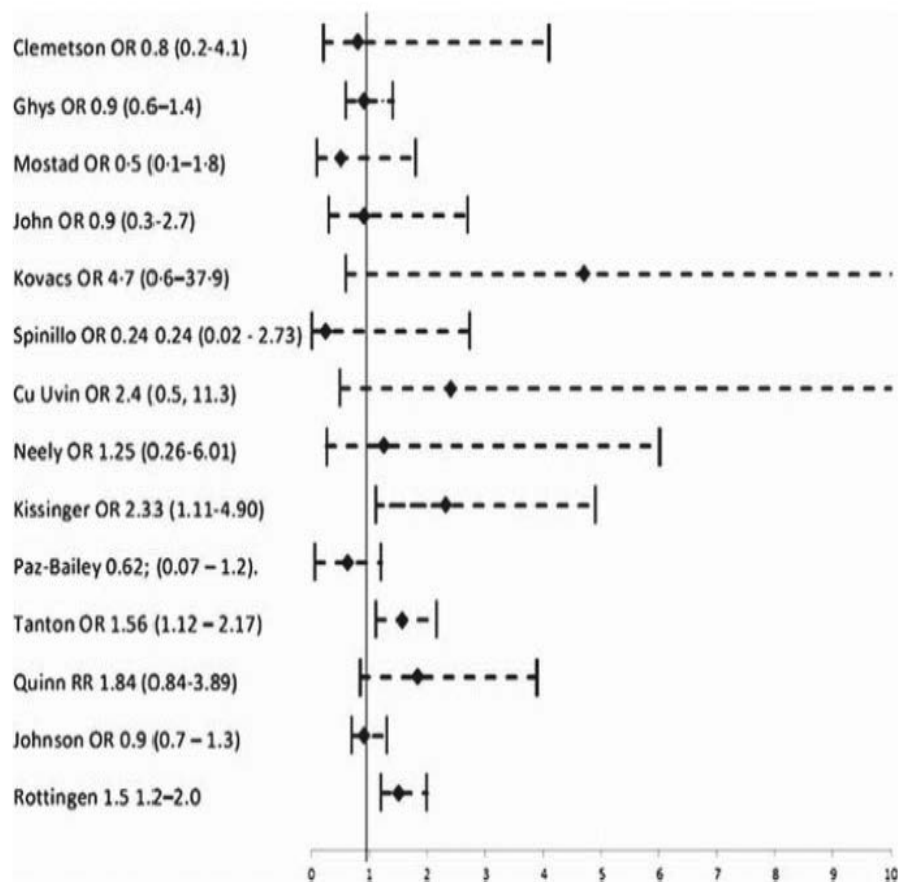


Figure 2.

Trichomonas and HIV genital shedding. *The findings of Hobbs³⁹ and Price⁴² are not shown in the figure because they did not present effect measures.

Recommendations for TV Screening in the General Population

- **Women presenting with genital complaints**
- **Women presenting for STD evaluation**
- **Women at “high risk”**
- **HIV-infected women**

Diagnosis

Clinical Manifestations of *T. vaginalis*

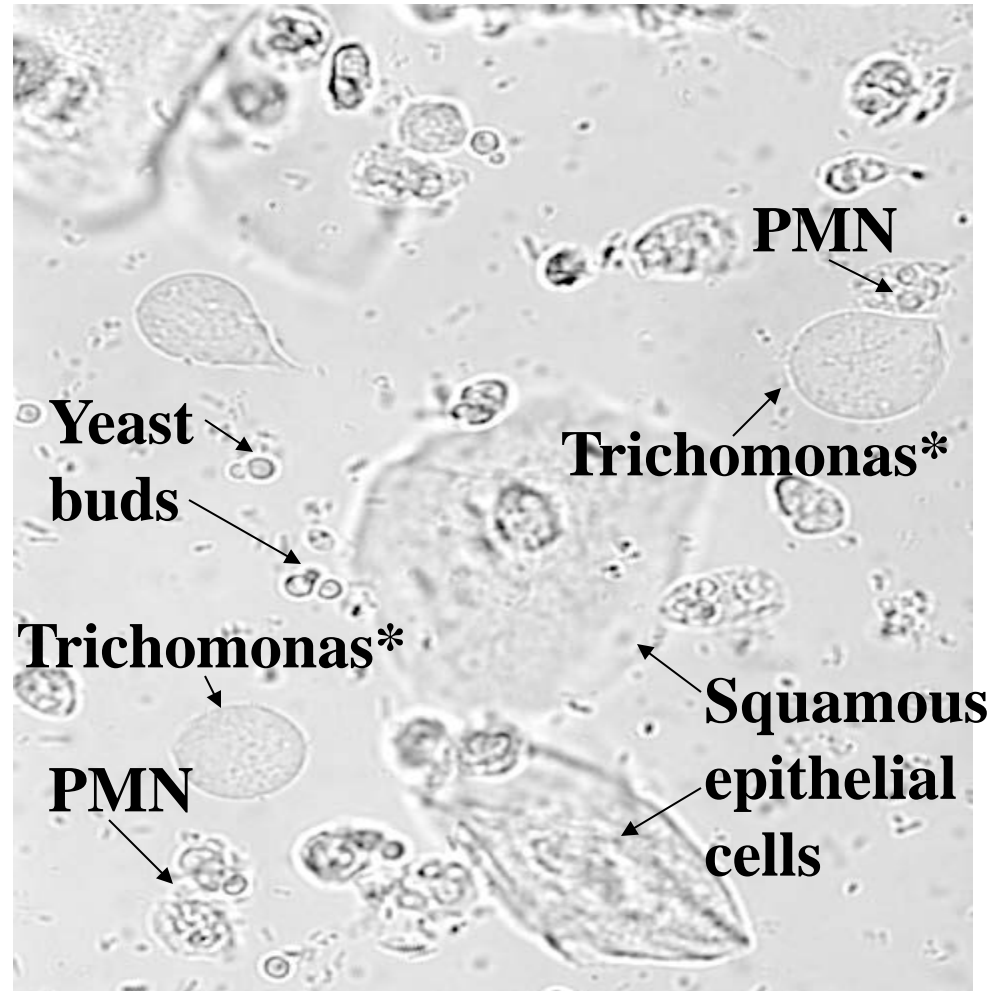
Abnormal genital discharge, dysuria, urinary frequency, itching, burning, dyspareunia, NGU in men



MOST TRICHOMONAL INFECTIONS ARE ASYMPTOMATIC!!!

Wet Prep: Trichomoniasis

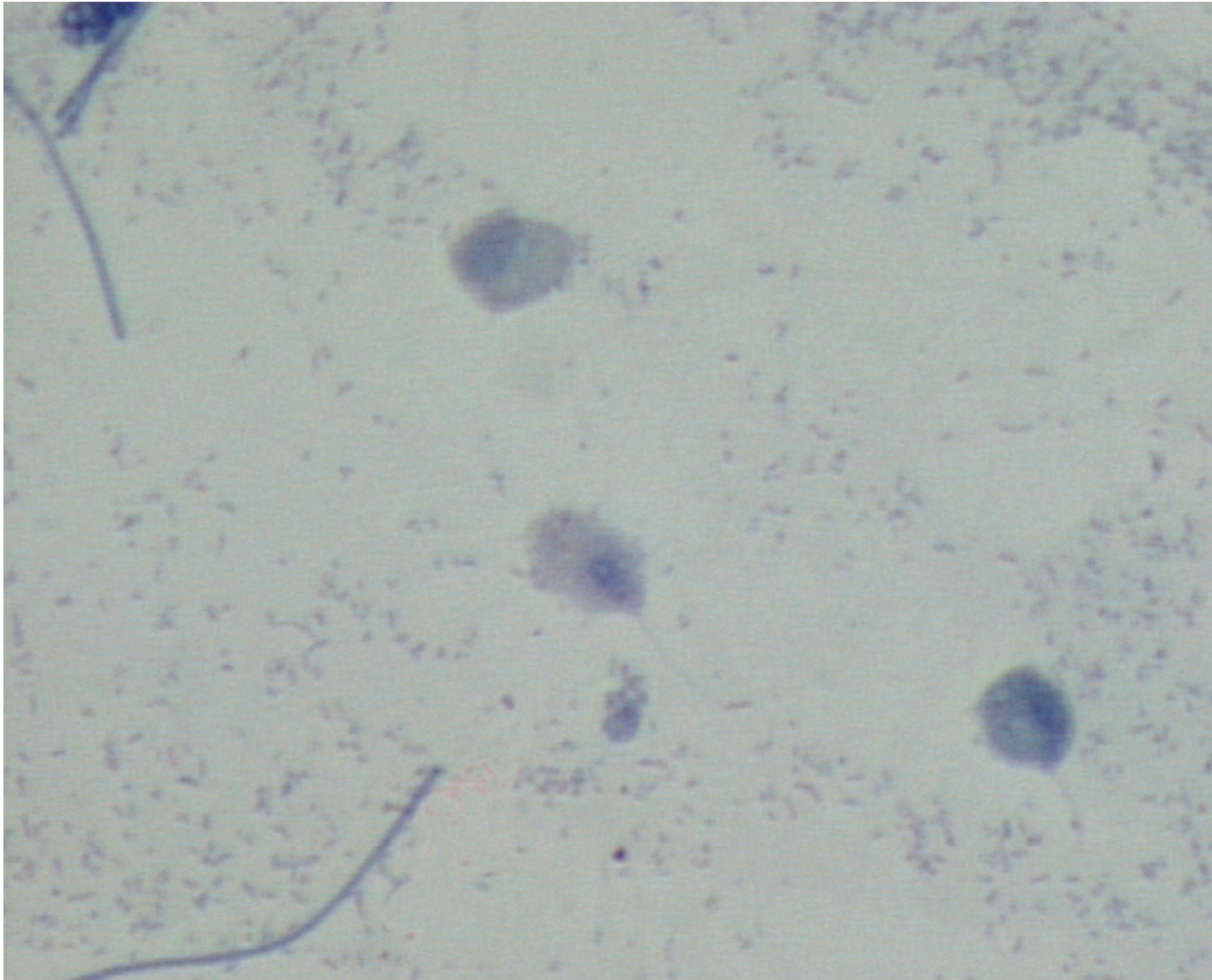
Saline: 40X objective



*Trichomonas shown for size reference only: must be motile for identification

Source: Seattle STD/HIV Prevention Training Center at the University of Washington

Trichomonas – Pap Smear



Diagnostic test	Technique	Time to result	Specimen	Sensitivity	Specificity
Wet Mount	Vag swab with saline microscopy	Minutes, in office	Vag swab	35-82%	99.6-100%
Culture	Media: Diamond's, Trichosel, InPouch TV	24-120h; send out	Vag swab, urethral swab, urine, semen	F:75-87% M: 28.6-48%	100%
APTIMA Trichomonas (GenProbe)	NAAT – TMA to detect species specific 16S rRNA	Hours; send out	Vag swab (F) Urine (F) ThinPrep (F) Urethral swab (M) Urine (M)	96.6-98.4% 87.5% 96-100% 95.2% 73.8%	98-100% 100% 98.8-99.9% 96.5% 98.4%
Affirm VPIII (BD Diagnostics)	Direct specimen nucleic acid probe assay	45 min; send out or equipped office	Vag swab	83-90.5%	99.8-100%
OSOM Trichomonas rapid test (Genzyme Diagnostics)	Immunochromatographic capillary flow assay with murine monoclonal antibody	10 min; in office	Vag swab	82-94.7%	98.8-100%

Adapted from Miller and Nyirjesy, Curr Infect Dis Rep 2011 13:595-603;Schwebke JCM Dec 2011; p4106-4111

Treatment Issues



2010 CDC STD Treatment Guidelines: Trichomoniasis

New Episode

Tinidazole 2 g PO single dose OR
Metronidazole 2 g PO single dose

-Metronidazole 500 mg po BID for 7 days (alternative, rec if HIV+)

Treatment Failure of 2 g metronidazole single dose*

-Metronidazole 500 mg BID x 7d

Treatment Failure – Additional Options*

Tinidazole or Metronidazole 2 g PO daily x 5d



2014 CDC STD Treatment Guidelines: Trichomoniasis (proposed)

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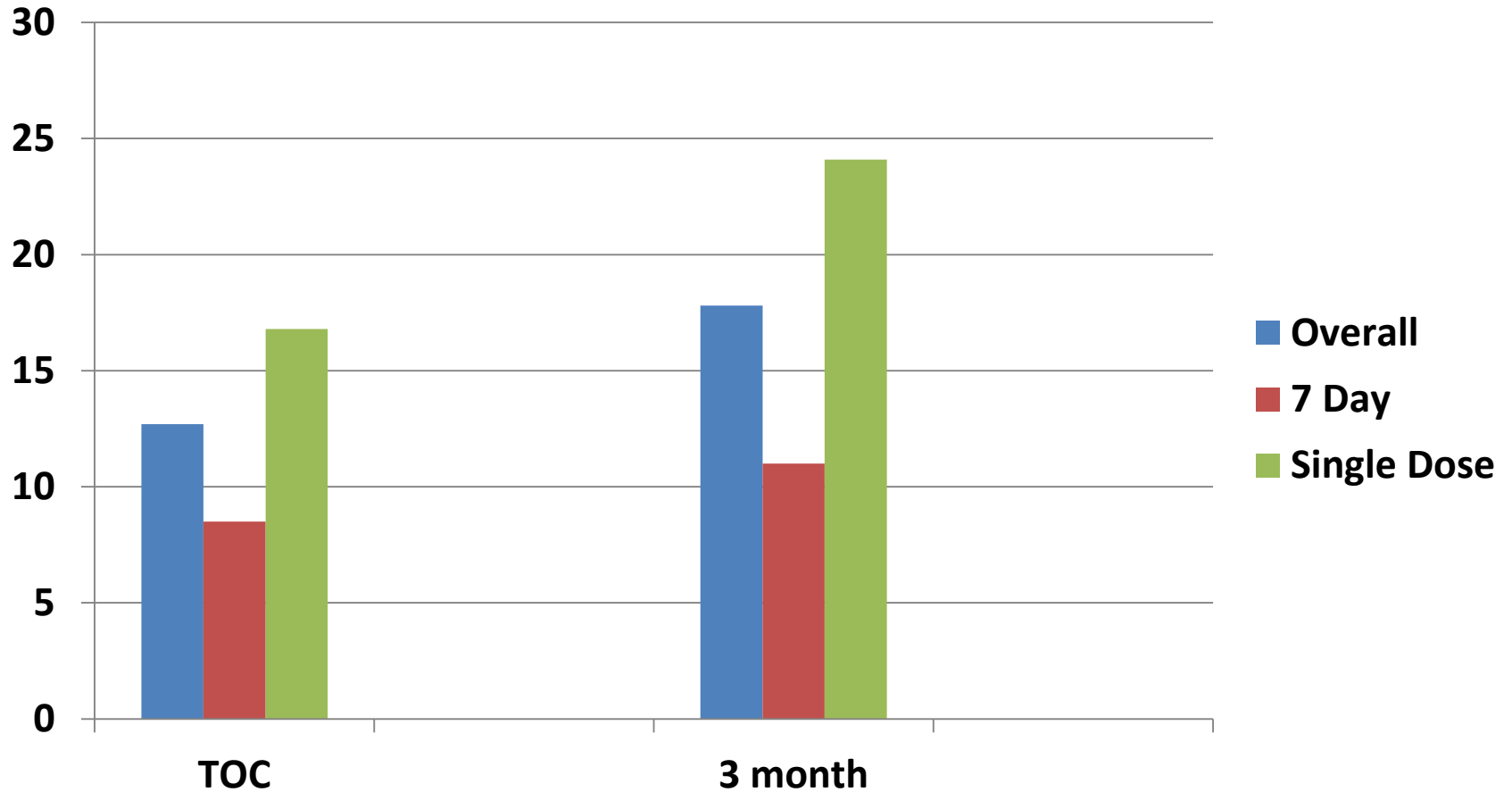
Treatment Failure – Additional Options*

Tinidazole or Metronidazole 2 g PO daily x ~~5d~~ 7d

Tinidazole 2-3g PO daily x 14d plus intravaginal tinidazole



A Randomized Treatment Trial: Single Versus 7-Day Dose of Metronidazole for The Treatment of Trichomonas Vaginalis Among HIV-Infected Women



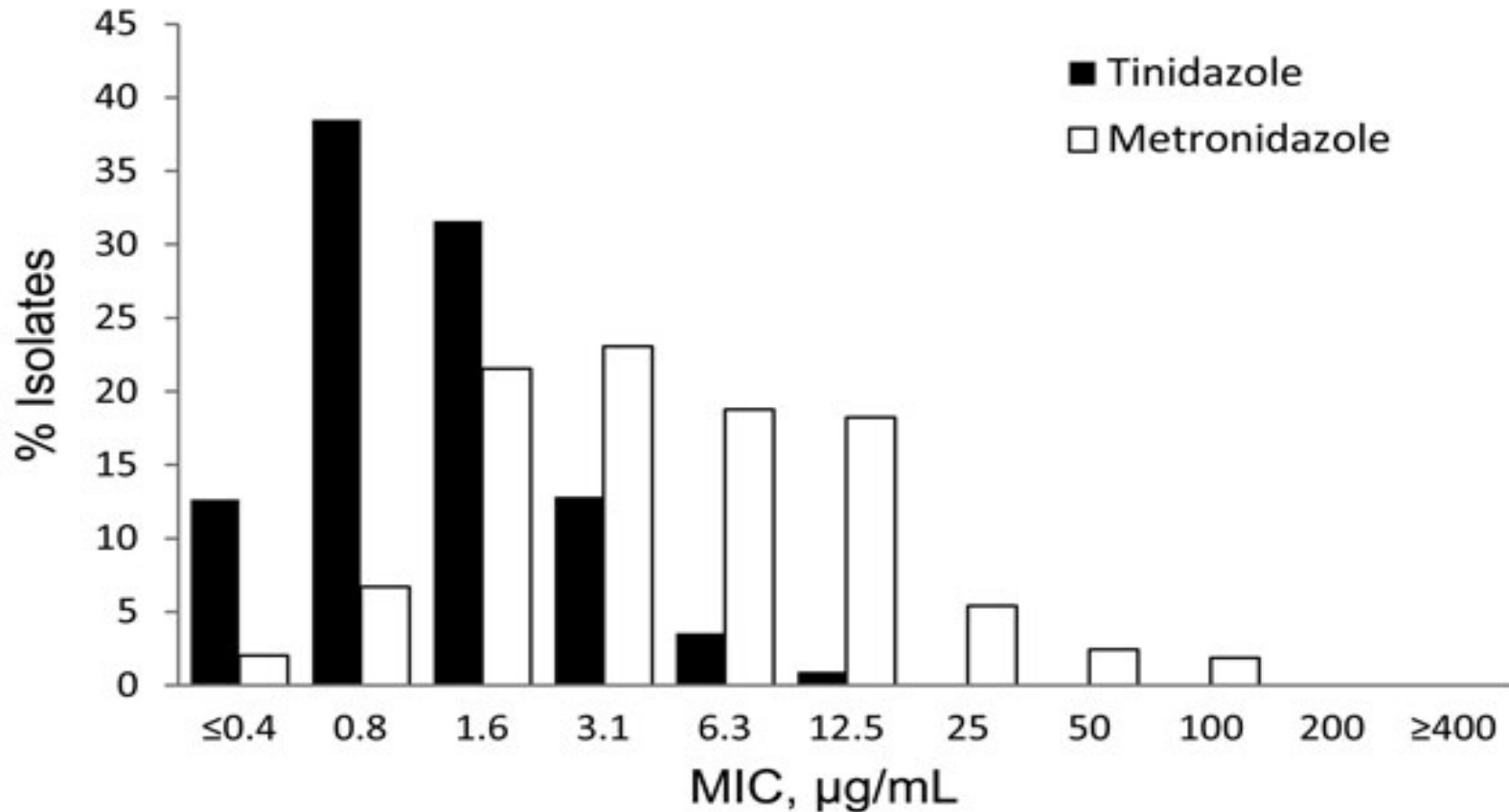
Repeat/Persistent Infection

- **High rates of repeat infection following 2g metronidazole in all women**
 - Increased concern secondary to treatment failure (vs reinfection)
- **Range repeat/persistent infection from 18.3-36.9% in HIV positive women**
- **Role of BV, Antiretroviral therapy**

Peterman et al (Clin Infect Dis 2009; 48(2):259-260); Gatskin and Kissinger (Clin Infect Dis 2010; 51(1):114-115); Kissinger (Sex Transm Inf 2013; 89(6): 426-33; Nicolai Sex Transm Dis 2000; 27: 284-8; Gatski Sex Transm Infect 2011; 87: 205-8; Balkus Sex Transm Dis 2013; 40(6): 499-505

What about resistant *T. vaginalis*?

6 US Cities, STD Surveillance Network, 2009-2010



4.3% with low-level resistance (MIC 50-100µg/mL) to metronidazole; no mod-high level resistance to metronidazole or tinidazole resistance!

Treatment Conundrums

5-nitroimidazole resistance

- **New evidence that susceptibility testing leading to tailored treatment may have beneficial role for management of women with persistent TV***

5-nitroimidazole allergy

- **Alternative regimens (poor efficacy)**
- **Desensitization**

CDC (telephone: 404-718-4141; website: <http://www.cdc.gov/std>)

*Bosserman EA et al. Sex Trans Dis
2011; 38(10):983-987

Alternative Treatments

- **Various regimens of high-dose 5-nitroimidazoles**
 - Tinidazole 1g PO TID + 500mg PV TID x 14d
- **Paromomycin (alone or with tinidazole) → paromomycin 5% cream – 5g PV qd + Tinidazole 1g PO TID x 14d**
- **Clotrimazole**
- **Acetarsol Pessary**
- **Povidine-Iodine**
- **Nonoxynol-9**
- **Zinc-sulfate**
- **Furazolidone**
- **Trichofuran**
- **Boric acid**
- **Vaginal/bladder irrigation**
- **AVC Tablets (1.05g sulfanilamide, allantoin, aminacrine HCL)**

TV in pregnancy

- Associated with preterm delivery and low birth weight
- Studies to date yield conflicting results regarding benefit

Bottom line...

- Treat if symptomatic (or if found) – metronidazole 2gm po x 1
- Do not aggressively screen (accept if HIV+)

Partner Management

- **TV concordance between partners 22-71.7%**
- **Sex partners should be treated (partners within the last 60 days or last partner if longer)**
- **Patient-delivered partner therapy has not definitively been found to decrease recurrent TV in women though adherence with PDPT high**

**Repeat testing in 3 months
for patients treated for TV...**

**Consistent with recommendations
for GC/CT retesting**

Resources



www.stdptc.org

www.nnptc.org

