

Standard treatment regimens for nongonococcal urethritis have similar but declining cure rates: a randomized controlled trial.

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Abstract

BACKGROUND:

Azithromycin or doxycycline is recommended for nongonococcal urethritis (NGU); recent evidence suggests their efficacy has declined. We compared azithromycin and doxycycline in men with NGU, hypothesizing that azithromycin was more effective than doxycycline.

METHODS:

From January 2007 to July 2011, English-speaking males ≥ 16 years, attending a sexually transmitted diseases clinic in Seattle, Washington, with NGU (visible urethral discharge or ≥ 5 polymorphonuclear leukocytes per high-power field [PMNs/HPF]) were eligible for this double-blind, parallel-group superiority trial. Participants received active azithromycin (1 g) + placebo doxycycline or active doxycycline (100 mg twice daily for 7 days) + placebo azithromycin. Urine was tested for *Chlamydia trachomatis* (CT), *Mycoplasma genitalium* (MG), *Ureaplasma urealyticum* biovar 2 (UU-2), and *Trichomonas vaginalis* (TV) using nucleic acid amplification tests. Clinical cure (< 5 PMNs/HPF with or without urethral symptoms and absence of discharge) and microbiologic cure (negative tests for CT, MG, and/or UU-2) were determined after 3 weeks.

RESULTS:

Of 606 men, 304 were randomized to azithromycin and 302 to doxycycline; CT, MG, TV, and UU-2 were detected in 24%, 13%, 2%, and 23%, respectively. In modified intent-to-treat analyses, 172 of 216 (80%; 95% confidence interval [CI], 74%-85%) receiving azithromycin and 157 of 206 (76%; 95% CI, 70%-82%) receiving doxycycline experienced clinical cure ($P = .40$). In pathogen-specific analyses, clinical cure did not differ by arm, nor did microbiologic cure differ for CT (86% vs 90%, $P = .56$), MG (40% vs 30%, $P = .41$), or UU-2 (75% vs 70%, $P = .50$). No unexpected adverse events occurred.

CONCLUSIONS:

Clinical and microbiologic cure rates for NGU were somewhat low and there was no significant difference between azithromycin and doxycycline. *Mycoplasma genitalium* treatment failure was extremely common. Clinical Trials Registration.NCT00358462.