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.

PMID: 23223595