

Azithromycin for PID beats doxycycline on all counts, *J Fam Pract* 2007; 56:1006–1009

PURLs review form

SECTION 1: IDENTIFYING INFORMATION

1.1 Citation	Savaris, RF, Teixeira LM, Torres TG, Edelweiss MI, Moncada J, Schachter J. Comparing ceftriaxone plus azithromycin or doxycycline for pelvic inflammatory disease: a randomized controlled trial. <i>Obstet Gynecol</i> 2007; 110:53–60.
1.2 PubMed ID	17601896
1.3 Reviewer name	Kate Rowland, MD
1.4 Reviewer affiliation	Department of Family Medicine, University of Chicago
1.5 Date review due	August 30, 2007

SECTION 2: DETAILED STUDY DESCRIPTION

2.1 Number of patients starting each arm of the study?	Azithromycin: 67, Doxycycline: 66
2.2 Main characteristics of study patients? (Inclusions, exclusions, demographics, settings, etc)	Inclusion: female, presenting to ER with pelvic pain for fewer than 30 days, cervical leukorrhea or mucopurulent cervicitis, pelvic tenderness Exclusion: fever, inability to tolerate PO, current or recent pregnancy, homelessness, other diagnosis that explains pelvic pain (UTI, appendicitis, diverticulitis, etc)
2.3 Intervention(s) being investigated?	Azithromycin 1g PO weekly for 2 weekly + ceftriaxone 250 mg IM x 1 dose
2.4 Comparisons of treatment(s), placebo, usual care, and/or no treatment?	Doxycycline 100 mg PO BID x 2 weeks + ceftriaxone 250 mg IM x 1 dose
2.5 Length of follow up? (Note specified endpoints, eg, death, cure, etc)	Reassessment at 2, 7, 14, and 30 days Primary endpoints: clinical cure, defined as reduction of pain scores by 70% at 14 days, and lack of need for surgery, hospitalization, or additional therapy Secondary endpoints: decreased pelvic tenderness, lack of fever, WBC count <10K [microbiologic cure]
2.6 What outcome measures are used? (List all measures used to assess effectiveness)	Visual analog pain scale Modified McCormack pain scale Physical exam findings [Endometrial biopsy]

<p>2.7 What is the effect of the intervention(s)? (Include absolute risk, relative risk, NNT, CI, <i>P</i>-values, etc)</p>	<p>Azithromycin produced clinical cure in 56 of 62 patients (90.3%; 95% CI, 0.80–0.96) while doxycycline produced clinical cure in 42/58 (72.4%; 95% CI, 0.58–0.82). <i>P</i>-value between these 2 cure rates is .01.</p>
<p>SECTION 3: INTERNAL VALIDITY</p>	
<p>3.1 Study addresses an appropriate and clearly focused question</p>	<p>Well addressed</p>
<p>3.2 Random allocation to comparison groups</p>	<p>Well addressed</p>
<p>3.3 Concealed allocation to comparison groups</p>	<p>Well addressed</p>
<p>3.4 Subjects and investigators kept “blind” to comparison group allocation status</p>	<p>Well addressed</p>
<p>3.5 Comparison groups are similar at the start of the trial</p>	<p>Well addressed</p>
<p>3.6 Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential source of bias</p>	<p>Well addressed</p>
<p>3.7 Were all relevant outcomes measured in a standardized, valid, and reliable way?</p>	<p>Well addressed</p>
<p>3.8 Are patient-oriented outcomes included? If yes, what are they?</p>	<p>Yes</p>
<p>3.9 What percent dropped out and were lost to follow up? Could this bias the results? How?</p>	<p>Lost to follow up: 7/67 = 10.4% in the control (doxycycline) group; 4/66 = 6.1% in the intervention (azithromycin) group. Dropped out but included in the analysis: 9/6 = 13.4% in the doxycycline group; 2/66 = 3.0% in the azithroycin group</p>
<p>3.10 Was there an intention-to-treat analysis? If not, could this bias the results? How?</p>	<p>Modified; ITT was performed after 13 patients who were randomized and then discovered not to have PID were removed from analysis.</p>
<p>3.11 If a multisite study, are results comparable for all sites?</p>	<p>N/A</p>
<p>3.12 Is the funding for the trial a potential source of bias? If yes, what</p>	<p>Small potential for bias; one of the authors received azithromycin from Pfizer to perform other studies.</p>

measures, if any, were taken to insure scientific integrity?	
SECTION 4: EXTERNAL VALIDITY	
4.1 To which patients might the findings apply? (Include patients in the study and other patients to whom the findings may be generalized)	Results likely generalizable to any healthy ambulatory population
4.2 In what care settings might the findings apply, or not apply?	Ambulatory care settings
4.3 To which clinicians or policy-makers might the findings be relevant?	Those who treat PID and those who make treatment guidelines
SECTION 5: REVIEW OF SECONDARY LITERATURE	
5.1 DynaMed excerpts	DynaMed cites this article to recommend azithromycin and ceftriaxone for mild PID
5.2 DynaMed citation/access date	Pelvic inflammatory disease. In Dynamed [online database]. Available at: www.dynamicmedical.com . Accessed on 8/30/07.
5.3 UpToDate excerpts	Does not currently recommend azithromycin for PID.
5.4 UpToDate citation/access date	Hynes N. Treatment of pelvic inflammatory disease. In UptoDate Online 15.2. Available at: www.utdol.com . Accessed on 8/30/07.
5.5 PEPID PCP excerpts	Does not currently recommend azithromycin for PID.
5.6 PEPID citation/access data	Pelvic inflammatory disease. In PEPID-PCP [online database]. Available at www.pepidonline.com . Accessed on 8/30/07.
5.7 Other excerpts (USPSTF; other guidelines; etc)	None
5.8 Citations for other excerpts	
SECTION 6: CONCLUSIONS	
6.1 How well does the study minimize sources of internal bias and maximize internal validity? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)	1

<p>6.2 If 6.1 was coded as 4 or below, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?</p>	
<p>6.3 Are the results of this study relevant to the health care needs of patients cared for by “full scope” family physicians, general internists, general pediatricians, or general ob/gyns? Are they applicable without significant change in programs or policies such as the organization or financing of practice? Give one number of a scale of 1 to 7 (1=absolutely relevant; 4=neutral; 7=not at all relevant)</p>	1
<p>6.4 Please explain your response to item 6.3.</p>	
<p>6.5 What is the main recommendation for change in practice, if any? Include a description of the change in practice, the indications, and the target population.</p>	Azithromycin 1 g PO weekly for 2 weeks with one dose of ceftriaxone 250 mg IM is appropriate treatment for mild, uncomplicated cases of PID in women in the ambulatory care setting.
<p>SECTION 7: EDITORIAL DECISION</p>	
<p>7.1 FPIN PURLs editorial decision</p>	PURL
<p>7.2 Editor (BE or JH)</p>	Bernard Ewigman, MD, MSPH, Professor & Chairman, Department of Family Medicine, The University of Chicago
<p>7.3 Date of decision</p>	October 1, 2007
<p>7.4 Brief summary of reason for decision</p>	Well-done trial shows that azithromycin is superior to doxycycline even when doxycycline compliance is high. In actual practice, compliance with doxycycline is lower than reported in this trial, so azithromycin is likely even more advantageous than suggested by the findings of this RCT. CDC does not currently recommend azithromycin. This is a practice changer.