

Appendix 1: Main characteristics of randomized controlled trials included in the meta-analysis of studies comparing fluoroquinolones and β -lactam antibiotics for the treatment of acute bacterial sinusitis (part 1 of 3)

Study	Design	Study population	Inclusion criteria	Mean age, yr	No. of patients			Antibiotic regimen (duration of treatment)	
					Enrolled (% women)	Intention-to-treat	Clinically evaluable	Fluoroquinolone	β -Lactam
Arrieta et al ²¹ (2007, Mexico)	Open-label, multicentre prospective randomized phase IIIb clinical trial	Adult outpatients with acute bacterial sinusitis	Clinical: 7-28 d duration; at least one of facial pain or tightness spontaneously or after pressure in any sinus site, anterior or posterior nasal discharge, or cough and 2 or more within 2 d before enrolment of fever, headache, nasal congestion, lacrimation Computed tomography or radiography	37 v. 38	576 (63 v. 62)	289 v. 286	226 v. 233	Moxifloxacin 400 mg by mouth once daily (7 d)	Amoxicillin-clavulanate 500/125 mg by mouth three times daily (7 d)
Henry et al ²² (2004, United States)	Multicentre randomized double-blind clinical trial	Adult outpatients with acute uncomplicated maxillary rhinosinusitis	Clinical: 7-21 d duration; facial pain or pressure in one or both maxillary sinuses, facial swelling or toothache, purulent nasal discharge Computed tomography or radiography: air-fluid level or opacity in one or both maxillary sinuses	40.4 v. 42.5	271 (60 v. 61)	133 v. 138	118 v. 123	Levofloxacin 500 mg by mouth once daily (10 d)	Cefdinir 600 mg by mouth once daily (10 d)
Jareoncharsri et al ²³ (2004, Thailand)	Open-label randomized comparative clinical trial	Outpatients • 16 yrs old with acute or acute exacerbation of chronic sinusitis	Clinical: < 28 d duration; nasal obstruction, purulent nasal discharge or postnasal drip, impairment of sense of smell, foul smell, headache Radiography: air-fluid level, opacity, mucosal thickening	35.5	60 (62)	34 v. 26	34 v. 26	Levofloxacin 300 mg by mouth once daily (14 d)	Amoxicillin-clavulanate 625 mg by mouth three times daily (14 d)
Sher et al ²⁴ (2002, United States)†	Multicentre randomized investigator-blinded clinical trial	Adult patients with acute uncomplicated maxillary sinusitis	Clinical: 7-28 d duration; facial pain or tenderness in one or both maxillary sinuses, purulent nasal or postnasal discharge Radiography: air-fluid level, opacity, mucosal thickening \geq 5 mm in one or both maxillary sinuses	[41.1 v.] 42.4 v. 41.9	445 ([64 v.] 65 v. 64)	[149 v.] 141 v. 155	[137 v.] 127 v. 141	[Gatifloxacin 400 mg by mouth once daily (5 d) v.] gatifloxacin 400 mg by mouth once daily (10 d)	Amoxicillin-clavulanate 875 mg by mouth twice daily (10 d)

Appendix 1: Main characteristics of randomized controlled trials included in the meta-analysis of studies comparing fluoroquinolones and β -lactam antibiotics for the treatment of acute bacterial sinusitis (part 2 of 3)

Study	Design	Study population	Inclusion criteria	Mean age, yr	No. of patients			Antibiotic regimen (duration of treatment)	
					Enrolled (% women)	Intention-to-treat	Clinically evaluable	Fluoroquinolone	β -Lactam
Rakkar et al ²⁵ (2001, United States)	Open-label multicentre prospective randomized phase IIIb clinical trial	Adult outpatients with acute bacterial maxillary sinusitis	Clinical: 7-30 d duration; nasal congestion and purulent discharge, coughing, frontal headache, malar pain	43 v. 42	475 (69 v. 65)	238 v. 237	170 v. 171	Moxifloxacin 400 mg by mouth twice daily (10 d)	Amoxicillin/clavulanate 875 mg by mouth twice daily (10 d)
Siegert et al ²⁶ (2000, Germany)	Multicentre randomized double-blind phase III clinical trial	Adult outpatients with acute bacterial sinusitis	Clinical: > 7 d duration; 2 or more of nasal congestion and purulent discharge, coughing, frontal headache and malar pain Radiography: air-fluid level, opacity, mucoperiosteal thickening	40.4 v. 40.3	498 (55 v. 56)	242 v. 251	211 v. 225	Moxifloxacin 400 mg by mouth once daily (7 d)	Cefuroxime axetil 250 mg by mouth twice daily (10 d)
Adelglass et al ²⁷ (1999, United States)	Open-label, multicentre randomized comparative clinical trial	Adult outpatients with acute sinusitis	Clinical: < 4 wk duration; 2 or more of fever, headache, purulent nasal discharge, facial pain, malar tenderness Computed tomography or radiography: air-fluid level, opacity, mucosal thickening \geq 4 mm in at least one sinus	39.2 v. 38.6	615 (62 v. 64)	306 v. 309*	267 v. 268	Levofloxacin 500 mg by mouth once daily (10-14 d)‡	Amoxicillin-clavulanate 500/125 mg by mouth three times daily (10-14 d)‡
Burke et al ²⁸ (1999, United States)	Multicentre randomized double-blind clinical trial	Adult outpatients with acute maxillary sinusitis	Clinical: 7-28 d duration; 2 or more of nasal congestion, postnasal drainage, purulent nasal discharge, coughing, malar tenderness, frontal headache Radiography: air-fluid level, opacity, mucosal thickening \geq 6 mm	40 v. 39	542 (62 v. 60)	267 v. 275	223 v. 234	Moxifloxacin 400 mg by mouth once daily (10 d)	Cefuroxime axetil 250 mg by mouth twice daily (10 d)
Johnson et al ²⁹ (1999, United States)	Prospective multicentre randomized double-blind clinical trial	Adult outpatients with acute bacterial maxillary sinusitis or acute exacerbation of chronic sinusitis	Clinical: \leq 28 d duration; 2 or more of fever > 38°C, leukocytes > $10 \times 10^9/L$, chills, malaise, toothache, headache, nasal congestion, postnasal drainage, coughing, malar tenderness, edema Radiography: air-fluid level, opacity, mucosal thickening \geq 6 mm	40 v. 43	501 (60 v. 57)	250 v. 251	228 v. 225	Ciprofloxacin 500 mg by mouth twice daily (10 d)	Cefuroxime axetil 250 mg by mouth twice daily (10 d)

Appendix 1: Main characteristics of randomized controlled trials included in the meta-analysis of studies comparing fluoroquinolones and β -lactam antibiotics for the treatment of acute bacterial sinusitis (part 3 of 3)

Study	Design	Study population	Inclusion criteria	Mean age, yr	No. of patients			Antibiotic regimen (duration of treatment)	
					Enrolled (% women)	Intention-to-treat	Clinically evaluable	Fluoroquinolone	β -Lactam
Weis et al ³⁰ (1998, United States)	Open-label multicentre randomized double-blind clinical trial	Adult outpatients with acute bacterial sinusitis	Clinical: < 28 d duration; at least 2 major symptoms or 1 major and 2 minor symptoms, where major symptoms are fever, facial congestion, nasal obstruction, purulent nasal drainage, facial pain, and hyposmia, and minor symptoms are headache, ear pain, dental pain, fatigue, halitosis, and cough	43.5 v. 43.5	1414 (68 v. 66)	711 v. 700	613 v. 606	Ciprofloxacin 500 mg by mouth twice daily (10 d)	Cefuroxime axetil 250 mg by mouth twice daily (10 d)
Gehanno et al ³¹ (1996, France)	Multicentre randomized double-blind clinical trial	Adult outpatients with purulent maxillary sinusitis	Clinical: < 21 d duration; pus on middle meatus, purulent rhinorrhea, pain or tenderness over the affected sinuses	41 v. 42	382 (61 v. 54)	190 v. 184*	155 v. 149	Sparfloxacin loading dose 400 mg (1 d), then 200 mg by mouth once daily (4 d), then placebo (3 d)	Cefuroxime axetil 250 mg by mouth twice daily (8 d)

*Modified intention-to-treat population.

†Data in square brackets refer to gatifloxacin regimen (5-day duration), which were not taken into account in the meta-analysis.

‡Duration of treatment varied according to clinical indications. Mean duration of treatment was 13 days for levofloxacin and 12 days for amoxicillin-clavulanate.