

Appendix 2: Outcome data from the 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 2)

Study	Primary outcome	Time of outcome evaluation after start of treatment, d	Clinical success at test-of-cure evaluation, n/N (%) [*]		Bacteriologic success, n/N (%) [†]		Adverse events [‡] , n/N (%)			Relapse, [‡] n/N (%); time after end of treatment
			Fluoroquinolone	β -Lactam	Fluoroquinolone	β -Lactam	Total	Withdrawn	Severe	
Arrieta et al ²¹	Total resolution of symptoms and improvement in imaging appearance of sinuses, without need for additional therapy	14-21	Clinically evaluable: 211/226 (93) Intention-to-treat: 241/289 (83)	Clinically evaluable: 216/233 (93) Intention-to-treat: 240/283 (85)	109/113 (96) [§]	117/121 (97) [§]	93/289 (32) v. 84/283 (30)	10/289 (3) v. 6/283 (2)	1/289 (< 1) v. 1/283 (< 1)	
Henry et al ²²	Resolution of at least one of acute signs and symptoms of sinusitis accompanied by absence of findings on imaging studies	19-24	Clinically evaluable: 101/118 (86)	Clinically evaluable: 102/123 (83)			Incidence of drug-related adverse events generally comparable between treatment groups	2/133 (2) v. 3/138 (2)	0/118 (0) v. 0/123 (0)	
Jareoncharsri et al ²³	Complete or incomplete resolution of symptoms and signs, supported by absence or improvement of radiologic findings	21	Clinically evaluable, intention-to-treat: 31/34 (91)	Clinically evaluable, intention-to-treat: 22/26 (85)	22/28 (79)	14/20 (70)	3/34 (9) v. 2/26 (8)	0/34 (0) v. 0/26 (0)	0/34 (0) v. 0/26 (0)	
Sher et al ^{24¶}	Resolution or improvement of all acute symptoms	17-24	Clinically evaluable: [102/137 (74) v.] 101/127 (80)	Clinically evaluable: 101/141 (72)			Incidence of drug-related adverse events was comparable between treatment groups	[2/149 (1) v.] 5/141 (4) v. 3/155 (2)	[99% v.] 95% v. 97% of adverse events were mild or moderate	6/445 (1), 21-28 d
Rakkar et al ²⁵	Disappearance or improvement of acute signs and symptoms	24-31	Clinically evaluable: 146/170 (86) Intention to treat: 199/234 (85)	Clinically evaluable: 144/171 (84) Intention-to-treat: 194/237 (82)			136/234 (58) v. 124/237 (52)	12/234 (5) v. 8/237 (3)	\geq 87% of adverse events were mild or moderate	6/170 (4) v. 6/171 (4), 1-2 mo

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Study	Primary outcome	Time of outcome evaluation after start of treatment, d	Clinical success at test-of-cure evaluation, n/N (%) [*]		Bacteriologic success, n/N (%) [†]		Adverse events [‡] , n/N (%)			Relapse, [§] n/N (%); time after end of treatment
			Fluoroquinolone	β -Lactam	Fluoroquinolone	β -Lactam	Total	Withdrawn	Severe	
Siegert et al ²⁶	Resolution of symptoms	14	Clinically evaluable: 204/211 (97) Intention to treat: 216/242 (89)	Clinically evaluable: 204/225 (91) Intention-to-treat: 219/251 (87)	103/109 (94)	96/115 (83)	105/242 (43) v. 88/251 (35)	14/242 (6) v. 11/251 (4)	3/242 (1) v. 8/251 (3)	12/204 (6) v. 13/204 (6), 27-31 d
Adelglass et al ²⁷	Complete or incomplete resolution of symptoms (proven radiographically)	12-19	Clinically evaluable: 236/267 (88)	Clinically evaluable: 234/268 (87)			114/297 (38) v. 146/302 (48)	11/297 (4) v. 16/302 (5)	7/297 (2) v. 15/302 (5)	5/233 (2) v. 9/231 (4), 28-32 d
Burke et al ²⁸	Complete or incomplete resolution of symptoms (proven radiographically)	17-24	Clinically evaluable: 200/223 (90) Intention to treat: 237/263 (90)	Clinically evaluable: 209/234 (89) Intention-to-treat: 247/274 (90)			96/263 (37) v. 70/274 (26)	15/263 (6) v. 6/274 (2)	7/263 (3) v. 10/274 (4)	3/184 (2) v. 5/202 (2), 27-31 d
Johnson et al ²⁹	Resolution or improvement of symptoms (proven radiographically)	11-17	Clinically evaluable: 144/164 (88)	Clinically evaluable: 133/158 (84)	89/92 (97)	78/82 (95)	115/250 (46) v. 113/251 (45)	1/250 (<1) v. 6/251 (2)	0/250 (0) v. 1/250 (<1)	
Weis et al ³⁰	Complete resolution or significant improvement of symptoms	14-26	Clinically evaluable: 559/613 (91)	Clinically evaluable: 546/606 (90)			136/711 (19) v. 115/700 (16)	27/711 (4) v. 26/700 (4)		
Gehanno et al ³¹	Resolution of all signs and symptoms	10-12	Clinically evaluable: 134/153 (88)	Clinically evaluable: 130/149 (87)	102/109 (94)	99/111 (89)	19/190 (10) v. 15/184 (8)	7/190 (4) v. 5/184 (3)		

^{*}Clinically evaluable population consisted of the patients who fulfilled the criteria for evaluation; intention-to-treat population consisted of the patients randomly assigned to receive treatment.

[†]Bacteriologic success was defined as eradication or presumed eradication of the pathogens isolated before treatment.

[‡]Presented as fluoroquinolones v. β -lactams.

[§]Based on data for the bacteriologically valid per-protocol population.

[¶]Data in brackets refer to the 5-day gatifloxacin regimen, which were not taken into account in the meta-analysis.