

# Patients Receiving Systemic Steroid for Rash

STUDY  
344

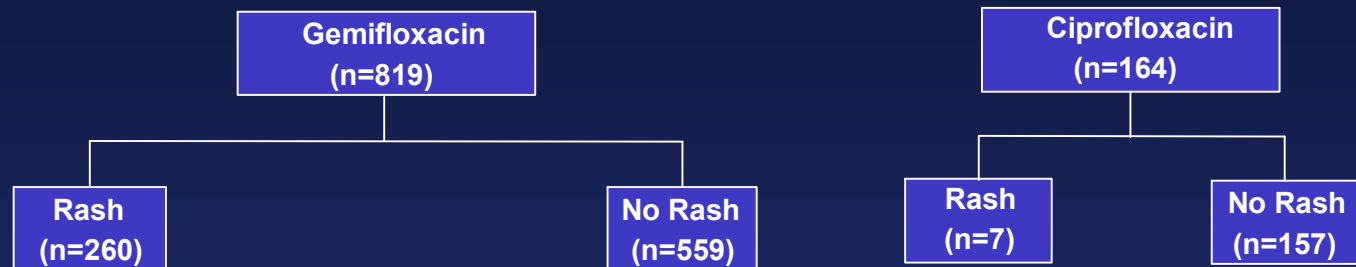
Treatment	n/N
Ciprofloxacin	0/14
Gemifloxacin	12/268
Placebo	0/7

# Inclusion Criteria

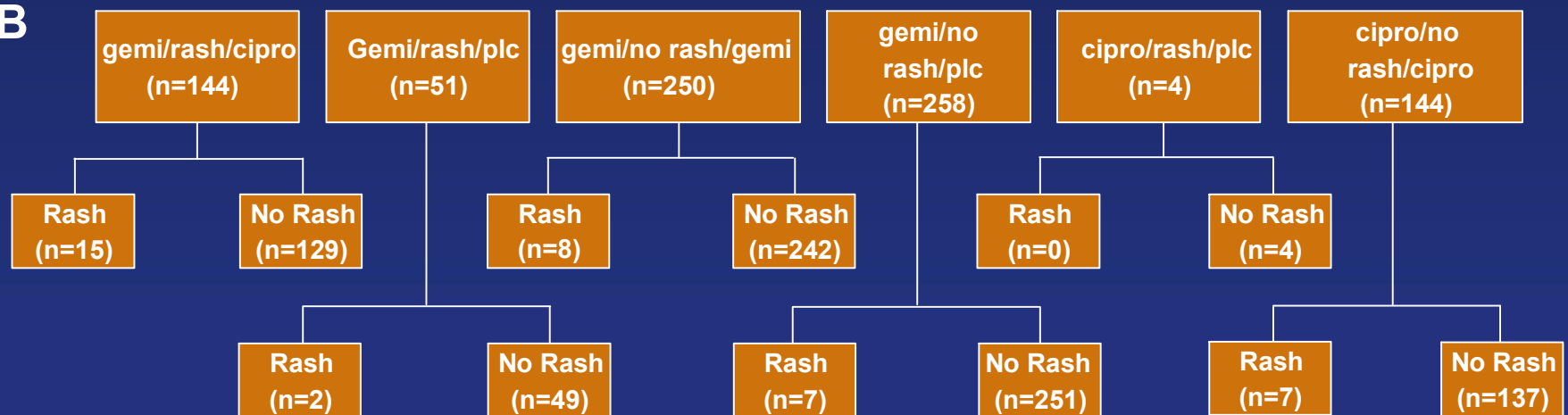
- Key Inclusion Criteria
  - Healthy female, age 18-40 yrs
  - Skin type I-IV
  - Two methods of contraception, pregnancy test at screening
  - No clinically relevant findings in ECG, vital signs, clinical chemistry, hematology, or uninalysis
  - Negative Hepatitis B test
  - Negative urine drug screen
  - Written informed consent

# Figure 11: Subject Disposition in Part A and Part B

## Part A



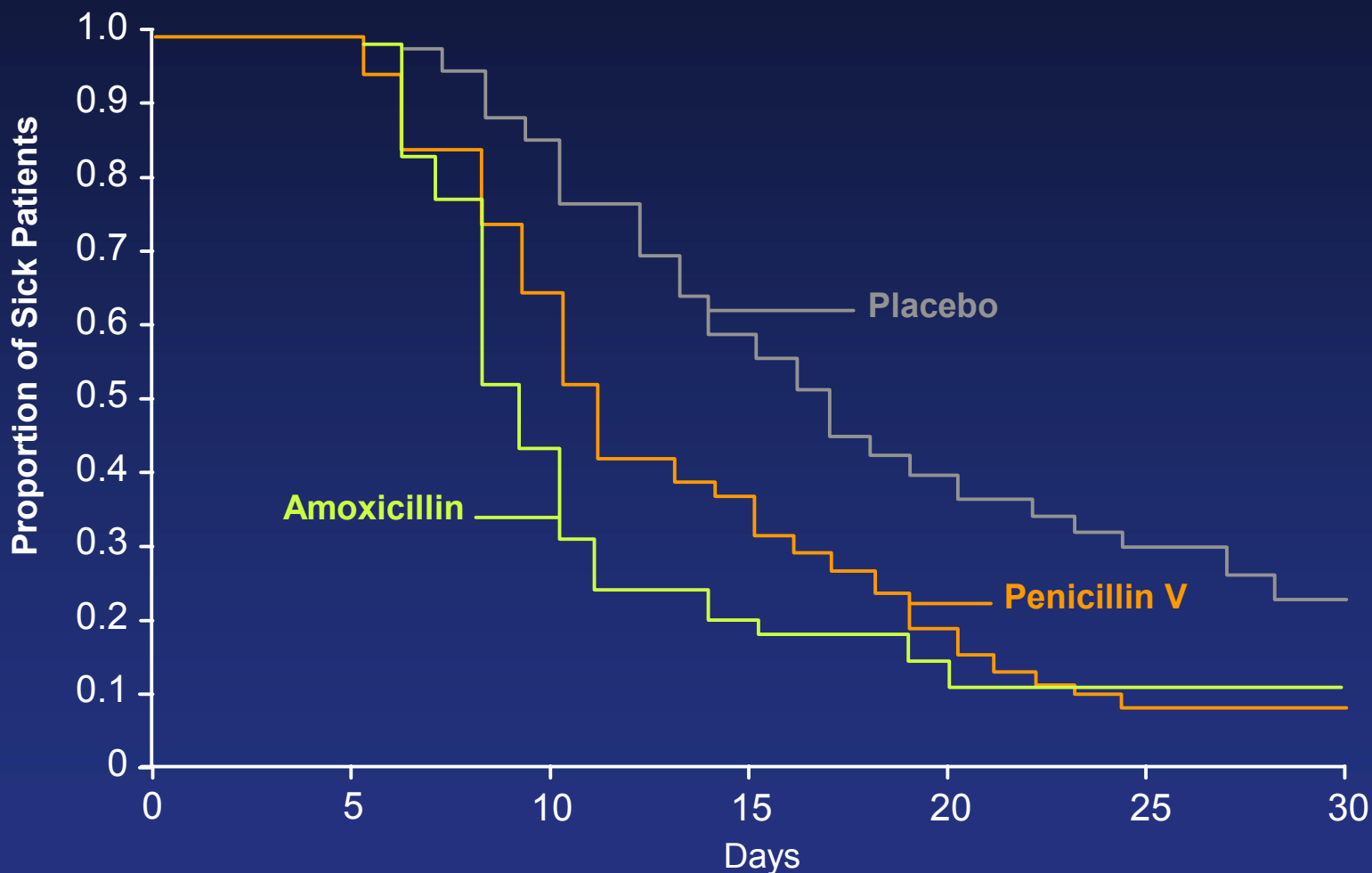
## Part B



# Patients with Rash by Age and Gender According to Planned Treatment Duration *Clinical Trial Population*

Duration of Treatment Gender/ Age (yrs)	Gemifloxacin 320 mg PO			All Comparators		
	5 Days n (%)	7 Days n (%)	10 Days n (%)	5 Days n (%)	7 Days n (%)	10 Days n (%)
Both, <40	16/755 (2.1)	75/860 (8.7)	27/205 (13.2)	0/1	3/156 (1.9)	9/523 (1.7)
Both, ≥40	40/2,941 (1.4)	60/1,871 (3.2)	28/653 (4.3)	3/333 (0.9)	21/2,078 (1.0)	12/1,396 (0.9)
All Males	16/1,859 (0.9)	52/1,437 (3.6)	16/419 (3.8)	2/202 (1.0)	8/1,157 (0.7)	6/967 (0.6)
Males <40	6/356 (1.7)	26/453 (5.7)	7/74 (9.5)	0/1	2/82 (2.4)	3/211 (1.4)
Males ≥40	10/1,503 (0.7)	26/984 (2.6)	9/345 (2.6)	2/201 (1.0)	6/1,075 (0.6)	3/756 (0.4)
All Females	40/1,837 (2.2)	83/1,294 (6.4)	39/439 (8.9)	1/132 (0.8)	16/1,077 (1.5)	15/952 (1.6)
Females <40	10/399 (2.5)	49/407 (12.0)	20/131 (15.3)	0/0	1/74 (1.4)	6/312 (1.9)
Females ≥40	30/1,438 (2.1)	34/887 (3.8)	19/308 (6.2)	1/132 (0.8)	15/1,003 (1.5)	9/640 (1.4)

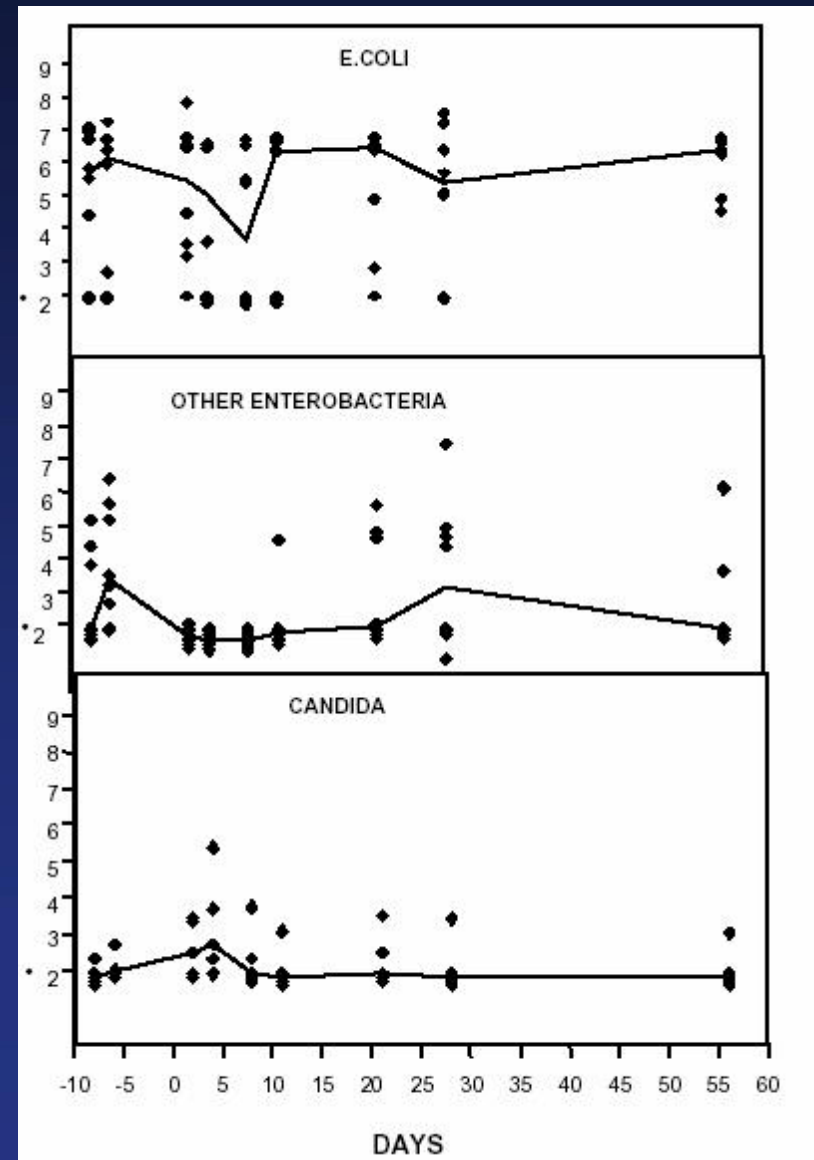
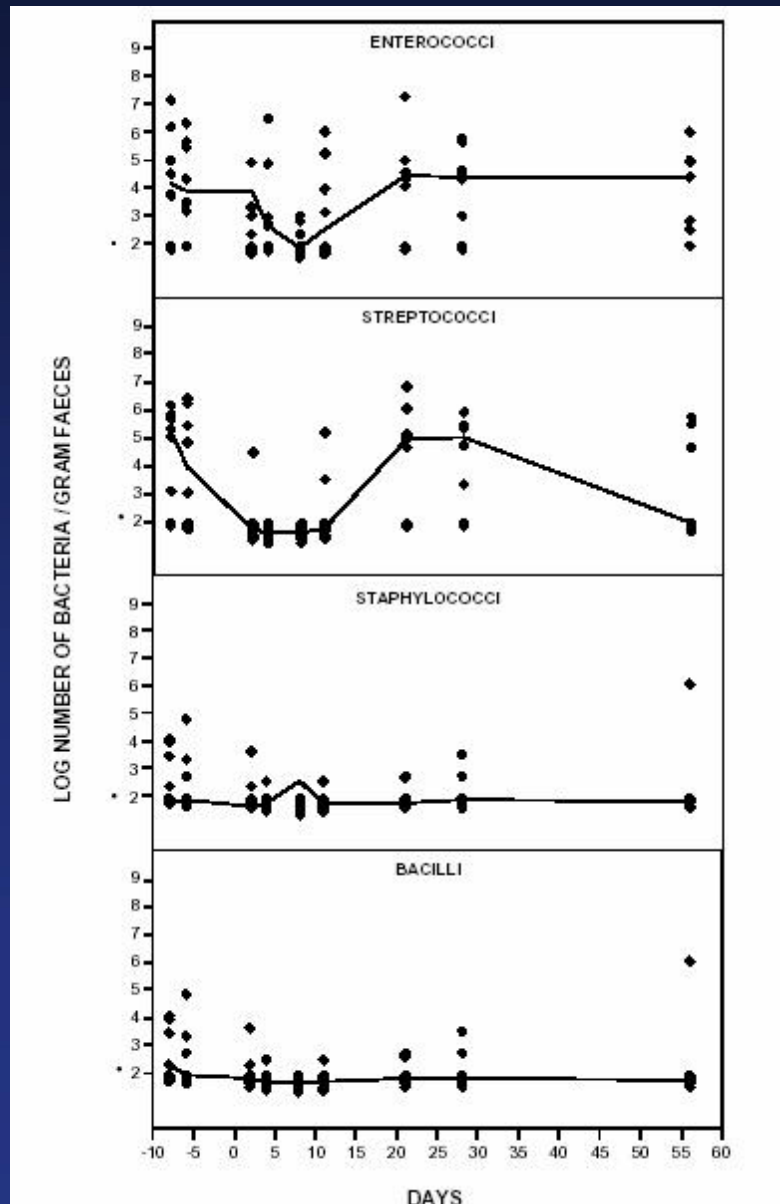
# Figure 6: Duration of Illness in Adults with Acute Community-Acquired Sinusitis in a Randomized Double-Blind Clinical Trial of Antimicrobial Treatment



Penicillin V, n=39; Amoxicillin, n=44; Placebo, n=44

From Lindbaek M, Hordahl P, Johnsen U, Randomised, double-blind, placebo-controlled trial of penicillin V and amoxicillin in treatment of acute sinus infections in adults. *BMJ*. 1996;313:325-329

# Impact of Repeat Dose Gemifloxacin (320 mg) on the Intestinal Aerobic Microflora



# Activity Against Anaerobes

		MIC <sub>90</sub> (µg/mL)		
		GEM	MOX	LEV
<i>B. fragilis</i>	(28)	2	4	4
<i>C. difficile</i>	(15)	>16	2	>16
<i>C. perfringens</i>	(13)	0.06	0.5	1
<i>F. nucleatum</i>	(12)	0.25	0.25	0.5
<i>P. anaerobius</i>	(13)	0.06	0.25	0.5
<i>P. magnus</i>	(14)	0.03	8	4

GEM = gemifloxacin, MOX = moxifloxacin, LEV = levofloxacin, CIP = ciprofloxacin

# Table 18: Comparative Bacteriological Cure Rates (Determined by Sinus Puncture) in Patients with Acute Community-Acquired Bacterial Sinusitis

Reference	No. Bacteriologic Cures/No. Cases
(Carenfelt et al. 1975)	
Antibiotic concentration $\geq$ MIC of causative bacteria <sup>1</sup>	19/21 (90%)
Antibiotic concentration < MIC of causative bacteria	15/33 (45%)
(Hamory et al. 1979)	
Appropriate antimicrobial and dose	47/49 (96%)
Inappropriate antimicrobial <sup>2</sup>	0/6 (0%)
(Carenfelt et al. 1990)	
Appropriate antimicrobial and dose	105/115 (91%)
Suboptimal dose <sup>3</sup>	37/50 (74%)
(Gwaltney, Jr. et al. 1992)	
Appropriate antimicrobial and dose	126/136 (93%)
Suboptimal dose <sup>3</sup>	1/5 (20%)
Suboptimal dose <sup>4</sup>	15/21 (71%)

<sup>1</sup> Antibiotic concentration in sinus aspirate after 2 to 3 days of treatment;

<sup>2</sup> Clindamycin for *H. influenzae*;

<sup>3</sup> Cefaclor 500 mg bid;

<sup>4</sup> Cefaclor 500 mg three times daily (tid)