Amoxicillin/clavulanate was significantly more effective than azithromycin against both S. pneumoniae, and H. influenzae.

Bacteriologic success was defined as the eradication of the initial AOM pathogen with or without a new pathogen, based on a lack of middle-ear fluid.

Bacteriologic success at an "on-therapy" visit 4-6 days after the start of treatment was associated with clinical success at the end of therapy in 96 of 105 children (91.4%) in the amoxicillin/clavulanate group and 80 of 89 (89.9%) in the azithromycin group.

Amoxicillin/clavulanate was significantly more effective than azithromycin against both S. pneumoniae (96.0% vs. 80.4%) and Haemophilus influenzae (96.7% vs. 52.9%). The distribution of pathogens was similar between the two groups. H. influenzae was the more common, found in 48.6% of the amoxicillin/clavulanate group and 50.6% of the azithromycin group.

In the subset of 101 amoxicillin/clavulanate patients and 82 azithromycin patients who demonstrated bacteriologic response after 4-6 days, amoxicillin/clavulanate was significantly more effective than azithromycin against penicillin-resistant S. pneumoniae, with eradication in 23 of 25 cases (92.0%) vs. 12 of 22 cases (54.5%), respectively.

Although significantly more children in the amoxicillin/clavulanate group withdrew from the study due to an adverse event, compared with the azithromycin group (21 vs. 7), the total number of adverse events was not significantly different between the two groups (139 vs. 128).