

Susceptibility of *Gardnerella vaginalis* to Solithromycin (CEM-101)

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Background: Solithromycin (CEM-101), a new macrolide and the first fluoroketolide, is in Phase 3 development for CABP and gonococcal urethritis. It has shown to be efficacious and safe in Phase 2 trials in these indications when used as monotherapy. In addition to activity against *Neisseria gonorrhoeae*, solithromycin also has demonstrated activity against *Chlamydia trachomatis* and *Mycoplasma genitalium* in urethritis. *Gardnerella vaginalis* is implicated in bacterial vaginosis and is also associated with non-gonococcal urethritis in men and women. The objective of this study was to determine the in vitro susceptibility of *Gardnerella vaginalis* to solithromycin.

Methods: MICs of solithromycin and comparator drugs were determined for 21 clinical strains of *Gardnerella vaginalis* cultured from vaginal specimens collected in 2012 from patients and submitted to the Clinical Microbiology Laboratories at the University of Rochester Medical Center, Rochester, NY. MICs were determined by broth microdilution methodology in cation-adjusted Mueller-Hinton broth supplemented with 2.5% lysed horse blood as recommended by CLSI M7-A8. Microdilution trays were incubated for 72 hours at 36° C in ambient air supplemented with 5% CO₂. The range of MICs, MIC₅₀s and MIC₉₀s of all drugs were determined.

Results: The MIC range and MIC₉₀ of solithromycin for *Gardnerella vaginalis* were ≤0.002-0.12 µg/ml and 0.12 µg/ml. The MIC₉₀s of clindamycin, azithromycin, doxycycline and metronidazole were 0.12, 8.0, 2.0 and 64 µg/ml, respectively.

Conclusion: Solithromycin was more active than metronidazole and equal to clindamycin against *Gardnerella vaginalis*. Solithromycin could provide broader coverage than metronidazole and clindamycin for organisms implicated in bacterial urethritis. In addition to covering gonococcus, chlamydia and mycoplasma, solithromycin could also cover *Gardnerella vaginalis* in bacterial urethritis. Solithromycin may also be useful in treating bacterial vaginosis caused by *Gardnerella vaginalis*.