Multicenter Evaluation of Tigecycline Activity in Latin America: Report from the SENTRY Antimicrobial Surveillance Program (2009)

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ABSTRACT

Background: Tigecycline, the first glycylcycline, presents a therapy option for emerging multidrug-resistant (MDR) Gram-positive (GP) and -negative (GN) pathogens in complicated intra-abdominal, skin structure, and respiratory infections. Latin American countries have high and increasing prevalence of MDR isolates of Enterobacteriaceae (ESBLs), *Acinetobacter* spp. (carbapenem-resistant) and Gram-positive cocci (MRSA, VRE). The aim of this study was to assess the activity of tigecycline and comparator antimicrobials against recent (2009) isolates from Latin America.
Methods: Ten sites forwarded 2,672 strains to a central laboratory (JMI Laboratories, North Liberty, IA, USA). Infection types (n) were: bloodstream (1139), community respiratory (59), hospitalized pneumonia (424), skin and skin structure (514), GP miscellaneous (536). Country (n sites; n isolates) were: Argentina (2; 641), Brazil (4; 977), Chile (2; 557), and Mexico (2; 497) Susceptibility testing against a large panel of antimicrobials was performed by CLSI methods (M07-A8, 2009). Identifications were confirmed and interpretive/screening criteria were also by CLSI guidelines (M100-S19, 2009), except for tigecycline where United States - Food and Drug Administration (USA-FDA) breakpoints were applied.
Results: Tigecycline was active against 96-100% of indicated/tabulated species (see Table). Tigecycline MIC_{90} values were not influenced by oxacillin or vancomycin susceptibility patterns for *S. aureus* and enterococci, respectively (0.25 µg/ml for total *S. aureus* and enterococci, MSSA, MRSA, VRS, and VRE). Resistance patterns noted were: tetracycline (see Table), ESBL- and fluoroquinolone resistance in Enterobacteriaceae (28.8, 33.7%, respectively), VRE (9.9%), MRSA (47.7%) and *Acinetobacter* spp. carbapenem (imipenem)-resistant (76.1%).

Organism (no. tested)	Cum. % inhibited at tigecycline MIC (µg/ml): ≤0.06	0.12	0.25	0.5	1	2	4	Tig % S[a]	Tet % R[b]
S. aureus (688)	10	46	99	>99	100			99.9	6.7
CoNS (221)	8	35	89	>99	100			99.5	7.7
Enterococci (292)	18	49	97	100				96.6	61.0
E. coli (291)	4	35	90	>99	>99	>99	100	99.7	47.8
Enterobacter (107)	0	4	41	81	98	100		100.0	16.8
Klebsiella (202)	0	3	43	85	95	99	100	98.5	29.2
Acinetobacter (205)	2	5	28	60	89	99	100	98.5	28.3

a. Tigecycline susceptibility by USA-FDA and Jones et al. (2007) criteria.
b. Tetracycline resistance by CLSI criteria.

Conclusions: MDR rates across all GP and GN species have increased in Latin America. However, tigecycline remained very active against these MDR strains. Tigecycline exhibited promising spectrum/potency exceeding currently available agents against sampled isolates from Latin America.

INTRODUCTION

Tigecycline is a glycylcycline that was first licensed by the United States (USA) Food and Drug Administration (FDA) in 2005 and the European Medicines Agency (EMEA) in 2006 as a parenteral agent for the treatment of complicated skin and skin structure infections (cSSSI) and intra-abdominal infections (IAI). This unique agent has stability against mechanisms of tetracycline resistance including increased binding affinity to tetracycline-resistant ribosomes and inhibition of efflux determinants; and represents a therapy option for emerging multidrug-resistant (MDR) Gram-positive and -negative pathogens.

Latin American countries have high and increasing prevalence of MDR isolates of Enterobacteriaceae (extended spectrum β-lactamase [ESBL] and AmpC derepressed), *Acinetobacter* spp. (carbapenem-resistant) and Gram-positive cocci (methicillin-resistant *Staphylococcus aureus* [MRSA] and vancomycin-resistant enterococci [VRE]). The aim of this study was to assess the activity of tigecycline and comparator antimicrobials against recent (2009) isolates from Latin American medical centers participating in the SENTRY Antimicrobial Surveillance Program.

MATERIALS AND METHODS

Organisms: Clinical isolates of aerobic bacteria were collected from 10 Latin American medical centers distributed throughout nine cities (six countries): São Paulo, Florianópolis, Porto Alegre and Brasília, Brazil (977 isolates); Buenos Aires and San Isidro, Argentina (641 isolates); Santiago (two centers), Chile (557 isolates); and Guadalajara and Durango, Mexico (497 isolates). The participant medical centers were directed by protocol to collect isolates from consecutive patients from specific sites of infections. The sites forwarded 2,672 strains to a central laboratory (JMI Laboratories, North Liberty, IA, USA). Infection types were (no. of isolates): bloodstream (1139), community respiratory tract infection (59), hospitalized pneumonia (424), skin and skin structure infection (514), miscellaneous Gram-positive infections (536).

Susceptibility testing: Susceptibility testing of antimicrobials was performed by CLSI methods (M07-A8, 2009). Identifications were confirmed and interpretive criteria were also by Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) guidelines (M100-S19, 2009), except for tigecycline where USA-FDA breakpoints were applied. Quality control measures were utilized by testing *Streptococcus pneumoniae* ATCC 49619, *S. aureus* ATCC 29213, *Enterococcus faecalis* ATCC 29212, *Escherichia coli* ATCC 25922, and *Pseudomonas aeruginosa* ATCC 27853.

SELECTED REFERENCES

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RESULTS

- Tigecycline was highly active against both oxacillin-resistant and -susceptible *S. aureus* (MIC_{50} and MIC_{90}, 0.25 µg/ml for both groups). More than 99% of strains were tigecycline-susceptible (MIC, ≤0.5 µg/ml; Table 1). Resistance to either oxacillin or tetracycline did not affect tigecycline in vitro activity against staphylococci.
- Similar to *S. aureus*, both oxacillin-resistant and -susceptible coagulase-negative staphylococci (CoNS) were very susceptible to tigecycline (MIC_{50}, 0.25 µg/ml and MIC_{90}, 0.5 µg/ml [Table 1]; 99.6% inhibited at ≤0.5 µg/ml).

Table 1. Antimicrobial activity of tigecycline and comparator antimicrobial agents when tested against Gram-positive isolates collected in Latin American medical centers.

Antimicrobial agent	MIC in µg/ml 50%	90%	Range	%S / %R[a]
S. aureus (688)				
Tigecycline[b]	0.25	0.25	≤0.03 – 1	99.9 / -
Oxacillin	1	>2	≤0.25 – >2	52.3 / 47.7
Erythromycin	0.5	>2	≤0.25 – >2	56.3 / 43.2
Clindamycin	≤0.25	>2	≤0.25 – >2	64.8 / 35.0
Levofloxacin	≤0.5	>4	≤0.5 – >4	62.6 / 36.8
Linezolid	2	2	0.5 – 2	100.0 / -
Tetracycline	≤2	≤2	≤2 – >8	92.9 / 6.7
Trimethoprim/sulfamethoxazole	≤0.5	≤0.5	≤0.5 – >2	96.1 / 3.9
Teicoplanin	≤2	≤2	≤2 – 8	100.0 / 0.0
Vancomycin	1	1	0.5 – 2	100.0 / 0.0
Oxacillin-susceptible (360)				
Tigecycline[b]	0.25	0.25	0.06 – 0.5	100.0 / -
Erythromycin	≤0.25	>2	≤0.25 – >2	86.1 / 13.3
Clindamycin	≤0.25	≤0.25	≤0.25 – >2	97.2 / 2.8
Levofloxacin	≤0.5	≤0.5	≤0.5 – >4	95.8 / 3.3
Linezolid	2	2	0.5 – 2	100.0 / -
Tetracycline	≤2	≤2	≤2 – >8	91.9 / 7.2
Trimethoprim/sulfamethoxazole	≤0.5	≤0.5	≤0.5 – >2	99.2 / 0.8
Teicoplanin	≤2	≤2	≤2 – 4	100.0 / 0.0
Vancomycin	1	1	0.5 – 2	100.0 / 0.0
Oxacillin-resistant (328)				
Tigecycline[b]	0.25	0.25	≤0.03 – 1	99.7 / -
Erythromycin	>2	>2	≤0.25 – >2	23.5 / 75.9
Clindamycin	>2	>2	≤0.25 – >2	29.3 / 70.4
Levofloxacin	>4	>4	≤0.5 – >4	26.2 / 73.5
Linezolid	2	2	0.5 – 2	100.0 / -
Tetracycline	≤2	≤2	≤2 – >8	93.9 / 6.1
Trimethoprim/sulfamethoxazole	≤0.5	≤0.5	≤0.5 – >2	92.7 / 7.3
Teicoplanin	≤2	≤2	≤2 – 8	100.0 / 0.0
Vancomycin	1	1	0.5 – 2	100.0 / 0.0
CoNS (221)				
Tigecycline[b]	0.25	0.5	≤0.03 – 1	- / -
Oxacillin	>2	>2	≤0.25 – >2	19.0 / 81.0
Erythromycin	>2	>2	≤0.25 – >2	31.7 / 68.3
Clindamycin	>2	>2	≤0.25 – >2	48.0 / 50.7
Levofloxacin	4	>4	≤0.5 – >4	37.1 / 61.1
Linezolid	1	1	0.5 – 2	100.0 / -
Tetracycline	≤2	4	≤2 – >8	92.3 / 7.7
Trimethoprim/sulfamethoxazole	2	>2	≤0.5 – >2	57.0 / 43.0
Teicoplanin	≤2	8	≤2 – >16	95.5 / 0.5
Vancomycin	2	2	0.25 – 4	100.0 / 0.0
Enterococcus spp. (292)				
Tigecycline[b]	0.25	0.25	≤0.03 – 0.5	96.6 / -
Ampicillin	≤1	>16	≤1 – >16	86.6 / 13.4
Erythromycin	>2	>2	≤0.25 – >2	10.3 / 56.2
Levofloxacin	2	>4	≤0.5 – >4	67.1 / 31.8
Linezolid	2	2	0.5 – 2	100.0 / 0.0
Quinupristin/dalfopristin	>2	>2	≤0.25 – >2	13.7 / 75.7
Teicoplanin	≤2	≤2	≤2 – >16	92.1 / 7.9
Tetracycline	>8	>8	≤2 – >8	39.0 / 61.0
Vancomycin	1	4	0.25 – >16	90.1 / 8.9
Vancomycin-susceptible[c] (263)				
Tigecycline[b]	0.25	0.25	≤0.03 – 0.5	96.2 / -
Ampicillin	≤1	4	≤1 – >16	93.2 / 6.8
Clindamycin	>2	>2	≤0.25 – >2	- / -
Erythromycin	>2	>2	≤0.25 – >2	10.6 / 52.1
Levofloxacin	1	>4	≤0.5 – >4	73.8 / 25.1
Linezolid	2	2	0.5 – 2	100.0 / 0.0
Quinupristin/dalfopristin	>2	>2	≤0.25 – >2	8.4 / 81.0
Teicoplanin	≤2	≤2	≤2	100.0 / 0.0
Tetracycline	>8	>8	≤2 – >8	34.6 / 65.4
Vancomycin	1	2	0.25 – 4	100.0 / 0.0
Vancomycin-resistant[d] (29)				
Tigecycline[b]	0.12	0.25	≤0.03 – 0.25	100.0 / -
Ampicillin	>16	>16	≤1 – >16	27.6 / 72.4
Erythromycin	>2	>2	≤0.25 – >2	6.9 / 93.1
Levofloxacin	>4	>4	2 – >4	6.9 / 93.1
Linezolid	1	2	0.5 – 2	100.0 / 0.0
Quinupristin/dalfopristin	1	>2	≤0.25 – >2	62.1 / 27.6
Teicoplanin	>16	>16	≤2 – >16	20.7 / 79.3
Tetracycline	≤2	>8	≤2 – >8	79.3 / 20.7
Vancomycin	>16	>16	8 – >16	0.0 / 89.7
S. pneumoniae (66)				
Tigecycline[b]	0.06	0.12	≤0.03 – 0.5	77.3 / -
Penicillin[e]	≤0.03	0.5	≤0.03 – 8	97.0 / 1.5
Penicillin[f]	≤0.03	0.5	≤0.03 – 8	72.7 / 9.1
Amoxicillin/clavulanate	≤1	≤1	≤1 – 4	95.5 / 0.0
Cefuroxime	≤1	≤1	≤1 – 8	92.0 / 8.0
Ceftriaxone	≤0.25	≤0.25	≤0.25 – 2	93.9 / 0.0
Erythromycin	≤0.25	>2	≤0.25 – >2	74.2 / 25.8
Clindamycin	≤0.25	≤0.25	≤0.25 – >2	93.9 / 6.1
Levofloxacin	1	1	≤0.5 – 2	100.0 / 0.0
Tetracycline	≤2	>8	≤2 – >8	84.8 / 12.1
Trimethoprim/sulfamethoxazole	≤0.5	>2	≤0.5 – >2	60.6 / 27.3
Vancomycin	≤1	≤1	≤1	100.0 / -
β-haemolytic streptococci[g] (91)				
Tigecycline[b]	≤0.03	0.06	≤0.03 – 0.25	100.0 / -
Penicillin	≤0.015	0.06	≤0.015 – 0.12	100.0 / -
Erythromycin	≤0.25	≤0.25	≤0.25 – >2	90.1 / 9.9
Clindamycin	≤0.25	≤0.25	≤0.25 – >2	94.4 / 5.6
Levofloxacin	≤0.5	1	≤0.5 – 2	100.0 / 0.0
Linezolid	1	1	0.5 – 2	100.0 / -
Tetracycline	≤2	>8	≤2 – >8	62.6 / 35.2
Vancomycin	0.5	0.5	0.25 – 0.5	100.0 / -
Viridans group streptococci[h] (21)				
Tigecycline[b]	0.06	0.12	≤0.03 – 0.5	95.2 / -
Penicillin	0.12	2	≤0.015 – 16	52.4 / 9.5
Erythromycin	≤0.25	>2	≤0.25 – >2	52.4 / 42.9
Clindamycin	≤0.25	0.5	≤0.25 – >2	85.7 / 9.5
Levofloxacin	1	2	≤0.5 – >4	95.2 / 4.8
Linezolid	1	1	0.5 – 2	100.0 / -
Tetracycline	≤2	>8	≤2 – >8	61.9 / 33.3
Vancomycin	0.5	1	≤0.12 – 1	100.0 / -

a. Criteria as published by the CLSI [2009].
b. Criteria as published by USA-FDA [Tygacil Package Insert, 2009].
c. Includes: *Enterococcus avium* (9 strains), *E. casseliflavus* (2 strains), *E. durans* (1 strain), *E. faecalis* (221 strains), *E. faecium* (27 strains), *E. gallinarum* (2 strains), and *E. hirae* (1 strain).
d. Includes: *Enterococcus faecalis* (6 strains), *E. faecium* (21 strains), and *E. gallinarum* (2 strains).
e. Criteria as published by CLSI [2009] for parenteral penicillin (non-meningitis).
f. Criteria as published by CLSI [2009] for oral penicillin V.
g. Includes: *Streptococcus dysgalactiae* (4 strains), Group A *Streptococcus* (32 strains), Group B *Streptococcus* (34 strains), Group C *Streptococcus* (13 strains), and Group G *Streptococcus* (8 strains).
h. Includes: *Streptococcus anginosus* (2 strains), *S. milleri* (1 strain), *S. mitis* (11 strains), *S. porcinus* (1 strain), *S. salivarius* (4 strains), and unspeciated viridians group streptococci (2 strains).

- The highest tigecycline MIC value among *Enterococcus* spp. strains was 0.5 µg/ml (MIC_{50} and MIC_{90}, 0.25 µg/ml; 96.6% susceptible). Linezolid (MIC_{50} and MIC_{90} of 2 µg/ml) was also very active against *Enterococcus* spp. (100.0% susceptible), while 9.9% of strains were vancomycin-non-susceptible (VRE). All VRE strains were susceptible to tigecycline (Table 1).
- Tigecycline was highly active against *S. pneumoniae* (highest MIC was 0.12 µg/ml), including isolates resistant to penicillin and/or tetracycline and/or erythromycin. β-haemolytic and viridans group streptococci were also very susceptible to tigecycline (MIC_{90}, 0.06 and 0.12 µg/ml, respectively; Table 1).
- As shown in Table 2, *E. coli* (MIC_{90}, 0.25 µg/ml) strains were slightly more susceptible to tigecycline compared to *Klebsiella* spp. and *Enterobacter* spp. (MIC_{90}, 1 µg/ml for both organisms). Among these frequently isolated enteric pathogens, 98.5-100.0% of strains were susceptible to tigecycline.
- Tigecycline was active against Enterobacteriaceae isolates with ESBL or AmpC derepressed phenotypes found within this collection of isolates (data not shown).
- Tigecycline exhibited limited activity against *P. aeruginosa* isolates (Table 2). In contrast, greater tigecycline activity was observed against *Acinetobacter* spp. (MIC_{90}, 2 µg/ml and 98.5% of isolates inhibited at ≤2 µg/ml) and *S. maltophilia* (MIC_{90}, 1 µg/ml and 95.0% inhibited at ≤2 µg/ml).

Table 2. Antimicrobial activity of tigecycline and comparator agents tested against Gram-negative organisms collected in Latin American medical centers.

Antimicrobial agent	MIC in µg/ml 50%	90%	Range	%S / %R[a]
E. coli (291)				
Tigecycline[b]	0.25	0.25	0.06 – 4	99.7 / 0.0
Piperacillin/tazobactam	2	32	≤0.5 – >64	86.6 / 3.1
Ceftazidime	≤1	>16	≤1 – >16	84.9 / 10.3
Ceftriaxone	≤0.25	>32	≤0.25 – >32	73.5 / 23.4
Gentamicin	≤2	>8	≤2 – >8	79.4 / 19.9
Levofloxacin	≤0.5	>4	≤0.5 – >4	55.0 / 42.6
Imipenem	0.25	0.25	≤0.12 – 1	100.0 / 0.0
Polymyxin B[c]	≤0.5	≤0.5	≤0.5 – >4	99.7 / 0.3[c]
Klebsiella spp.[d] (202)				
Tigecycline[b]	0.5	1	0.12 – 4	98.5 / 0.0
Piperacillin/tazobactam	4	>64	1 – >64	68.3 / 19.8
Ceftazidime	≤1	>16	≤1 – >16	69.8 / 23.8
Ceftriaxone	≤0.25	>32	≤0.25 – >32	57.9 / 39.1
Gentamicin	≤2	>8	≤2 – >8	68.8 / 25.2
Levofloxacin	≤0.5	>4	≤0.5 – >4	66.3 / 31.2
Imipenem	0.25	0.5	≤0.12 – >8	99.0 / 1.0
Polymyxin B[c]	≤0.5	≤0.5	≤0.5 – >4	97.0 / 3.0[c]
Enterobacter spp.[e] (107)				
Tigecycline[b]	0.5	1	0.12 – 2	100.0 / 0.0
Piperacillin/tazobactam	4	>64	1 – >64	79.4 / 10.3
Ceftazidime	≤1	>16	≤1 – >16	67.3 / 28.0
Ceftriaxone	0.5	>32	≤0.25 – >32	59.8 / 23.4
Gentamicin	≤2	>8	≤2 – >8	84.1 / 13.1
Levofloxacin	≤0.5	>4	≤0.5 – >4	84.1 / 14.0
Imipenem	0.5	1	≤0.12 – 2	100.0 / 0.0
Polymyxin B[c]	≤0.5	>4	≤0.5 – >4	85.0 / 14.0[c]
S. marcecens (56)				
Tigecycline[b]	1	2	0.25 – >4	94.6 / 3.6
Piperacillin/tazobactam	2	16	1 – >64	92.9 / 3.6
Ceftazidime	≤1	8	≤1 – >16	92.9 / 3.6
Ceftriaxone	≤0.25	>32	≤0.25 – >32	71.4 / 14.3
Gentamicin	≤2	>8	≤2 – >8	83.9 / 12.5
Levofloxacin	≤0.5	>4	≤0.5 – >4	87.5 / 10.7
Imipenem	1	1	0.25 - 2	100.0 / 0.0
Polymyxin B	>4	>4	>4	- / -
P. mirabilis (38)				
Tigecycline[b]	2	4	0.25 – >4	73.7 / 5.3
Piperacillin/tazobactam	≤0.5	2	≤0.5 – 4	100.0 / 0.0
Ceftazidime	≤1	8	≤1 – 8	100.0 / 0.0
Ceftriaxone	≤0.25	32	≤0.25 – >32	78.9 / 7.9
Gentamicin	≤2	>8	≤2 – >8	71.1 / 28.9
Levofloxacin	≤0.5	>4	≤0.5 – >4	65.8 / 34.2
Imipenem	1	2	0.25 - 4	100.0 / 0.0
Polymyxin B	>4	>4	>4	- / -
Acinetobacter spp. (205)				
Tigecycline[f]	0.5	2	≤0.03 – 4	98.5 / 0.0[f]
Piperacillin/tazobactam	>64	>64	≤0.5 – >64	9.3 / 87.8
Ampicillin/sulbactam	>16	>16	≤2 – >16	13.7 / 78.0
Ceftazidime	>16	>16	≤1 – >16	12.2 / 84.4
Ceftriaxone	>32	>32	≤0.25 – >32	3.9 / 88.8
Levofloxacin	>4	>4	≤0.5 – >4	13.7 / 84.4
Amikacin	>32	>32	0.5 – >32	25.9 / 62.9
Tobramycin	16	>16	0.25 – >16	46.3 / 51.2
Imipenem	>8	>8	≤0.12 – >8	23.9 / 76.1
Polymyxin B	≤0.5	≤0.5	≤0.5 – >4	98.0 / 2.0
P. aeruginosa (299)				
Tigecycline	>4	>4	0.06 – >4	- / -
Piperacillin/tazobactam	16	>64	1 – >64	75.3 / 24.7
Ceftazidime	8	>16	≤1 – >16	58.9 / 29.4
Levofloxacin	4	>4	≤0.5 – >4	48.8 / 46.5
Amikacin	4	>32	0.5 – >32	68.6 / 27.4
Tobramycin	1	>16	≤0.12 – >16	60.2 / 39.1
Imipenem	2	>8	≤0.12 – >8	58.2 / 32.8
Polymyxin B	1	1	≤0.5 – 4	99.7 / 0.0
S. maltophilia (20)				
Tigecycline[f]	0.5	1	0.25 – 4	95.0 / 0.0[f]
Ceftazidime	8	>16	≤1 – >16	60.0 / 35.0
Levofloxacin	≤0.5	2	≤0.5 – >4	95.0 / 5.0
Polymyxin B	2	>4	≤0.5 – >4	63.2 / 21.1[c]
Ticarcillin/clavulanate	64	128	≤16 – >128	30.0 / 35.0
Trimethoprim/sulfamethoxazole	≤0.5	≤0.5	≤0.5 – 2	100.0 / 0.0

a. Criteria as published by the CLSI [2009]
b. USA-FDA breakpoints were applied [Tygacil Product Insert, 2009].
c. CLSI [2009] breakpoints for *P. aeruginosa* were applied for comparison purposes.
d. Includes: *Klebsiella oxytoca* (14 strains), *K. ozaenae* (1 strain), *K. pneumoniae* (186 strains) and unspeciated *Klebsiella* (1 strain).
e. Includes: *Enterobacter aerogenes* (10 strains), *E. asburiae* (1 strain), *E. cloacae* (85 strains), *E. gergoviae* (2 strains) and unspeciated *Enterobacter* (9 strains).
f. USA-FDA breakpoints for Enterobacteraiceae were applied for comparison purposes.

CONCLUSIONS

- Tigecycline showed sustained activity and spectrum against Gram-positive and -negative bacteria, including MDR strains, causing infection in patients hospitalized in selected Latin American medical centers.
- The results of the present study (2009) indicate that tigecycline may have an important role in the treatment of both hospital- and community-acquired infections in the Latin American region.