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Outpatient treatment of acute bacterial skin and skin structure infections (ABSSSI) with tedizolid phosphate and linezolid in patients in the United States

Subgroup analysis of 2 randomized phase 3 trials

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Abstract

Background: Acute bacterial skin and skin structure infections (ABSSSI) are a frequent cause of hospital admissions in the United States. Safe and effective outpatient treatments may lower ABSSSI-associated health care costs by reducing unnecessary hospital admissions. Using data from 2 phase 3 trials (ESTABLISH-1, NCT01170221; ESTABLISH-2, NCT01421511), this post-hoc analysis explored the efficacy and safety of tedizolid in an outpatient setting.

Methods: Subgroup analysis was performed on US outpatients (defined as patients who were not in hospital at the time of treatment initiation) with ABSSSI caused by presumed or proven gram-positive pathogens. Patients were randomly assigned to receive tedizolid phosphate 200 mg once daily for 6 days (n = 403) or linezolid 600 mg twice daily for 10 days (n = 410). The primary end point was early clinical response (48–72 hours after the start of treatment). Secondary end points included investigator-assessed clinical response at end of therapy (EOT) and post-therapy evaluation (PTE; 7–14 days after therapy). Additional assessments included the patient-reported level of pain using a visual analog scale (VAS) and the per-pathogen favorable microbiological response rate at the PTE visit. Compliance with treatment and safety outcomes was also recorded.

Results: Early clinical response was similar between treatment groups (tedizolid, 82.4%; linezolid, 79.0%), as was investigator-assessed clinical response at EOT (tedizolid, 87.1%; linezolid, 86.1%) and PTE (tedizolid, 83.1%; linezolid, 83.7%). Mean changes from baseline to days 10 to 13 in VAS scores were identical between treatment groups (tedizolid, –51.9 mm; linezolid, –51.9 mm). Microbiological eradication rates were generally similar in both treatment groups for all key pathogens. Patients in both groups had favorable response at PTE. More tedizolid-treated patients (89.3%) than linezolid-treated patients (77.3%) were compliant with treatment. The most frequently reported drug-related treatment-emergent adverse events were nausea (tedizolid, 10.7%; linezolid, 13.8%), diarrhea (tedizolid, 4.5%; linezolid, 5.9%), and headache (tedizolid, 5.5%; linezolid, 4.4%). Treatment discontinuation rates were low for both treatment groups (tedizolid, 0.7%; linezolid, 1.0%).

Conclusion: Short-course therapy with tedizolid can successfully treat patients with ABSSSI caused by presumed or proven gram-positive pathogens in an outpatient setting.

Abbreviations: ABSSSI = acute bacterial skin and skin structure infections, AEs = adverse events, CI = confidence interval, EOT = end of therapy, ITT = intent to treat, MRSA = methicillin-resistant *Staphylococcus aureus*, PTE = post-therapy evaluation, TEAEs = treatment-emergent adverse events, VAS = visual analog scale,.

Keywords: ABSSSI, antibacterial, gram-positive bacteria, linezolid, outpatients, tedizolid phosphate

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1. Introduction

Acute bacterial skin and skin structure infections (ABSSSI) are a frequent cause of hospital admissions in the United States.[1,2] The number of admissions has been rising steadily for more than a decade,[1,2] placing increased pressure on health care resources. However, a large proportion of patients with ABSSSI may not require hospital care and could thus be suitable for outpatient treatment.[2,3] Outpatient treatment could prevent hospital stays, reduce health care costs, and decrease the incidence of nosocomial infections.[3] The decision to provide outpatient treatment is generally based on clinical assessment of the patient's severity of infection and comorbidities.[3]

Treatment agents that have long half-lives, allow for short courses of therapy, and provide good tolerability profiles are likely to be the most suitable for outpatient treatment of patients with ABSSSI.[2,3] Tedizolid phosphate, the prodrug of the oxazolidinone antibacterial tedizolid, has pharmacokinetic properties that allow once-daily dosing and has demonstrated potent activity against a wide variety of gram-positive pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA).[4] Clinical trials have demonstrated an at least fourfold greater potency for tedizolid over linezolid against these pathogens.[5–9] Given that MRSA is the most frequent cause of ABSSSI in the United States,[10,11] there is a need for oral antibacterials with activity against this pathogen.

Two phase 3 trials, ESTABLISH-1 and ESTABLISH-2, demonstrated the noninferiority of tedizolid phosphate (200 mg once daily for 6 days) to linezolid (600 mg twice daily for 10 days) in patients with ABSSSI caused by confirmed or suspected gram-positive pathogens.[12,13] As previously reported, the tedizolid group in ESTABLISH-1 showed early clinical response rates (the primary endpoint) of 79.5% (95% CI, 74.8%–83.7%) compared with the linezolid group (79.4% [95% CI, 74.7%–83.6%]) for a treatment difference of 0.1% (95% CI, −6.1%–6.2%). In ESTABLISH-2, 85% of patients in the tedizolid group and 83% in the linezolid group achieved early clinical response (difference 2.6%, 95% CI −3.0–8.2). The subpopulation of nonhospitalized US-based patients from both ESTABLISH trials was analyzed post hoc in this study to determine the efficacy and tolerability of tedizolid in an outpatient setting.

2. Methods

2.1. Study design

ESTABLISH-1 (ClinicalTrials.gov, NCT01170221) and ESTABLISH-2 (ClinicalTrials.gov, NCT01421511) were double-blind, double-dummy, multicenter, randomized phase 3 trials in patients with ABSSSI.[12,13] Patients were randomly assigned to receive tedizolid phosphate 200 mg once daily for 6 days (n = 664) or linezolid 600 mg twice daily for 10 days (n = 669). ESTABLISH-1 patients received oral therapy exclusively, whereas ESTABLISH-2 patients first received intravenous therapy for 24 hours and then were switched to oral study drug when prespecified clinical improvement criteria were met.

2.2. Patient selection

Patients were ≥18 (ESTABLISH-1) or ≥12 (ESTABLISH-2) years of age, and key inclusion criteria were diagnosis of ABSSSI (cellulitis/erysipelas, wound infection, or major cutaneous abscess), lesion surface area ≥75 cm^2 (wound infections and abscesses also required erythema extending ≥5 cm from the edge of the wound or abscess to the lesion margin), ≥1 regional or systemic sign of infection (lymphadenopathy, temperature ≥38°C, white blood cell count ≥10,000 cells/mm^3 or <4000 cells/mm^3, or immature neutrophil count >10%), and suspected or documented gram-positive pathogen. Key exclusion criteria included uncomplicated or gram-negative ABSSSI, use of any systemic or topical antibiotic with activity against gram-positive bacteria within 96 hours before the first dose of study drug, previous unsuccessful treatment of the same infection site, infection close to a prosthetic device, severe sepsis or known bacteremia at the time of enrollment, or confirmed immunocompromised status.

All patients or their guardians provided written informed consent. Institutional review boards or the equivalent at each study center approved the trial. A data and safety monitoring board reviewed safety data during the conduct of the study.

2.3. Assessments

2.3.1. Efficacy. The primary end point for the integrated data analysis of the ESTABLISH trials was early clinical response, defined as a reduction in lesion area of ≥20% at 48 to 72 hours after the start of study drug. Important secondary end points were investigator-assessed clinical response at the end of therapy (EOT) and at the PTE, which was assessed 7 to 14 days after EOT. A two-sided 95% confidence interval was calculated for the observed difference in outcome rates using the method of Miettinen and Nurminen.[14]

Patient-reported level of pain was assessed using a visual analog scale (VAS) at baseline and on study days 10 to 13. The VAS is a 100-mm line on which the 0-mm point indicates no pain and the 100-mm point indicates worst pain ever; patients were required to indicate their pain levels on the VAS twice within 5 minutes. If the VAS scores were different by >10 mm, the patient was to complete the VAS a third time. The 2 closest scores were recorded. The baseline VAS pain score, the score on study days 10 to 13, and the change from baseline (visit minus baseline) were summarized.

The per-pathogen microbiological response rate at the PTE visit was determined programmatically based on the data from the central microbiology laboratory and the investigator's assessment of clinical response. A favorable response was defined as eradication or presumed eradication of the original baseline pathogen. The number and percentage of patients classified with a favorable microbiological response were tabulated for both treatment groups.

2.3.2. Compliance. Treatment-compliant patients were defined as outpatients who took all doses (100%) of their assigned treatment. For tedizolid phosphate (200 mg once daily for 6 days), compliant patients received 6 doses; for linezolid (600 mg twice daily for 10 days), compliant patients received 20 doses. Patients were categorized as noncompliant if they missed ≥1 dose.

2.3.3. Safety. Safety evaluations included assessment of treatment-emergent adverse events (TEAEs), clinical laboratory results, vital signs and electrocardiograms, and physical examinations.

2.4. Analysis populations

Only outpatients from the pooled US population in the ESTABLISH trials were included in this analysis; US patients who were hospitalized at the time of treatment initiation were considered inpatients and were excluded from this analysis. The intent-to-treat (ITT) population (all randomly assigned US

Table 1

Patient demographics and clinical characteristics of US-based outpatients (ITT population).

Parameter	Tedizolid 200 mg N = 403	Linezolid 1200 mg N = 410
Original trial enrollment, n (%)		
ESTABLISH-1	259 (64.3)	263 (64.1)
ESTABLISH-2	144 (35.7)	147 (35.9)
Age, years, mean (range)	40.3 (17.0–85.0)	40.9 (15.0–89.0)
Male, n (%)	265 (65.8)	254 (62.0)
Type of ABSSSI, n (%)		
Cellulitis/erysipelas	126 (31.3)	135 (32.9)
Infected wound	138 (34.2)	141 (34.4)
Major cutaneous abscess	139 (34.5)	134 (32.7)
Lesion surface area, cm^2, mean (range)	253.4 (22.5–2030.0)	259.8 (27.0–2490.0)
>300 cm^2, n (%)	83 (20.6)	88 (21.5)
Location of ABSSSI, n (%)		
Chest/abdomen	28 (6.9)	21 (5.1)
Groin/buttock/back	80 (19.9)	66 (16.1)
Head/neck	20 (5.0)	21 (5.1)
Lower extremity (foot/leg/knee)	135 (33.5)	148 (36.1)
Upper extremity (hand/arm)	140 (34.7)	154 (37.6)
Signs/symptoms of infection, n (%)		
Fever (≥38°C)	32 (7.9)	21 (5.1)
Lymphadenopathy	366 (90.8)	375 (91.5)
SIRS	55 (13.6)	29 (7.1)
WBC count (≥10,000 or <4000 cells/mm^3)	182 (45.2)	156 (38.0)
Comorbidities, n (%)		
Hepatitis C positive	152 (37.7)	173 (42.2)
Obesity	111 (27.5)	135 (32.9)
History of diabetes mellitus	28 (6.9)	24 (5.9)
Risk factors, n (%)		
IV drug use	178 (44.2)	200 (48.8)
Previous ABSSSI lesion	120 (29.8)	122 (29.8)

ABSSSI = acute bacterial skin and skin structure infection; IV = intravenous; SIRS = systemic inflammatory response syndrome; WBC = white blood cell.

outpatients) was the primary population for efficacy analyses. The clinically evaluable analysis set at PTE included all patients in the ITT population who completed the investigator's assessment of outcome at the PTE visit without major protocol violations or receipt of treatments that might confound outcomes. The microbiological ITT population included all US outpatients for whom the baseline pathogen had been identified. Safety analyses were performed in the safety population (all US outpatients who received ≥1 dose of study drug).

3. Results

3.1. Patient characteristics

The pooled ITT population consisted of 813 outpatients from the ESTABLISH studies; 403 of these patients were randomly assigned to receive tedizolid phosphate, and 410 were randomly assigned to receive linezolid (Supplementary Figure 1, http://links.lww.com/MD/C41). Patient demographics and clinical characteristics are described in Table 1. Demographics were comparable between both treatment groups. Severity of infection, comorbidities, and type of ABSSSI were also generally similar between tedizolid- and linezolid-treated patients. Systemic inflammatory response syndrome, however, was about twice as common in the tedizolid group. A large proportion of patients in both treatment groups currently or recently received intravenous drugs (tedizolid, 44.2%; linezolid, 48.8%). Based on their clinical characteristics, the patient population in both treatment groups was moderately to severely ill, and ~21% had large (>300 cm^3) lesions.

The most common pathogen isolated at baseline was *S aureus* (Table 2); slightly more than half the *S aureus* isolates were MRSA. The second most common pathogens were of the *Streptococcus anginosus* group (*S anginosus*, *Streptococcus constellatus*, and *Streptococcus intermedius*). Baseline pathogens were similar between treatment groups.

3.2. Efficacy

Early clinical response (≥20% reduction in lesion size at 48–72 hours) was similar between treatment groups (tedizolid, 82.4%; linezolid, 79.0%) (Fig. 1A). Clinical success rates at EOT were slightly higher than early response rates but remained similar between the tedizolid (87.1%) and linezolid (86.1%) treatment groups (Fig. 1B). Rates of clinical success at PTE were also similar between the tedizolid (83.1%) and linezolid (83.7%) treatment groups (Fig. 1C).

Changes from baseline in VAS scores are shown in Figure 2. Results were similar between treatment groups. Patients recorded mean scores of 59.5 mm (tedizolid) and 58.1 mm (linezolid) at baseline, which were reduced to 7.6 mm (tedizolid) and 6.1 mm (linezolid) on study days 10 to 13.

Microbiological response rates for key pathogens are shown in Table 3. Eradication rates were generally similar in both treatment groups for all key pathogens, and most patients in both groups had a favorable response at PTE. More than 86% of patients in both treatment groups had a favorable response for *S aureus*.

Both test agents demonstrated a relatively narrow range of MIC values for *S aureus* (including methicillin-sensitive *S aureus* and MRSA), which was the most commonly isolated pathogen in the studies in the full patient population of the

Table 2

Baseline pathogens isolated from primary infection site or blood culture of US-based outpatients (MITT population).

Pathogen, n (%)	Tedizolid 200 mg N = 294	Linezolid 1200 mg N = 290
Gram-positive aerobes	284 (97.9)	288 (98.0)
Staphylococcus aureus	243 (83.8)	246 (83.7)
MRSA	135 (55.6)	140 (56.9)
MSSA	108 (44.4)	109 (44.3)
Staphylococcus hominis	1 (0.3)	3 (1.0)
Staphylococcus lugdunensis	3 (1.0)	5 (1.7)
Enterococcus faecalis	5 (1.7)	1 (0.3)
Streptococcus pyogenes	5 (1.7)	4 (1.4)
Streptococcus anginosus group	29 (10.0)	24 (8.2)
Streptococcus agalactiae	6 (2.1)	7 (2.4)
Streptococcus mitis	2 (0.7)	7 (2.4)
Streptococcus sanguinis	4 (1.4)	2 (0.7)
Streptococcus viridans group	3 (1.0)	7 (2.4)
Gram-positive anaerobes	10 (3.4)	12 (4.1)
Clostridium perfringens	4 (1.4)	2 (0.7)
Gram-negative aerobes*	5 (1.7)	5 (1.7)
Gram-negative anaerobes*	0	2 (0.7)

MRSA = methicillin-resistant *S aureus*, MSSA = methicillin-susceptible *S aureus*.

* These patients did not have monomicrobial infections because eligible patients were required to have suspected or documented gram-positive pathogens at baseline.

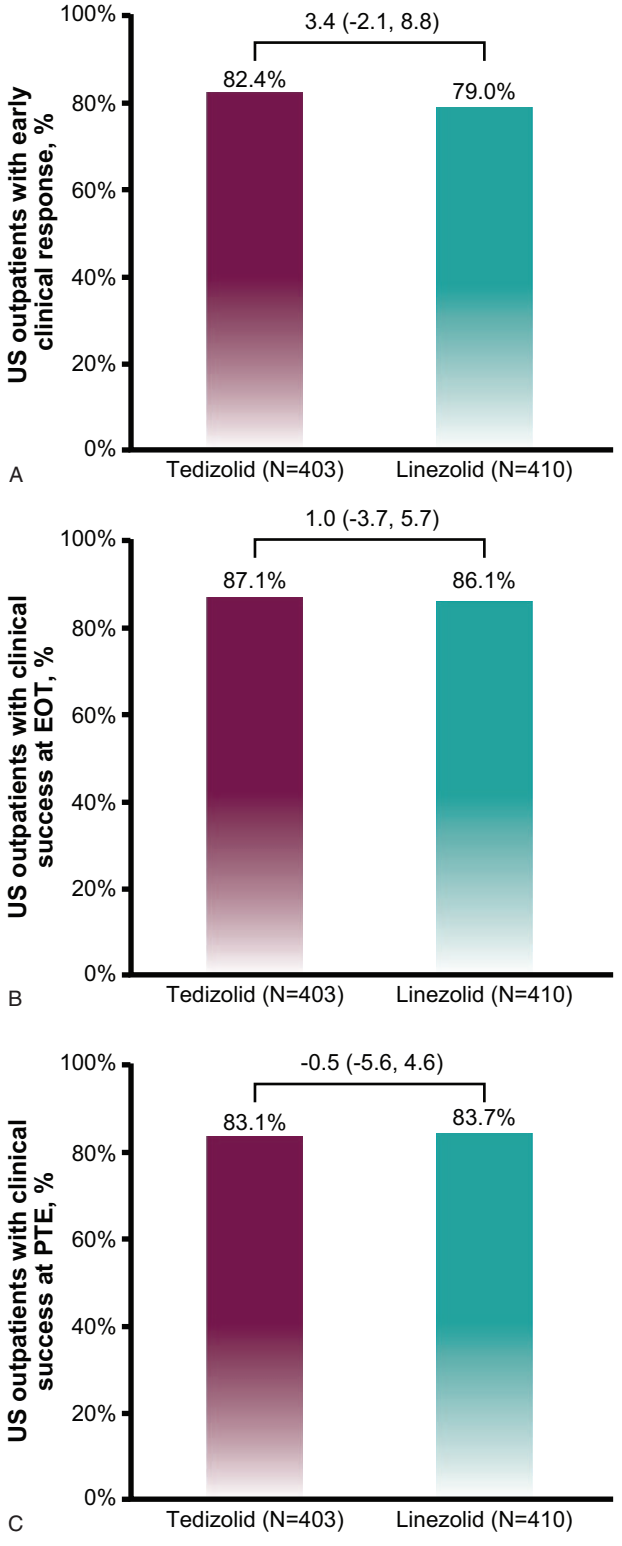
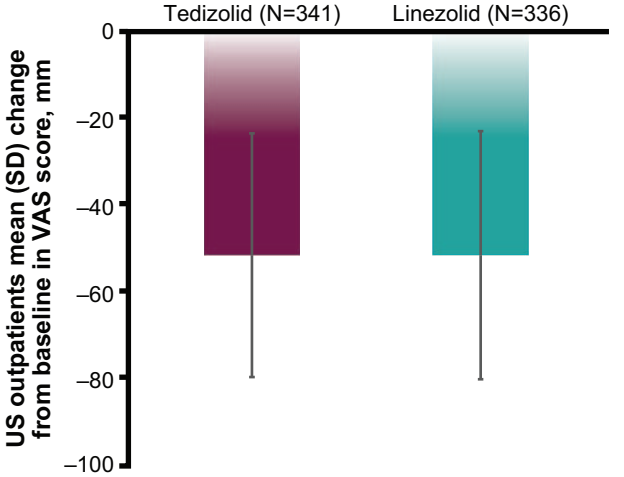


Figure 1. Clinical response in US-based outpatients (ITT population). (A) Early clinical response. (B) Clinical success at EOT evaluation. (C) Clinical success at PTE evaluation. Value above brackets indicates treatment difference (95% confidence interval). EOT = end of therapy, ITT = intent-to-treat, PTE = post-therapy evaluation.

phase 3 studies (0.12 to 0.5 μg/mL for tedizolid, 1.0 to 4.0 μg/mL for linezolid).[12,13] Other pathogens were found in much lower numbers but were also highly susceptible to both tedizolid and linezolid.



	VAS Score, mm Mean (SD)	
	Tedizolid (N=341)	Linezolid (N=336)
Baseline	59.5 (27.2)	58.1 (26.9)
Days 10–13	7.6 (14.7)	6.1 (13.7)

Figure 2. VAS scores in US-based outpatients at baseline and at days 10 to 13 (ITT population). ITT = intent-to-treat; SD = standard deviation; VAS = visual analog scale.

3.3. Compliance

More patients receiving tedizolid phosphate (89.3%) than those receiving linezolid (77.3%) were compliant with treatment (Fig. 3). The difference in compliance may be attributable to both shorter duration of treatment and fewer doses associated with tedizolid phosphate compared with linezolid as a result of the once-daily and twice-daily dosing regimens. The mean (±standard deviation) number of doses taken was 5.7 (±1.0) for tedizolid phosphate and 18.0 (±4.7) for linezolid.

3.4. Safety

The overall incidence of TEAEs was comparable between tedizolid and linezolid (Table 4). Fewer gastrointestinal adverse events (AEs) were reported with tedizolid than with linezolid. Moreover, the incidence of abnormal platelet counts ($<112 \times 10^3/mm^3$) was lower in the tedizolid group (11 patients; 2.7%) than in the linezolid group (20 patients; 4.9%). Overall, 5 (1.2%) patients in the tedizolid group and 7 (1.7%) patients in the linezolid group experienced serious TEAEs (Table 4). Serious TEAEs in the tedizolid group included abscess, dehydration, endophthalmitis, nephrolithiasis, septic shock, 7th nerve paralysis, vomiting, and weight decrease. Serious TEAEs in the linezolid group included acute coronary syndrome, anaphylactic reaction, blood glucose increase, cellulitis, diabetic ketoacidosis, major depression, suicidal ideation, and urinary tract infection.

The number of patients who discontinued treatment because of a TEAE was similar between groups: 3 (0.7%) patients in the tedizolid group and 4 (1.0%) patients in the linezolid group. Drug-related TEAEs occurred at a similar frequency between treatment groups (Table 5). The majority of drug-related TEAEs were mild for both tedizolid (76.0%) and linezolid (71.6%). The

Table 3

Microbiological response for key pathogens from primary infection site or blood culture at the PTE visit (MITT population).

Pathogen*	Tedizolid 200 mg N = 290		Linezolid 1200 mg N = 294	
	N1	Favorable response n (%)	N1	Favorable response n (%)
Any target pathogen	279	236 (84.6)	279	239 (85.7)
Staphylococcus aureus	243	211 (86.8)	246	213 (86.6)
MRSA	135	115 (85.2)	140	115 (82.1)
MSSA	108	96 (88.9)	108	100 (92.6)
Staphylococcus lugdunensis	3	3 (100.0)	5	4 (80.0)
Enterococcus faecalis	5	3 (60.0)	1	1 (100.0)
Streptococcus pyogenes	5	5 (100.0)	4	4 (100.0)
Streptococcus anginosus group	29	21 (72.4)	24	21 (87.5)
Streptococcus agalactiae	6	5 (83.3)	7	5 (71.4)

MITT = microbiological intent-to-treat, MRSA = methicillin-resistant *S aureus*, MSSA = methicillin-susceptible *S aureus*, n = number of patients in the specific category, N1 = number of patients in the analysis set with the baseline pathogen, PTE = post-therapy evaluation.

Percentages are calculated as 100 × (n/N1).

* Responses from patients with more than one pathogen may be counted in more than one row.

most frequently reported drug-related TEAEs were nausea (tedizolid, 10.7%; linezolid, 13.8%), diarrhea (tedizolid, 4.5%; linezolid, 5.9%), and headache (tedizolid, 5.5%; linezolid, 4.4%). Only one patient experienced a serious drug-related TEAE, an anaphylactic reaction in the linezolid treatment group.

4. Discussion

In this post hoc analysis, tedizolid and linezolid were evaluated for the treatment of ABSSSI in an outpatient population that was moderately to severely ill and had a high level of complicating factors. Both tedizolid and linezolid proved efficacious in outpatients with ABSSSI. Clinical response was achieved by ≥79% of patients in both groups at the time points evaluated. In addition, both treatment groups demonstrated similar rates of early, EOT, and late clinical response in the treatment of outpatients with ABSSSI. These data are further supported by a pooled analysis of ESTABLISH-1 and ESTABLISH-2 results, which demonstrated that treatment success at 48 to 72 hours after the first dose of oxazolidinones is a good indicator of late clinical cure.[15] Rapid, sustained clinical response will reduce the spread of lesions, thus reducing the need for hospital admission and further decreasing the need for additional care after antimicrobial therapy has been discontinued.

Although mean VAS scores ≥58 mm at baseline indicated a fairly high level of pain, both treatments were able to noticeably reduce pain scores (to <8 mm) by study days 10 to 13. Similarly, microbiological responses for key pathogens were generally comparable in both treatment groups, with most patients having favorable response at PTE.

Overall, AEs were comparable between treatment groups, though patients treated with tedizolid had fewer gastrointestinal AEs and fewer abnormalities in their platelet counts. Fewer tedizolid-treated patients (n = 125) than linezolid-treated patients (n = 153) experienced drug-related TEAEs. The most frequently reported treatment-related TEAEs were similar between both treatment groups. Tedizolid-treated patients were more

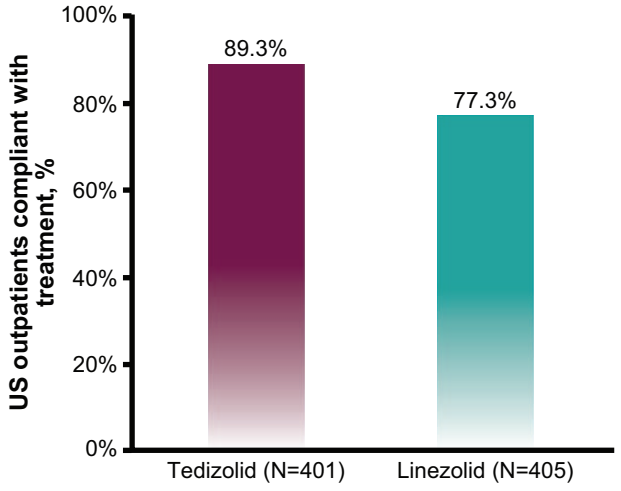


Figure 3. Treatment compliance of US-based outpatients (safety population).

Table 4

TEAEs experienced by US-based outpatients (safety population).

Parameter, n (%)	Tedizolid 200 mg N = 401	Linezolid 1200 mg N = 405
Any TEAE	204 (50.9)	210 (51.9)
Serious TEAE	5 (1.2)	7 (1.7)
TEAE leading to discontinuation	3 (0.7)	4 (1.0)
Any TEAE leading to death	0	0
TEAE by system organ class and preferred term occurring in ≥2% of patients in any group		
Gastrointestinal disorders	86 (21.4)	119 (29.4)
Diarrhea	19 (4.7)	25 (6.2)
Nausea	46 (11.5)	68 (16.8)
Vomiting	19 (4.7)	32 (7.9)
Infections and infestations	79 (19.7)	63 (15.6)
Secondary abscess	35 (8.7)	25 (6.2)
Secondary cellulitis	16 (4.0)	13 (3.2)
Vulvovaginal mycotic infection	2 (0.5)	9 (2.2)
Nervous system disorders	47 (11.7)	44 (10.9)
Dizziness	10 (2.5)	11 (2.7)
Headache	32 (8.0)	27 (6.7)
Psychiatric disorders	12 (3.0)	6 (1.5)
Insomnia	8 (2.0)	4 (1.0)
Skin and subcutaneous tissue disorders	37 (9.2)	33 (8.1)
Pruritus	2 (0.5)	8 (2.0)
Pruritus generalized	10 (2.5)	6 (1.5)

TEAE = treatment-emergent adverse event.

Table 5

Drug-related TEAEs experienced by US-based outpatients (safety population).

Parameter, n (%)	Tedizolid 200 mg N = 401	Linezolid 1200 mg N = 405
Drug-related TEAE	125 (31.2)	153 (37.8)
Drug-related TEAEs by severity*		
Mild	95 (76.0)	110 (71.9)
Moderate	28 (22.4)	39 (25.5)
Severe	2 (1.6)	4 (2.6)
Drug-related serious TEAE	0	1 (0.2)
Drug-related TEAEs by preferred term occurring in ≥2% of patients in any group		
Gastrointestinal disorders	78 (19.5)	101 (24.9)
Diarrhea	18 (4.5)	24 (5.9)
Nausea	43 (10.7)	56 (13.8)
Vomiting	15 (3.7)	29 (7.2)
Infections and infestations	8 (2.0)	21 (5.2)
Vulvovaginal mycotic infection	2 (0.5)	8 (2.0)
Nervous system disorders	33 (8.2)	32 (7.9)
Dizziness	8 (2.0)	10 (2.5)
Headache	22 (5.5)	18 (4.4)
Skin and subcutaneous tissue disorders	26 (6.5)	18 (4.4)
Pruritus generalized	10 (2.5)	6 (1.5)
Drug-related serious TEAEs by system organ class and preferred term occurring in patients in any group		
Immune system disorders	0	1 (0.2)
Anaphylactic reaction	0	1 (0.2)

TEAE = treatment-emergent adverse event.

* Drug-related TEAEs by severity are calculated as percentage of patients who experienced drug-related TEAEs. Patients were counted only once based on the maximal severity of drug-related TEAE reported.

compliant with their medication (89.3%) than linezolid-treated patients (77.3%), possibly because of the combination of shorter duration of treatment and fewer doses. Both treatment groups had a low incidence of discontinuations due to AEs (tedizolid, n = 3; linezolid, n = 4).

With use of the clinical assessment of infection severity, stable underlying comorbidities, and reliable home and social support networks, patients can be selected for outpatient treatment of ABSSSI. This may prevent or reduce hospital admissions, which leads to reduced treatment costs, decreased incidence of nosocomial infections, and decreasing readmission rates.[3]

The findings of this study are subject to the limitations inherent to all post hoc analyses and should, therefore, be interpreted with caution. However, until such time as robust prospective data are available, the results presented herein provide clinicians with additional information to assist with therapeutic decision-making in the outpatient setting.

5. Conclusion

In conclusion, these results, which were observed in a population with significant comorbidities, suggest that ABSSSI caused by confirmed or suspected gram-positive pathogens can be successfully treated in an outpatient setting with short course tedizolid therapy.

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