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REVIEW

The efficacy of dalbavancin and impact on hospitalization and treatment costs in patients with ABSSSI

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ABSTRACT

Acute bacterial skin and skin structure infections (ABSSSIs) represent a common and costly healthcare burden, accounting for millions of annual infections and billions of dollars in healthcare expenditures. Dalbavancin is a long-acting glycopeptide antibiotic that has demonstrated efficacy and safety in the treatment of ABSSSIs. This review article will examine the efficacy of dalbavancin and focus on its impact on the hospital length of stay and costs associated with management of these infections.

Keywords: ABSSSI, Dalbavancin, Dehospitalization, Infection management, Healthcare costs

Introduction

Acute bacterial skin and skin structure infections (ABSSSIs) represent the most common gram-positive infectious diseases, and are a major burden in terms of morbidity, mortality, healthcare engagement including hospitalization, and costs. Furthermore, patients affected by ABSSSIs and their families experience major impairment in their productivity and quality of life, and increased expenditures.

These infections, primarily caused by *Staphylococcus aureus* and other gram-positive bacteria, encompass a spectrum of severity, ranging from mild cellulitis to severe abscesses. In severe cases, ABSSSIs can lead to sepsis, which is associated with heightened morbidity and mortality.

While generally treatable with standard intravenous antibiotics, oral treatment is frequently hindered in ABSSSIs by tolerance issues, contraindications, drug-drug pharmacokinetic interactions with concurrent non-antimicrobial therapy, presence of multidrug-resistant bacteria, or expected low adherence to therapy in difficult-to-treat patients. These difficulties often lead to the need for infusional drugs and hospitalization, and impose as well substantial economic and social consequences.

In addition, many patients with ABSSSIs are not hospitalized, but instead receive treatment in an outpatient setting. However, outpatient parenteral antibiotic therapy (OPAT), if requiring daily infusions, also engages healthcare resources and is inconvenient for patients, possibly impairing their quality of life and causing several complications related to intravenous infusional lines.

Dalbavancin (DBV), a long-acting glycopeptide antibiotic, with high anti-gram-positive bactericidal activity, can be administered either as a single dose or as two doses 1 week apart, thus yielding an effective antimicrobial activity for as long as 14 days. Therefore, DBV has emerged as a promising therapeutic option for ABSSSIs, offering the potential to alleviate the burden of hospitalization and associated costs.

This review article delves into the impact of DBV on hospital length of stay (LOS) and overall healthcare expenditures in the management of ABSSSIs.

DBV clinical efficacy

DBV has demonstrated a non-inferiority with respect to standard intravenous antibiotics in the treatment of ABSSSIs.

Two identically designed phase 3 non-inferiority trials, DISCOVER-1 and DISCOVER-2 (1), investigated DBV as a treatment for ABSSSIs. These studies enrolled 652 individuals with ABSSSIs, and compared therapy based on two doses of DBV (1,000 mg on day 1 followed by 500 mg on day 8) to intravenous vancomycin administered for at least 3 days (1 g every 12 hours), with the option to switch to oral linezolid in order to complete 10-14 days of treatment. The primary endpoint was a clinical success measured at 48-72 hours of therapy. Both trials demonstrated non-inferiority of DBV compared to vancomycin.

A further randomized clinical trial with 698 ABSSSI patients (2) compared the traditional two-dose DBV regimen with a single dose of 1,500 mg. The results showed no significant difference in effectiveness between the two regimens,

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and there was no increase in adverse events with the single dose. Subsequently, regulatory agencies like the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) extended their approval to include the single-dose option.

A sub-analysis of the phase III trial (3) revealed that DBV performed equally well with both single- and two-dose regimens for both outpatients and hospitalized patients.

A further analysis focusing specifically on people who inject drugs (PWIDs) (212 participants) found that the effectiveness of DBV was consistent across both single- and two-dose regimens, and this held true for both PWID and non-PWID individuals at all measured time points (4).

In an open-label prospective study by Nadipelly et al, 200 patients with ABSSSIs were randomly assigned to receive either a single 1,500 mg dose of intravenous DBV or intravenous telavancin at 10 mg/kg every 24 hours for 6 days. "Clinical success," defined as complete resolution of key infection signs and symptoms, was achieved in 86.6% of the DBV group and 81.5% of the telavancin group (5).

Following the initial studies, numerous observational trials examined how effectively DBV treated ABSSSIs in real-world settings (6-14). While most studies included patients with other infections beyond ABSSSIs, DBV consistently demonstrated clinical efficacy, with cure rates ranging from 80% to 98%.

Notably, DBV also exhibited a remarkably favorable safety profile (15). The DISCOVER trials reported fewer adverse events, including nephrotoxicity, in patients treated with DBV compared to those receiving vancomycin or linezolid (1). This finding was echoed in a safety analysis of 1,778 DBV-treated patients and 1,224 comparator-treated patients (16). Notably, the duration of adverse events remained comparable between DBV and the comparator regimens, indicating that the extended half-life of DBV did not translate to heightened safety concerns (16). Consistent with these findings, observational studies confirmed a low incidence of adverse events, ranging from 2% to 13% across studied populations. Importantly, the majority of these events were mild in nature (6-14).

Impact of DBV on hospital LOS, hospitalization rate, and treatment costs

Table 1 shows a prospect of some recent studies targeting how DBV can reduce hospital LOS and treatment costs.

The cost of DBV is higher than the cost of majority of standard intravenous antibiotics. However, the reduced need for inpatient care and therefore the shorter hospital LOS associated with DBV can lead to cost savings. Indeed, several studies have shown that DBV is associated with a shorter LOS and lower costs as compared with standard intravenous antibiotics for the treatment of ABSSSIs. The reduced LOS associated with DBV use in ABSSSIs has been mostly due to its single intravenous dose (or two doses 1 week apart), which allows patients to be discharged from the hospital sooner.

TABLE 1 - Impact of dalbavancin on hospital length of stay and treatment costs in ABSSSI

Author, year (ref.)	Type of study	Clinical efficacy of DBV vs SoC	Mean reduction in hospital LOS allowed by DBV use vs SoC (days/pt)	Mean difference in treatment costs (DBV vs SoC, €/pt)	Notes
McCarthy et al, 2020 (17)	Pre- vs post-period pragmatic trial	Complete response: 57% vs 50%	1.6 (3.2 vs. 4.8 days; P = 0.003)	n.a.	Improvement in work productivity and activity impairment outcomes post-DBV use (p ≤ 0.01)
Marcellusi et al, 2019 (19)	Decision-analytic model	n.a.	3.3 (2,5-4,15)	<€1	
Papavramidis et al, 2023 (23)	Retrospective, multicenter	Failure 4% vs 2.5% (clinical outcome evaluable for 46% patients in DBV group and in 29.2% in SoC)	5.3 (7.8 vs 14.1 days)	n.a.	LOS reduction was confirmed in subpopulations of patients receiving one or more concomitant antibiotics active for gram-positives or MRSA, and in patients with the most prevalent comorbidity (i.e., diabetes)
Bai et al, 2023 (8)	Retrospective, multicenter	n.a.	4,2 (5 ± 7.47 days for DBV vs 9.2 ± 5.59 days for SoC; p < 0.00001)	€23 (€3,470 ± 2,768 for DBV vs €3,493 ± 1,901 for SoC; p = 0.9401)	LOS was reduced also for first-line DBV in comparison with second-, third-, or higher-line groups, and for DBV monotherapy vs combination therapy. Mean direct medical costs were significantly lower in first-line DBV compared with higher lines.
Wilke, et al 2019 (28)	Health economic analysis using real-world patient data	n.a.	6.45	€2,865	

ABSSSI = acute bacterial skin and skin structure infections; DBV = dalbavancin; LOS = length of stay; n.a. = not assessed; SoC = standard of care.

Shorter hospital stays associated with DBV use lead to several other benefits for both patients and the healthcare system:

- Lower organizational burden on the healthcare system, including reduced occupancy of ward beds and absence of overcrowding of emergency departments (EDs)
- Reduced risk of hospital-acquired infections (HAIs) and their associated complications
- Lower expenses related to inpatient care
- Fewer disruptions to the daily lives of patients and their families, reduced family expenses, and, consequently, increased productivity, comfort, and overall quality of life.

The ENHANCE trial, a single-center, pre- vs post-period pragmatic trial (48 vs 43 patients, respectively), showed that DBV use in hospitalized patients with ABSSSI allowed a reduction of almost 2 days in the mean infection-related LOS (3.2 vs 4.8 days; $p = 0.003$). Similar results emerged in an adjusted LOS analysis. Work productivity and activity impairment outcomes significantly improved in the post-period ($p \leq 0.01$) (17).

A comprehensive analysis, combining a systematic review, network meta-analysis, and cost evaluation, compared the effectiveness and cost of newer lipoglycopeptides against standard care and each other regimen for treating complex skin and soft tissue infections (SSTIs). Authors found that using DBV could potentially save third-party payers between $1,442 and $4,803 per patient compared to standard treatments (18).

Researchers in Italy, Romania, and Spain conducted a study to estimate the financial burden of treating severe ABSSSI patients from the national healthcare provider's perspective. They compared the hypothetical use of DBV with standard treatments (vancomycin, teicoplanin, or linezolid) and found that DBV could potentially reduce hospital stay by an average of 3.3 days per patient without adding significant costs to the national healthcare system (19).

A budget impact study analyzed data from national administrative databases in Italy, Spain, and Austria between 2006 and 2014, focusing on patients with non-severe ABSSIs who visited the ED (20). On average, there were 5,396, 7,884, and 1,788 such patients per year in each country, respectively. The researchers created a model to compare the costs of hypothetical early treatment with DBV (1,500 mg single dose) against the actual standard of care (SoC). In the first year of this hypothetical scenario, DBV would have reduced the total healthcare costs in Italy and Spain by €352,252 and €233,991, respectively. However, in Austria, it would have increased costs by €80,769. By the third year, all three countries would have seen cost reductions with DBV: €1.1 million in Italy, €810,650 in Spain, and €70,269 in Austria. This cost saving was mainly driven by the estimated increase of patients discharged directly by the ED combined with the reduced hospital LOS for those who were hospitalized, following the hypothetical DBV use rather than the actual SoC antimicrobial therapy. The estimated overall reduction in hospital stays over three years was −1,332 days in Italy, −1,187 days in Spain, and −1,537 days in Austria.

While the above-mentioned studies offer valuable insights, they have some limitations. Firstly, they often lack detailed information, making it difficult to draw definitive conclusions. Secondly, they estimate costs for large groups of patients instead of calculating individual costs, which might not accurately reflect real-world expenses. Finally, they do not account for potential variations in treatment costs across different regions and even within the same region. On the other hand, some real-life studies exploring the cost savings with DBV included patients with various infections beyond ABSSSI. This makes it difficult to pinpoint the exact cost savings specifically related to ABSSSI treatment (21,22).

A real-life, individual patient-based study calculated that an early discharge strategy following the antibiotic switch to DBV saved a median of €5,034 (interquartile range [IQR] 3,647-6,590) for each ABSSI case, as compared to the hypothetical prolongation of the standard hospital-restricted antimicrobial therapy administered before the switch to DBV (9).

The REDS study (23), which was conducted retrospectively among 16 Italian and Greek centers, reported that hospital LOS in subjects hospitalized with ABSSSI who received DBV (50 patients) was 6.5 days vs 11.0 days in the SoC group (120 subjects treated with vancomycin, teicoplanin, or daptomycin). Interestingly, the subpopulation analysis of patients receiving one or more concomitant antibiotics active for gram-positives, methicillin-resistant *S. aureus* (MRSA), and patients with the most prevalent comorbidity (i.e., diabetes) confirmed the DBV advantage in terms of LOS, with a general halved time to discharge.

Bai et al (8) demonstrated in a retrospective study performed in two infectious disease centers in Italy that treatment with DBV in 102 patients with ABSSSI was associated with a significant reduction of hospital LOS as compared with 126 subjects who received SoC (5 ± 7.47 days for DBV vs 9.2 ± 5.59 days for SoC; $p < 0.00001$). Authors also found that DBV use allowed for lower mean direct medical costs (€3,470 ± 2,768 for DBV; €3,493 ± 1,901 for SoC; $p = 0.9401$). Moreover, the same study demonstrated a reduced LOS for DBV as first-line therapy in comparison with its use as second-, third-, or higher-line groups. A LOS advantage resulted as well for DBV monotherapy vs combination therapy. Finally, mean direct medical costs were significantly lower in first-line DBV compared with higher lines of treatment.

Shorter hospital stays are a key reason why studies find DBV to be cost-effective. This is because hospitalization is expensive, although costs vary widely depending on location. In 2014, the cost of a hospital day in an internal medicine ward was €325 in Spain (21), and €361 in an infectious disease ward in Italy (4). In the United States, the average estimated cost per day in a state-local government hospital in 2020 was $2,606, ranging from $671 in Montana to a staggering $5,557 in Connecticut (24).

However, several indirect costs could be saved as well using long-acting antibiotics. For instance, daily infusion of antimicrobials often requires the use of a peripherally inserted central catheter (PICC), which carries extra costs. Placing a PICC costs an average of $873, and potential complications like infections or malfunctioning can add another $205 per patient (25). Moreover, infusional line-related costs markedly increase if systemic and serious complications occur (e.g., bacteremia, endocarditis, sepsis). Furthermore, for glycopeptides (vancomycin, teicoplanin) use, a therapeutic

drug monitoring is imperative, which may cost from €24 to 56 (19); in addition, these antibiotics can determine a transient nephrotoxicity, which is associated with additional costs and a prolonged in-hospital stay. Moreover, daily intravenous antibiotics also require nursing time. This includes tasks like preparing the medication, attaching and removing the infusion line, and monitoring the patient. These nursing costs vary depending on the hospital and region.

Finally, in a single-center, real-life study (17), introduction of DBV use as compared to usual antibiotics yielded significant improvements in patient satisfaction, ability to perform daily activities, and work productivity, thus saving private and social costs as well.

Impact of DBV on rate of hospitalization

Talan et al (26) conducted a preintervention vs postintervention trial among patients with moderately severe ABSSSI who presented to the ED but were clinically stable and did not require hospitalization for reasons other than ABSSSI. The study demonstrated that the introduction in the management of these patients of a pathway that included a single 1,500 mg dose of DBV resulted in a reduced rate of initial hospitalization (from 38.5% to 17.6%), with the effect persisting at a 44-day follow-up (from 44.9% to 28.8%). Subjects discharged from the ED received a 24-hour follow-up telephone call and had a 48- to 72-hour in-person visit.

Oliva et al (27), based on an extensive literature review, proposed an algorithm on how to safely select patients presenting to the ED with ABSSSIs who are poor candidates to oral antimicrobials and can be discharged from the ED after administration of a single DBV dose, either directly or following a short in-hospital observation with re-assessment at 48-72 hours. Patients directly dismissed should undergo a follow-up visit, possibly by a telemedicine aid.

Improved Quality of Life

Shorter hospital stays and reduced reliance on daily intravenous medications, by using long-acting antimicrobials such as DBV, contribute to enhanced patient well-being and quality of life.

In the above-mentioned ENHANCE pre-post trial, McCarthy et al (17) showed that treatment for ABSSSI with DBV in 43 subjects as compared with usual care in 48 patients was associated with a significant improvement in work productivity and activity impairment. In particular the DBV advantage vs usual care regarded the impairment while working (47.9% vs 8.9%; $p = 0.01$), the overall work impairment (59.3% vs 18.0%; $p = 0.01$), and the nonwork-related impairment of activity (60.2% vs 18.5%; $p < 0.001$).

Furthermore, a phase 3 randomized controlled trial involving 698 adult patients with ABSSSIs (15) and treated with DBV (386 and 312, respectively, managed in outpatient and inpatient settings) reported in a post hoc analysis that outpatients experienced significantly greater convenience and satisfaction with antibiotic treatment and setting of therapy than inpatients. In particular, a greater number of outpatients vs inpatients reported that antibiotic treatment did not interfere at all with daily activities (74% vs 42%; $p < 0.001$) and that they were easily able to modify their schedule to receive antibiotic therapy (97% vs 76%; $p < 0.001$).

Conclusions

DBV represents a promising innovative treatment for ABSSSIs. It is a long-acting antibiotic demonstrated as noninferior to standard intravenous antibiotics with regard to efficacy and safety profile. Due to its pharmacokinetic properties, DBV can be administered for this indication either as a single intravenous dose or as two doses 1 week apart, thus preventing the need for either short-term or mid-term intravenous infusional lines and their possible complications. These features make DBV a manageable, convenient, and effective option for both patients and healthcare personnel.

A significant number of studies demonstrate that ABSSSI treatment with DBV is associated with both a reduction in hospitalization rate and – for hospitalized patients – a shorter hospital LOS, which lead to an improved utilization of healthcare resources, including bed occupancy, ED overcrowding, and costs.

Finally, studies indicate that DBV use is able to reduce the organizational and economic strain on patients with ABSSSI and their families. This improvement can translate to increased comfort and a better quality of life for these individuals.

DBV-based therapy shows the greatest effectiveness, both in terms of organization and cost, in patients who are poor candidates for oral antibiotics, in those expected to be poorly adherent to treatment, as well as where OPAT is challenging to implement.

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