GRHTA
Glob Reg Health Technol Assess 2025; 12: 151-157
ISSN 2283-5733 | DOI: 10.33393/grhta.2025.3363
ORIGINAL RESEARCH ARTICLE

Cost-analysis from real-world REDS study on dalbavancin in inpatient treatment of acute bacterial skin and skin structure infections

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ABSTRACT

Introduction: Inpatient treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSIs) involves a significant economic burden on the healthcare system.
The aim of the present analysis was to estimate the expenditure, in terms of direct and indirect healthcare costs, for patients hospitalized with a confirmed diagnosis of ABSSSI, evaluating the impact of dalbavancin, compared to the other Standard of Care of the same IV antibiotic class, analyzed in the REDS study.
Methods: The analysis was carried out using data collected as part of the study "Retrospective Effectiveness study of dalbavancin and other Standard of care of the same class IV lipo and glycopeptides) in patients with ABSSSI" (REDS study).
In the present analysis, the economic impact of managing patients hospitalized for ABSSSI was estimated by evaluating both the direct healthcare costs relating to hospital and pharmaceutical care and the indirect costs relating to the loss of productivity due to the pathology.
Results and Conclusions: The analysis of data from the REDS study made it possible to estimate the economic impact of the management of patients hospitalized for ABSSSI, depending on the treatment received during hospitalization.
The results highlighted a reduction in costs for patients treated with dalbavancin, both for direct healthcare costs and indirect costs, over the entire observation period. Again, the reduction increases, reaching statistical significance, and the costs are evaluated from the beginning of the treatment.

Keywords: Acute bacterial skin and skin structure infections, ABSSSI, Cost-minimization analysis, Dalbavancin, Pharmacoeconomic

Introduction

Acute bacterial skin and soft tissue infections (ABSSSIs) are among the most common infections in the general population, with incidence constantly increasing (1,2).

The term "acute bacterial skin and skin structure infection" (ABSSSI) was coined in 2013 by the US Food and Drug Administration (FDA) to identify a subset of severe skin and soft tissue infections (SSTIs) typically treated with parenteral antibiotic therapy includes cellulitis/erysipelas, wound infection, and major cutaneous abscess with a minimum lesion surface area of 75 cm^2 (3).

Received: October 30, 2024
Accepted: May 15, 2025
Published online: June 9, 2025

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Causative pathogens are mostly gram-positive, with *Staphylococcus aureus*, including methicillin-resistant Staphylococcus aureus (MRSA) and *Streptococcus pyogenes* strains representing the most prevalent pathogens (3,4).

ABSSSIs represent a challenging medical problem since they can result in severe complications, imposing significant morbidity and a high economic burden on the healthcare systems due to the associated hospitalization and healthcare costs. (1,5-7).

The ABSSSI clinical outcome is influenced by risk factors such as advanced age, multiple comorbidities (especially diabetes, obesity, vascular insufficiency, immunodepression, and recent surgery) (8,9), and being colonized by MRSA. The emergence of MRSA infections, with high pathogenicity and multi-drug resistance, has reduced effective treatment options, causing prolonged hospitalization. A retrospective observational study from 12 European countries to evaluate treatment patterns of patients with MRSA estimated that the hospital length of stay (LoS) ranged from 15.2 to 25.0 days across Europe (11).

The standard treatment course for ABSSSI ranges from 5 to 14 days of systemic intravenous therapy (IV) (11), with

the necessity of long-lasting inpatient treatment; moreover, data indicate that many patients admitted with ABSSSI have minimal comorbidities and mild or no systemic signs of infection and often remain hospitalized after their acute infection resolves solely for continued intravenous antibiotics (12-14). The consequences of this practice on the healthcare system are substantial: data show that inpatient care for ABSSSI patients is 2-4 times more costly than outpatient care (15).

Clinical strategies to avoid hospitalization and/or minimize the LoS to prevent readmissions and hospital-acquired infections can reduce the ABSSSI-related healthcare burden (12).

The possibility of early discharge has been facilitated by the introduction of long-acting antibiotics such as dalbavancin that can be administered as a single dose or with a loading dose followed by a second dose after 1 week, allowing physicians to either discharge patients early or avoid hospitalization in patients who are clinically stable (16-19).

Dalbavancin is a lipoglycopeptide antibiotic with in vitro bactericidal activity against gram-positive pathogens and is indicated for use in adults with ABSSSI. Its concentration-dependent activity and prolonged half-life provide a convenient single-dose alternative to multi-dose daily therapies for ABSSSI (18).

While the tolerance, efficacy, and effect on LoS of dalbavancin have been confirmed both for on- and off-label indications (20-26), the associated economic benefit is mostly based on simulations (7,27,28). Most economic studies have extrapolated the reduction in the LoS observed in real-life studies compared to usual treatments to a reduction in hospitalization-related costs from a societal perspective (23,29,30). To date, real-life and budget impacts on the ABSSSI on-label indication have been poorly described, and it has not been formally confirmed whether dalbavancin use results in a LoS reduction compensating for the treatment cost (31).

The "REDS study" was an observational, multicentre, retrospective, cohort study conducted in 16 hospitals in Italy and Greece, including 170 adult patients of any age, hospitalized for at least 2 days with evidence of primary diagnosis of ABSSSI and treated with dalbavancin or Standard of Care (SoC) IV antibiotics (vancomycin, teicoplanin or daptomycin) (32).

The present pharmacoeconomic analysis was conducted to assess if the favorable results obtained in the REDS study with dalbavancin in terms of clinical cure, reduction of concomitant antibiotic treatment, and LoS were also associated with significant direct and indirect cost savings.

Methods

The analysis was carried out using data collected as part of the study "Retrospective Effectiveness Study of Dalbavancin and other Standard of care of the same class (IV lipo and glycopeptides) in patients with ABSSSI" (REDS study) (32).

In the present analysis, the economic impact of managing the patients hospitalized for ABSSSI was estimated by evaluating both the direct healthcare costs relating to hospital and pharmaceutical care and the indirect costs relating to the loss of productivity due to the pathology.

In particular, for direct healthcare costs, the following expenditure items were considered:

- Index hospitalization: i.e., the hospitalization that led to the inclusion of the patient in the study, valued by multiplying the number of days of hospitalization by the average cost of a day of hospitalization at a national level (33), equal to €834. To compare the cost associated with the patient depending on the treatment prescribed, the expense was obtained/estimated considering both the total duration and the days of hospital stay between the first administration of lipoglycopeptides and the date of discharge.
- Subsequent visits and hospitalizations: subsequent check-ups and unplanned hospitalizations were valued using the same procedure described for the index hospitalization, considering the days of hospitalization between the date of admission and discharge.
- Antibiotic treatment and concomitant drugs: The cost of the drugs was determined using the national reimbursement price at the time of dispensing.

For indirect costs, the loss of productivity was valued by applying the Human Capital Approach (HCA) method (34).

In detail, the days of work lost due to hospitalization were valued considering the average daily income by sex and age group (35) (15-24,25-34,35-44,45-54,55-64,65+), discounted by the sex- and age-specific unemployment rate (36). For subjects over 74 years of age, zero productivity loss was assumed. The sex and age-specific daily productivity thus obtained was multiplied by the number of days of work lost, considering both the period from hospitalization to discharge and the time span between the start of treatment and discharge.

For each patient, a total cost was obtained as the sum of direct healthcare costs and indirect costs. A descriptive analysis was performed evaluating the average costs per patient treated with dalbavancin or other drugs (others). The presence of statistically significant differences between the costs incurred for patients belonging to the two groups was assessed using the non-parametric Mann-Whitney-Wilcoxon (MWW) test.

Results

Direct healthcare costs

In the REDS study, out of 170 patients included, 50 (29.4%) were treated with dalbavancin, 120 with other IV Standard of care (SoC) of the same class (i.v. lipo and glycopeptides teicoplanin, daptomycin, and vancomycin).

The average LoS for the index hospitalization was 14.5 days, with a shorter duration in patients treated with dalbavancin (11.3) compared to SoC (15.8, Fig. 1). Considering the hospital stay starting from the first administration of the treatment, the average was equal to 7.8 days in patients treated with dalbavancin and 14.1 days in the ones treated with other SoC antibiotics (average in the entire population 12.2).

Applying the national average cost per day of hospitalization to these data, an average expense of €9,040 resulted in the dalbavancin group, compared to €13,177 in the SoC group (−28.5%). When only considering the cost of hospitalization

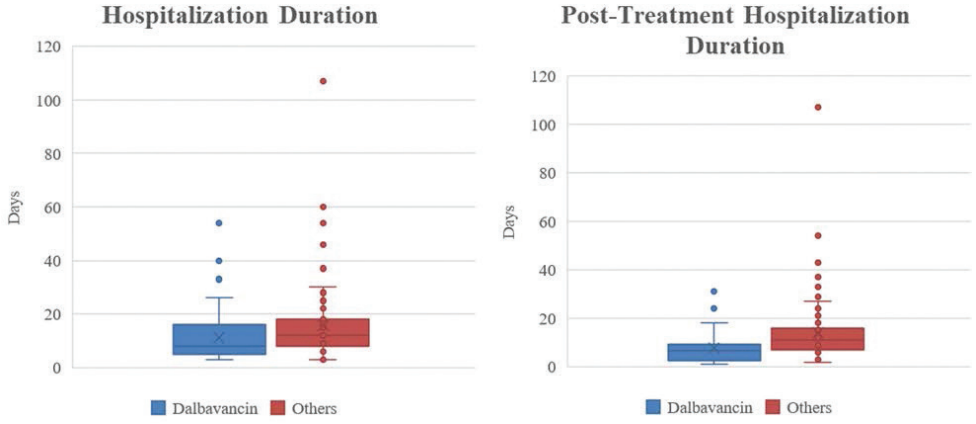

FIGURE 1 - Distribution of average hospital stay (total and following treatment) by type of lipoglycopeptide administered. Each box plot shows the average distribution of hospitalization duration (on the left) and Post-Treatment Hospitalization duration (on the right), comparing the use of dalbavacin (Blue) with SoC (Red). The horizontal bar in the box represents the median, the box represents the Interquartile range, the cross within the box represents the mean, and the vertical bars represent the standard deviation.

following the administration of the dalbavancin or SoC treatment, the expense dropped to €6,539 in patients treated with dalbavancin, compared to €11,725 in those treated otherwise (−44.2%).

During the follow-up, 6 (12.0%) patients in the dalbavancin group underwent further hospitalizations; in the SoC group, 15 (12.5%) patients were re-hospitalized. The average LoS was 8.0 and 8.6 days, respectively. For this expense item, average costs were estimated at €598 in the SoC group and €667 (+11.2%) in the Dalbavancin group.

The average expense for the antibiotic treatment was €2,944, with a higher cost for dalbavancin (€4,133) compared to SoCs (€2,519, +64.1%). Only 20.0% of patients treated with dalbavancin were found to use other drugs during the observation period, for an average expense of €9. However, 62 (51.7%) patients belonging to the SoC group were administered with other drugs for an average cost of €57.

Indirect costs

The distribution of the population under study by sex and age group is shown in Figure 2.

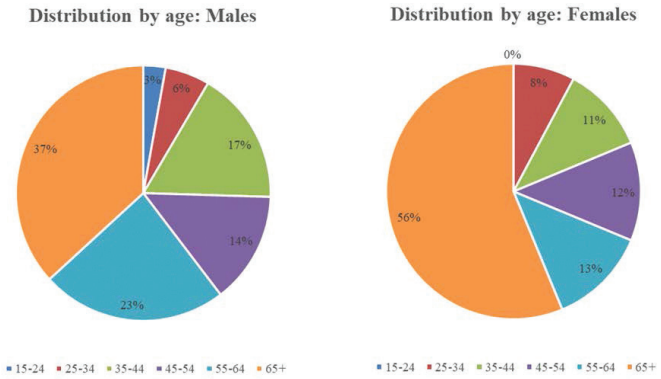

FIGURE 2 - Distribution by age and sex of the study population. Each pie chart shows the distribution by age for males (on the left) and for females (on the right). Each color represents an age range (years old): 15-24 (blue), 25-34 (red), 35-44 (green), 45-54 (violet), 55-64 (light blue), and 65+ (orange).

Mean age was comparable in the two groups analyzed (59.6 and 59.4), with a lower percentage of men in the dalbavancin group (52.0%) compared to the SoC group (66.7%).

When the entire duration of the index hospitalization was considered, a loss in productivity of €923 was estimated in the SoC group, compared to €584 in the dalbavancin group (−36.8%).

Taking into consideration the duration of hospitalization from treatment start, the expense dropped to €825 in the SoC group and to €402 in the Dalbavancin group (−51.2%)

Total costs

Table 1 shows the total costs obtained by adding all the expense items. On average, for a patient hospitalized with a diagnosis of ABSSSI, an estimated expense of €16,552 has been estimated starting from the date of admission to the hospital. Taking into consideration the entire duration of the first hospitalization, the average cost associated with a patient treated with dalbavancin was €14,817, -14.2% compared to that estimated for the other patients (€17,274). In this case, the MWW test did not highlight a statistically significant difference in the two groups (p-value 0.263). However, considering only the period following treatment, the average expense per patient treated with dalbavancin was €11,750, −25.3% compared to the SoC group (€15,724), the difference resulted statistically significant (p-value 0.016).

The MWW test was also used to evaluate the differences between the two groups for each single expense item: except for unplanned visits (p-value 0.923, Table 1), the average cost gap per patient was always statistically significant, with spending on antibiotics being the only category in which the cost was higher in the dalbavancin group.

Discussion

ABSSSIs are a frequent reason for hospital admission, and nearly 10% of all hospital antibiotic therapy is attributed to ABSSSIs, which is a consequently relevant healthcare system burden (37).

TABLE 1 - Summary of costs by expense item and type of lipoglycopeptide administered

Antibiotic Treatment	Cost of first hospitalization		Productivity loss		Antibiotics	Concomitant Treatment	Unplanned Visits	Total	
	Total hospitalization	Post-treatment hospitalization	Total	Post-treatment				Whole period	Post-treatment
Total	12,073 €	10,199 €	823 €	701 €	2,994 €	43 €	618 €	16,552 €	14,555 €
dalbavancin	9,424 €	6,539 €	584 €	402 €	4,133 €	9 €	667 €	14,817 €	11,750 €
Other	13,177 €	11,725 €	923 €	825 €	2,519 €	57 €	598 €	17,274 €	15,724 €
Δ (dalba - other)	−3,753 €	−5,186 €	−340 €	−423 €	1,614 €	−49 €	70 €	−2,457 €	−3,974 €
Variation %	−28.5%	−44.2%	−36.8%	−51.2%	64.1%	−84.9%	11.6%	−14.2%	−25.3%
MWW TEST (p-value)	0.002	<0.001	0.041	0.002	<0.001	<0.001	0.923	0.263	0.016

Δ: Delta (difference between dalbavancin and SoC group)

MWW TEST: Mann-Whitney-Wilcoxon test

Indeed, the management of ABSSSIs is complex, given the frequent association with comorbidities such as obesity, diabetes mellitus, and peripheral vascular disease, which may complicate the choice of the appropriate empirical antibiotic therapy. Early initiation of effective treatment and early response to treatment have been linked to better patient outcomes and reduced healthcare costs (38,39).

The REDS retrospective study, including patients with ABSSSIs treated in hospital setting with dalbavancin or other SoCs (teicoplanin, vancomycin, daptomycin), from 16 sites in Italy and Greece, added important real-life data about effectiveness and effect on LoS of dalbavancin compared to SoCs for the treatment of ABSSSI (32).

The present cost analysis enabled us to estimate the economic impact of the management of these patients, depending on the treatment received during hospitalization.

Overall, 170 patients were included in the REDS study and analyzed, 50 in dalbavancin and 120 in the SoC group, the rate as per protocol (1:2); no selection bias was applied. It should be noted that patient demographics and clinical characteristics were well balanced according to age, number of comorbidities, and severity of infection. Only the sex distribution was significantly different, with a lower percentage of men in the dalbavancin group (52.0%) compared to the control group (66.7%). The different sex distribution could explain why, from our cost analysis, the discounted median daily income resulted slightly higher in the SoC (€70) than in the dalbavancin group (€65).

The present analysis conducted on the REDS study database showed that dalbavancin-based treatment significantly reduced the LoS compared with the SoCs: the average LoS for the index hospitalization was 14.5 days, with a shorter duration in patients treated with dalbavancin (11.3) than in the others (15.8). The difference was even more evident when we considered the hospital stay starting from the first administration of the dalbavancin or SoC treatment: in fact, in this case, the average was equal to 7.8 days in patients treated with dalbavancin and 14.1 days in the others.

Applying to these data the national average cost of hospitalization per day, we obtained a lower average expense in the dalbavancin group compared to the rest of the population. The gap was accentuated when we considered the cost of hospitalization following the administration of antibiotic treatment.

To be noted that, in the REDS study, the elapsed days from the first evaluation of ABSSSI and the start of study therapy (dalbavancin or SoCs) was 3 days, (interquartile range (IQR): 1.0-5.0) in dalbavancin and 1 day (IQR 1.0-2.0) in SoCs. This observation probably means that clinicians started or continued wide-spectrum therapies (i.e., after surgery) before prescribing dalbavancin, while SoCs were started sooner, alone or in combination.

Our finding is in line with a recent study conducted in 2 sites in Italy with dalbavancin and SoC (40), where dalbavancin resulted associated with a significant reduction of LoS (5 ± 7.47 days for dalbavancin, 9.2 ± 5.59 days for SoC; $p < 0.001$) and maximum benefit in term of cost-saving with its early use (first- or second-line treatment), the authors suggesting that dalbavancin should be recommended as an early treatment rather than for compassionate use after failures of multiple other antibiotics. Another study based on an Italian cohort of patients who switched from SoC to dalbavancin for the treatment of ABSSSIs found that the length of hospital stay for these patients was 13 days, while the hypothetical duration of hospitalization, in the absence of the switch, would have been 30 days (41). The study thus highlighted a longer average length of stay than what we observed, but it demonstrated a similar impact of dalbavancin in halving the duration of the hospital stay.

Taking into consideration the other expenses, in our analysis, the average cost of dalbavancin treatment was higher compared to others, while the average cost of additional antibiotic treatments resulted in higher costs in the SoC group. This could be explained by the fact that the REDS study showed that the proportion of patients assuming more than one concomitant antibiotic was 22.0% in dalbavancin vs. 54.2% in SoCs, with 4.0% in dalbavancin and 31.7% in SoC

assuming more than two antibiotics. About 21% of patients in SoC switched to other antibiotics compared to 0.6% in dalbavancin. In summary, the number of antibiotics used from hospitalization to 30 days after discharge was 211 overall, with 32 antibiotics used for 50 patients in the dalbavancin group and 179 antibiotics used for 120 patients in the SoC group (32).

Even if the direct cost per patient of switching or concomitant use of multiple additional antibiotics could not appear significant by itself, the indirect cost in terms of drug-related safety events and of antibiotic resistance is not negligible at all: antibiotic resistance (AMR) has developed as one of the major urgent threats to public health causing serious issues to successful prevention and treatment of persistent diseases and misusing and overusing different antibacterial agents in the health care setting are considered the major reasons behind the emergence of antimicrobial resistance (42).

A recent OECD assessment estimated that, to date, AMR costs about EUR 1.1 billion per year in European countries, and in Italy, it will cost EUR 11 billion between now and 2050 (43).

As regards the indirect costs, if the entire duration of the index hospitalization was considered, a higher loss in productivity was estimated in the SoC group compared to the dalbavancin group. When we considered the duration of hospitalization starting from treatment, this gap increased further.

As regards the rehospitalizations that occurred during the follow-up, the rate was similar in the two groups; also, the average hospital stay was similar. For this expense item, the average cost in the dalbavancin group was estimated to be 11.2% more than the SoC group.

In conclusion, we found an overall expense of 14,817 Euros for ABSSSI management in the dalbavancin group, of which 9,040 were due to hospitalization costs (61%). Out of 17,274 for the SoC group, 13,177 euros were spent on hospitalization costs (76%). This is consistent with previous analysis showing that the significant costs related to ABSSSIs seem to be associated with hospitalizations, which could affect up to 70% of the total costs for the management of these infections (44).

In summary, our results highlighted a reduction in costs for patients treated with dalbavancin, both for direct healthcare costs and indirect costs, over the entire observation period; this is consistent with findings from other studies highlighting that the cost of the long-acting agent offset by an earlier discharge, especially when antibiotics also needs to cover MRSA; this antibiotic in fact allows a shorter length of hospitalization and a reduced number of procedures that are required for the administration of daily IV treatments, such as implantation of intravascular catheters (45,46).

Moreover, in Europe, an analysis conducted in NHS Greece, Italy, and Spain to assess the economic consequences of adopting ED strategy for the treatment of ABSSSI estimated a major reduction in total number of hospitalization days (32-41%) and total healthcare costs (30-42%) (27), consistent with the results of this dalbavancin study.

Again, the cost reduction increases with dalbavancin, reaching statistical significance ($p = 0.016$) and evaluating the costs starting from the beginning of the treatment.

All of the above suggests that early initiation of effective treatment could reduce healthcare costs (38,39,47), consistent with the outcome of a budget-impact analysis from the national public health system perspective developed by Marcellusi et al. in three European countries (Italy, Spain, Austria) where the increased early use of dalbavancin resulted potentially able to reduce both hospitalization rates and lengths of hospital stay in non-severe ABSSSI patients (48,49).

When changing the health economic perspective, further advantages can be highlighted in the early initiation with dalbavancin and early discharge: from the hospital management point of view, it may further optimize the resource allocation, increase the free hospital bed capacity, decrease the risk of nosocomial infections. From a patient perspective, it may imply advantages such as shorter periods of incapacity for work, higher quality of life, more effective use of antibiotics to prevent resistance, and less invasive catheters required for long-term application.

Limitation and Strength

One of the primary limitations of the REDS study lies in its small sample size, which is further divided across 16 centers in two countries. This fragmentation may reduce the statistical robustness of the findings and introduce potential biases related to center-specific practices or patient characteristics. Moreover, due to the retrospective nature of the study, there is an inherent risk of selection bias and incomplete data capture, which could impact the generalizability of the results. We recognize that these limitations may influence the reliability of our conclusions. To mitigate these concerns, future studies with larger and more homogenous datasets would be valuable in validating these findings across broader contexts.

Moreover, adverse events were not considered in the cost analysis anyway. No deaths or serious ADRs were reported in dalbavancin group (one SADR in the SoC group in the REDS study), where any adverse events/ adverse drug reactions (AEs/ADRs), serious adverse events/serious adverse drug reactions (SAEs/SADRs), any death and any readmissions for any reason up to 30 days from discharge and any available 90-day follow-up data for survival, recurrence of ABSSSI and health issues were collected.

Notwithstanding these limitations, we believe our study has strengths and originality with respect to the published literature: the direct comparison with other SoCs, the inclusion of multiple sites in two Countries, to cover the variety of situations in acute care hospitals, the analysis of multiple outcomes (overall hospital stay and from beginning of treatment, analysis of direct and indirect costs) in a real-world scenario.

Conclusions

The analysis of data from the REDS study made it possible to estimate the economic impact of the management of patients hospitalized for ABSSSI, depending on the treatment received during hospitalization.

The results highlighted a reduction in costs for patients treated with dalbavancin, both for direct healthcare costs and indirect costs, over the entire observation period. Again, the reduction increases, reaching statistical significance, and the costs are evaluated from the beginning of the treatment.

Disclosures

Conflict of interest: Alessandro Ruggieri and Agnese Cattaneo are Angelini SpA employees. Patrizia Mascagni is a Hippocrates Research SRL employee (CRO delegated for medical writing). The other authors declare no conflict of interest.

Financial support: The study was funded by Angelini Pharma SpA.

Authors' contribution statements: All authors contributed to the study's conception and design. Matteo Scortichini and Paolo Sciattella performed the economic analysis. The first draft of the manuscript was written by Patrizia Mascagni, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval: Ethics approval and consent are not applicable for the present economic analysis conducted starting from the database of the REDS study, for which conduction was approved by relevant ethics committees and for which consent to data collection was obtained.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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