



A retrospective multicentre study on dalbavancin effectiveness and cost-evaluation in sternotomic wound infection treatment: DALBA SWIT Study

Renato Pascale^{a,b}, Angelo Maccaro^a, Elisa Mikus^c, Maurizio Baldassarre^d, Beatrice Tazza^{b,*}, Fabio Esposito^a, Matteo Rinaldi^a, Elena Tenti^c, Simone Ambretti^e, Alberto Albertini^c, Pierluigi Viale^{a,b}, Maddalena Giannella^{a,b}, Michele Bartoletti^{a,b}

^a Infectious Diseases Unit, Department of Integrated Management of Infectious Risk, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

^b Department of Medical and Surgical Sciences, University of Bologna, Bologna, Italy

^c Maria Cecilia Hospital, GVM Care and Research, Cotignola, Ravenna, Italy

^d U.O. Medical Semiotics, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

^e Operative Unit of Microbiology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

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ABSTRACT

Objective: To evaluate the cost-effectiveness of dalbavancin compared with standard of care (SoC) treatment as daptomycin or teicoplanin in patients with sternal wound infections (SWI).

Methods: Multicentre retrospective study of patients diagnosed with SWI from January 2016 to December 2019 at two cardiac surgery facilities treated with dalbavancin, teicoplanin or daptomycin. Patients with SWI treated with dalbavancin were compared with SoC to evaluate resolution of infection at 90 and 180 days from infection diagnosis, length of stay (LoS) and management costs.

Results: 48 patients with SWI were enrolled, 25 (50%) male, median age 67 (60–73) years, Charlson index score 5 (4–7). Fifteen patients were treated with dalbavancin (31%) and 33 with SoC (69%): teicoplanin in 21 (63%), and daptomycin in 12 (37%). *Staphylococcus* species were the most frequent isolates (44, 92%), mostly (84%) resistant to methicillin. All patients were treated with surgical debridement followed by negative pressure wound therapy. Wound healing at day 90 and 180 was achieved in 46 (95.8%) and 34 (82.9%) of patients, respectively. A shorter length of hospitalization in patients treated with dalbavancin compared with SoC [12 (7–18) days vs 22 (12–36) days, $p:0.009$] was found. Treatment with dalbavancin resulted in total cost savings of €16 026 (95% CI 5976–26 076, $P < 0.001$). Savings were mainly related to the LoS that was significantly shorter in the dalbavancin group, generating significantly lower cost compared to SoC group.

Conclusion: Dalbavancin treatment of sternal wound infections is effective and seems to reduce hospitalization length, leading to significantly lower costs.

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Introduction

Sternal wound infection (SWI) is a serious complication of cardiac surgery, causing a delayed or compromised healing of wounds and a potential evolution towards life-threatening complications as

endocarditis, mediastinitis or chronic osteomyelitis [1–3]. SWI incidence varies between 0.7% and 3% of patients undergoing cardiac surgery. However, the development of minimally invasive and transcatheter procedures has reduced its incidence [1,4,5]. Gram-positive bacteria are the main causative agents, accounting for 80% of cases [2,5,6]. SWI is associated with high healthcare-associated costs, estimated to be as much as US \$35 000–500 000 for each patient, mainly due to the requirement for prolonged antimicrobial treatment and reoperation as well as a prolonged hospital length of stay [7–9].

* Corresponding author. Infectious Diseases Unit, IRCCS Policlinico Sant'Orsola, Bologna, Department of Medical and Surgical Sciences, University of Bologna, Via Massarenti 11, 40138 Bologna, Italy

E-mail address: beatrice.tazza@unibo.it (B. Tazza).

Dalbavancin is a second-generation, semisynthetic, lipoglycopeptide antibiotic binding to the terminal D-alanyl-D-alanine of the stem peptide in newly growing cell wall peptidoglycan, interrupting cell wall synthesis and resulting in bacterial cell death [10]. Differently to teicoplanin, its previous analogous, dalbavancin has an extended lipophilic side chain that allows to better anchor to the bacterial cell membrane, enhancing its potency and prolonging its half-life. Additionally, this drug has the unique pharmacokinetic property of a terminal half-life of 6 to 10 days that allows for once-weekly administration [11]. Similar to other glycopeptides, dalbavancin has a wide spectrum of in vitro activity against a variety of Gram-positive cocci such as *Staphylococci*, *Streptococci* and *Enterococci*, including methicillin-resistant strains of *Staphylococcus* spp. [12].

Dalbavancin is currently approved for the treatment of acute bacterial skin and skin structure infections (ABSSI) suspected or known to be caused by Gram-positive bacteria [13,14]. Of note, in the registration, surgical site infections were included in the study but no data on SWI were reported [15]. In addition, real-world data about the use of dalbavancin in patients SWI are limited to case reports or case series [13,14], without a comparator group. Thus, the effect of dalbavancin on length of stay and costs in comparison with SoC has not been assessed yet [15,16].

Therefore, the aims of our study are: (i) to evaluate the outcome of SWI at 90 and 180 days from infection diagnosis in patients treated with dalbavancin compared with that treated with standard of care (SoC), i.e., daptomycin and teicoplanin; (ii) to compare drug and hospitalization costs of patients treated with dalbavancin versus SoC.

2. Methods

2.1. Study design

We performed a retrospective, multicentre cohort study of adult patients diagnosed with SWI due to Gram-positive isolates from January 2016 to December 2019 treated with dalbavancin or SoC in two large cardiosurgical centres. Sternal wound Infection was defined according to CDC criteria [17]. The databases of Cardiac Surgery and Microbiology Laboratories were used as the data source. Clinical charts and hospital records of each patient with SWI diagnosis during the study period were reviewed to assess the presence of Gram-positive aetiology of infection and for data collection. Data were collected anonymously.

The study was approved by the Ethic Committees of both centres (Comitato Etico Indipendente di Area Vasta Emilia Centro, n. 647/2019/Oss/AOUBo and Comitato Etico della Romagna, ID study 2397. Prot. 8658/2020 I.5/269). Written informed consent was obtained for all patients, except if they are dead or lost to follow-up. Lost to follow-up patients was defined as those patients who after discharge from the hospital have been unreachable to obtain the written informed consent form and will be impossible to achieve by three different telephone calls in three different days at different times.

2.2. Population

All consecutive adult (aged ≥ 18 years) patients diagnosed with SWI caused by Gram-positive pathogens in the study centres treated with dalbavancin, teicoplanin and daptomycin during the study period were screened. Exclusion criteria were: age <18 years; microbiological diagnosis of Gram-negative infection/coinfection; concomitant mediastinitis and/or osteomyelitis; and clinical data not available.

2.3. Setting

Study centres are IRCCS Policlinico di S. Orsola (Bologna, Italy), a 1450-bed tertiary-care university hospital performing an average of 900 open heart surgeries per year and Maria Cecilia Hospital GVM Care and Research (Cotignola, Ravenna, Italy), a 200-bed hospital with a large cardiac surgeries facility performing approximately 1100 open heart surgery per year.

2.4. Variables and definitions

The exposure variable was dalbavancin treatment. The primary outcome was resolution of infection at 90 and 180 days after SWI diagnosis, defined as complete resolution of local purulent drainage and surrounding erythema, oedema and/or induration surrounding the surgical wound and cellulitis. The secondary outcomes were the length of stay and the drug and hospitalization costs. Predictor variables included age, sex and underlying conditions recorded according to the Charlson comorbidity index [18]. The causes of primary cardiac surgery intervention were assessed with any additional surgical intervention required.

SWI was defined by the presence of local purulent drainage and surrounding erythema, oedema and/or induration surrounding surgical wound and cellulitis [17].

Microbiological diagnosis was assessed through intraoperative sampling. Patients with SWI were managed with surgical debridement followed by at least 10 days of VAC therapy course. Antibiotic therapy was described as regards type of antibiotic use (dalbavancin or SoC) and duration of treatment. Dalbavancin was administered intravenously at a standard dose 1000 mg on day 1, followed by a dose of 500 mg on day 8 [19]. SoC included teicoplanin or daptomycin. Teicoplanin was administered intravenously with a loading dose of 12 mg/kg every 12 h for 3 doses followed by a maintenance dose of 12 mg/kg/day [20]. Therapeutic drug monitoring was performed during the duration of therapy to obtain target trough >15 mg/L. Daptomycin was administered intravenously at a standard bolus of 6–8 mg/kg/day [21]. All drugs (i.e., dalbavancin, teicoplanin and daptomycin) were administered with dosage adjustments for renal impairment as recommended by the manufacturers [19–21]. In addition, drugs were administered during the hospital stay or in a dedicated outpatient service. Duration of SoC therapy was at least 14 days up to a maximum of 21 days. Any adverse event or adverse drug reaction was recorded.

Antibiotic therapy costs were calculated for each patient and were assessed directly from the pharmacy's records considering the prices during their period of hospitalization. Hospitalization costs were estimate collecting direct medical costs, costs of drugs and supplies, laboratory tests, and general hospitalization cost according to the patient ward. These reports were provided by Hospital Administrative System Reports of the structures.

2.5. Statistical analysis

For descriptive analysis, categorical variables were presented as absolute numbers, and their relative frequencies, continuous variables were presented as mean and standard deviation (SD) if normally distributed, or as median and IQR if non-normally distributed. Patients treated with and without dalbavancin were compared using the χ^2 test, and the Fisher exact test was used when appropriate. Continuous variables were compared using the non-parametric Mann-Whitney test, while the Student's *t* test was used to compare normally distributed parameters. A cost minimization analysis taking into account drugs and hospitalization costs was performed to identify the least costly approach [22]. All tests were two-sided, and values of *P* less than 0.05 were considered statisti-

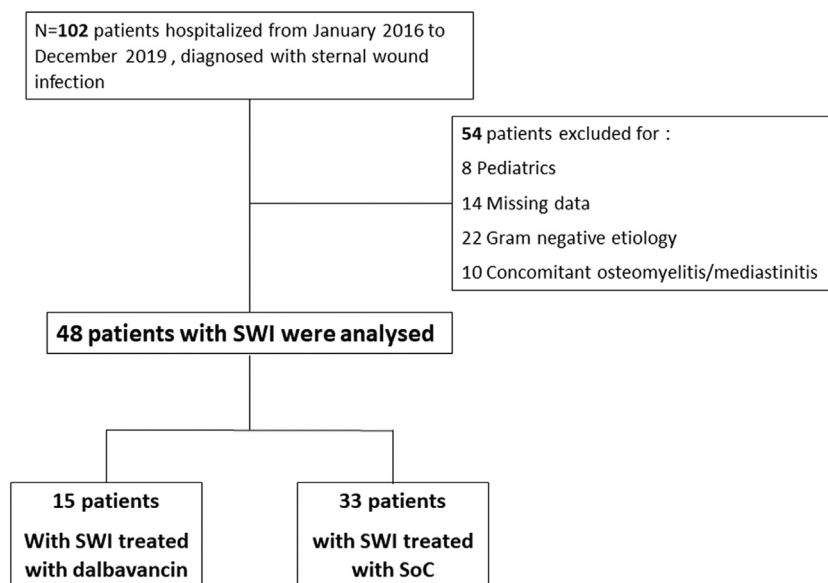


Fig. 1. Study population flow chart. SWI, sternal wound infection; SoC, standard of care.

cally significant. All the analyses were carried out using SPSS 21.00 software.

3. Results

Over the study period, 102 patients with SWI were screened. Of them, 54 were excluded: 22 patients had Gram-negative infection or coinfection, 10 patients had concomitant osteomyelitis/mediastinitis, 8 patients were paediatrics, and for 14 patients clinical data were not available. Thus, 48 patients were analysed (Fig. 1). There were 15 patients treated with dalbavancin (31%), and the remaining patients (33, 69%) were treated with SoC: 21 (63%) with teicoplanin, 12 (37%) with daptomycin. The characteristics of the overall population are shown in Table 1. Of them, 25 patients (50%) were male, with median age of 67 (60–73) years, median Charlson index score 5 (4–7). The main indications for surgery were coronary artery bypass graft (33, 69%) and valvular disease (15, 31%). Infection diagnosis was made after 26 (IQR 15–41) days from cardiac surgery. At time of infection diagnosis 10 patients (21%) presented fever, all had purulent drainage. Distribution of etiological pathogens was coagulase-negative *Staphylococci* (24, 50%) with rate of methicillin resistance of 92%, *Staphylococcus aureus* (21, 43%) with rate of methicillin resistance of 71%, and *Enterococcus* spp. (3, 6%). All isolates treated with dalbavancin were tested to define antibiotic susceptibility and showed minimal inhibitory concentrations (MICs) below the pre-established breakpoints.

All patients were treated with surgical debridement and consequent negative pressure wound therapy (NPWT) to provide better wound healing. Four patients needed a second surgical revision for persistence of wound dehiscence, all in the SoC group. There were no differences in demographics, clinical presentation, and management of SWI between patients treated with and without dalbavancin (Table 1).

Respecting the outcome, only two patients died during study period. In both cases, death was not related to SWI. Wound healing at day 90 was achieved in 46 (95.8%) patients, 14 (93%) in dalbavancin group and 32 (97%) in SoC group ($P = 0.559$). This favourable outcome was confirmed at 180-day follow-up with complete resolution of infection in 11 (92%) and 23 (79%) patients treated with dalbavancin and SoC, respectively ($P = 0.339$). No differences were found in outcome between two groups, except for

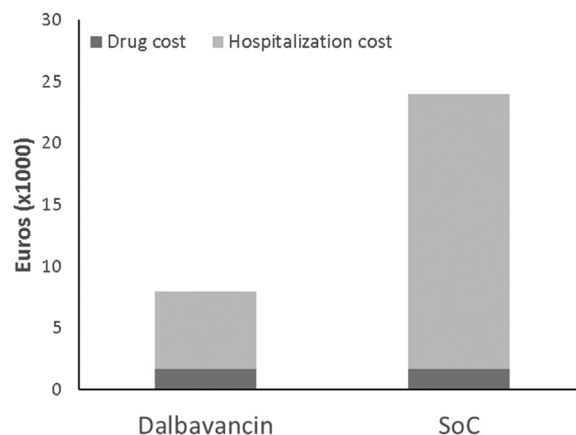


Fig. 2. Cost minimization analysis of patients treated with dalbavancin compared to SoC. SoC, standard of care.

a shorter length of hospitalization in patients treated with dalbavancin compared with SoC [12 (7–18) days vs 22 (12–36) days, $P = 0.009$]. No adverse events nor adverse drug reactions were recorded.

Regarding cost analysis, treatment with dalbavancin resulted in a mean total cost of €7975 (95% CI 6546–9405), while mean total cost associated with SoC was €24 001 (95% CI 17 211–30 791) per patient (Fig. 2). Treatment with dalbavancin resulted in total cost savings of €16 026 (95% CI 5976–26 076, $P < 0.001$). Savings are mainly related to the length of hospital stay that was significantly shorter in the dalbavancin group generating significantly lower cost compared to SoC group (€6265 [95% CI 4888–7643] vs €22 269 [95% CI 15 745–28 793], $P < 0.001$). No difference was detected for the drug cost between the two groups (€1710 [95% CI 1328–2092] vs €1732 [95% CI 1142–2321], $P = 0.962$).

4. Discussion

In this retrospective study, 15 patients receiving dalbavancin for the treatment of SWI were compared with 33 patients receiving teicoplanin or daptomycin. Overall, both groups showed a good clin-

Table 1
Characteristics of patients

	Total N = 48 (%)	Dalbavancin N = 15 (%)	Standard of care N = 33 (%)	P
Demographics				
Age (y) (median, IQR)	67 (60–73)	61 (57–68)	67 (61–78)	.064
Male sex	24 (50)	7 (46.7)	17 (51.5)	.755
Comorbidities				
Charlson index (median, IQR)	5 (4–7)	5 (2–8)	5 (4–7)	.778
Obesity	12 (25)	5 (33.3)	7 (21.2)	.369
Myocardial ischemia	26 (54.2)	8 (53.3)	18 (54.5)	.938
Chronic heart insufficiency	24 (41.7)	7 (46.7)	13 (39.4)	.636
Peripheral vasculopathy	18 (37.5)	3 (20)	15 (45.5)	.091
Diabetes	20 (41.6)	8 (53.3)	12 (36.3)	
Valvular disease	16 (33.3)	5 (33.3)	11 (33.3)	1
Valvular insufficiency				.958
Aortic insufficiency	4 (8.3)	1 (6.7)	3 (9.1)	
Mitral insufficiency	6 (12.5)	2 (13.3)	4 (12.1)	
Valvular stenosis				.309
Aortic stenosis	8 (16.7)	2 (13.3)	6 (18.2)	
Mitral stenosis	1 (2.1)	1 (6.7)	0 (0)	
Ischemic heart disease	26 (54.2)	8 (53.3)	18 (54.5)	.938
Aneurismatic dilatation	5 (33.3)	2 (13.3)	3 (9.1)	.318
Cardiac surgery				
First cardiac surgery	46 (95.8)	14 (93.3)	32 (97)	.559
Aortic valve surgery	11 (22.9)	4 (26.7)	7 (21.2)	.677
Mitral valve surgery	4 (8.3)	2 (13.3)	2 (6.1)	.398
CABG	33 (68.7)	9 (60)	24 (72)	.911
Aortic surgery	5 (10.4)	2 (13.3)	3 (9.1)	.656
Full sternotomy	45 (93.8)	13 (86.7)	32 (97)	.172
Mini thoracotomy	1 (2.1)	0 (0)	1 (3)	.496
Extracorporeal circulation	40 (85.1)	13 (86.7)	27 (84.4)	.837
Use of blood products	26 (56.5)	8 (53.3)	18 (58.1)	.762
Infection characteristics				
Fever at diagnosis	10 (21.3)	2 (14.3)	8 (24.2)	.446
Superficial infection	4 (6.2)	3 (13.3)	1 (3)	.172
Microbial aetiology				
<i>Coagulase negative Staphylococcus</i>	24 (50)	10 (66)	14 (42)	
<i>Methicillin-resistant CoNS*</i>	22 (92)	10 (100)	12 (36)	
<i>Staphylococcus aureus</i>	21 (43)	5 (33)	16 (48)	
<i>Methicillin-resistant S. aureus*</i>	15 (71)	5 (100)	10 (62.5)	
<i>Enterococcus spp.</i>	3 (6.25)	0 (0)	3 (9)	
Outcome				
Need for a second surgical revision	4 (8.3)	0 (0)	4 (12)	.159
Wound healing at day 90	46 (95.8)	14 (93)	32 (97)	.559
Wound healing at day 180	34 (82.9)	11 (91.7)	23 (79.3)	.339
Death	2 (4.2)	0 (0)	2 (6.1)	.330
Time from surgery to discharge, days (median, IQR)	17 (11–22)	12 (7–18)	22 (12–36)	.009

CABG, coronary artery bypass graft; CVC, central venous catheter; IQR, interquartile range; SOFA, sequential organ failure assessment.

* The percentages of resistance to methicillin refer to the total of microbiological isolates, respectively, CoNS and *S. aureus*.

ical outcome with complete resolution of infection at 90 and 180-day follow-up in a large majority of patients.

Clinical experience of dalbavancin use for treatment of SWI is limited to a single case report [14] and a case series previously published by our group [13]. In our previous collection, we described a retrospective series of 15 patients treated successfully with dalbavancin for deep sternal wound infection (DSWI). In this case series, dalbavancin was administered by two infusions in nine patients, whereas five patients received a median of four doses due to evolution of DSWI to mediastinitis.

In our current experience dalbavancin was administered at once-a-week dosing schedule with a total of two administrations since all the wounds were superficial. In addition to antibiotic therapy, the surgical debridement and the subsequent use of NPWT were confirmed to be crucial in resolution of the infection. There were no differences in efficacy between dalbavancin and SoC therapy for the treatment of SWI. To the best of our knowledge, this is the first report comparing dalbavancin and other lipopeptides/glycopeptides (i.e., daptomycin and teicoplanin) for the treatment of SWI.

In our work we also emphasized the cost-effectiveness of using dalbavancin, which led to a shorter hospitalization time and

a reduction in relative costs. SWIs are associated with increased healthcare costs, which are often related to the prolonged intravenous antibiotic treatment when oral strategies are not available, either because of patients' characteristics or because of microbiological isolates susceptibility [8,23]. Because of the long half-life of dalbavancin that allows a once-weekly dose regimen, patients were discharged earlier than patients treated with teicoplanin or daptomycin (12 vs 22 days, $p:0.009$). Therefore, treatment with dalbavancin led to a reduction of total cost compared to SoC, mainly because of the shorter hospital stay.

Our study confirms what is reported in other settings and experimental models, in which use of dalbavancin is associated with early discharge and consequent savings [24–26]. The largest study assessing the effects of dalbavancin on budgets is a French multi-centre cohort study [15]. The authors analysed 154 patients treated with dalbavancin for several indication (bone and joint infections, infective endocarditis and acute bacterial skin infections) compared with similar patients treated with standard therapy, demonstrating early discharge and consequent savings [15].

Our study has several limitations. First, the small sample size may have hampered a powerful analysis. However, this is one of the largest real-life experiences on dalbavancin use in patients

with SWI compared with alternative regimens. Second, the retrospective collection of patient and microbiological data could have limited integrity and accuracy. However, an accurate revision of all clinical report forms (CRFs) and reconciled data reports and missing data with the medical records was performed by the authors before including information in the database.

To conclude, our experience suggests that dalbavancin treatment of SWI is effective and seems to reduce time of hospitalization, leading to significantly lower costs. However, large studies are needed to confirm the clinical efficacy and cost-effectiveness of dalbavancin in the therapeutic armamentarium against SWI.

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Competing interests

None declared

Ethical approval

This study was approved by Comitato Etico Indipendente di Area Vasta Emilia Centro, n. 647/2019/Oss/AOUBo and Comitato Etico della Romagna, ID study 2397. Prot. 8658/2020 I.5/269.

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