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Short Communication

French national cohort of first use of dalbavancin: A high proportion of off-label use

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ABSTRACT

Dalbavancin is a glycopeptide antibiotic with a long half-life, recently marketed in Europe for skin and soft-tissue infections (SSTIs), but its real-life use is not well known. The aim of this study was to describe all first prescriptions in France over an 16-month period. A retrospective study on all adult patients receiving at least one dose of dalbavancin from 1 June 2017 to 31 September 2018 was performed (75 patients from 29 French hospitals). Data were collected via a standard questionnaire. Failure was defined as persistence or reappearance of signs of infection, and/or switch to suppressive antibiotic treatment, and/or death from infection. The main indications were bone and joint infection (BJI) (64.0%), endocarditis (25.3%), and SSTI (17.3%). The main bacteria involved were *Staphylococcus aureus* (51.4%), including methicillin-resistant *S. aureus* (MRSA) (19.4%), and coagulase-negative staphylococci (44.4%). Median minimum inhibitory concentrations (MICs) for staphylococci to vancomycin and dalbavancin ranged from 0.875–2.0 mg/L and 0.032–0.064 mg/L, respectively. Dalbavancin was used after a mean of 2.3 ± 1.2 lines of antimicrobial treatment. The main treatment regimens for dalbavancin were a two-dose regimen (1500 mg each) in 38 cases (50.7%) and a single-dose regimen (1500 mg) in 13 cases (17.3%). Overall, at the patient's last visit, clinical cure was observed in 54/68 patients, whilst failure was observed in 14/68

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patients. First use of dalbavancin in France was mostly off-label. Most were due to BJI, often as rescue therapy for severe infections. Even in off-label situations, dalbavancin appears safe and effective.

1. Introduction

Dalbavancin is a novel, long-lasting glycopeptide approved for the treatment of skin and soft-tissue infections (SSTIs) as an intravenous (i.v.) infusion of a single dose (1500 mg i.v.) or as two doses (1000 mg i.v. followed by 500 mg i.v. 7 days later) [1,2].

Dalbavancin has excellent bactericidal activity against Gram-positive bacteria, especially *Staphylococcus aureus*, and a prolonged half-life of 14–15 days [3,4]. Its unique pharmacokinetic properties enable the treatment of serious infections such as bone and joint infection (BJI) [5]. However, few data on its current use are available since it has been marketed.

The objective of this study was to describe a national cohort comprising the first prescriptions of dalbavancin in the 16 months following market access in France.

2. Materials and methods

A national retrospective study of all adult patients who received at least one dose of dalbavancin from 1 June 2017 to 31 September 2018 was performed. A standardised questionnaire was sent to prescribers to collect patients' baseline characteristics, infection type and management, identification of pathogens involved, reasons for dalbavancin use, doses and duration of dalbavancin treatment, adverse drug reactions, and outcome.

No patient included in the study expressed opposition to the use of clinical data in this retrospective study. The research was conducted in accordance with the Declaration of Helsinki as well as national and institutional standards.

Immunosuppression was defined as asplenia, neutropenia, agammaglobulinemia, organ transplant, haematological malignancies, known human immunodeficiency virus (HIV) infection and CD4 count $<400/mm^3$, or Child–Pugh class C cirrhosis. Immunosuppressive treatments were considered as follows: corticosteroid use if daily dose >20 mg of prednisolone equivalent; chemotherapy; or immunosuppressive treatment such as cyclophosphamide, azathioprine and cyclosporine.

Liver failure was defined by coagulation Factor V level ≤50% and/or hepatic encephalopathy.

Disseminated disease was considered when at least two different sites were infected.

Minimum inhibitory concentrations (MIC) of dalbavancin and vancomycin were determined by the agar dilution method or the broth microdilution procedure according to local procedure. The breakpoints used were those defined by the French Committee for Antimicrobial Susceptibility Testing (CA-SFM) [6].

Outcome was evaluated by the investigators at the patient's latest visit after completion of their dalbavancin treatment. In the case of suppressive treatment by dalbavancin, outcome was evaluated at the latest control visit.

Clinical cure was defined as the absence of clinical signs of infection and was confirmed by the physician in charge. Failure was defined as a composite of the following criteria: persistence or reappearance of signs of infection with or without microbiological identification; and/or switch to suppressive antibiotic treatment; and/or death from infection.

Quantitative variables are presented as the mean ± standard deviation or the median and interquartile range (IQR). Qualitative variables are presented as number of occurrences and relative frequencies. All statistical analyses were performed using SPSS Statistics v.17.0 software (SPSS Inc., Chicago, IL, USA).

3. Results

A total of 75 patients from 29 French hospitals were included in the study. The demographic and baseline characteristics of the study population are shown in Table 1.

The main types of infection treated by dalbavancin were BJI (64.0%), endocarditis (25.3%) and SSTI (17.3%). Concomitant bacteraemia was reported in 38 patients (50.7%).

Of 72 documented infections (Table 1), 25 (34.7%) were polymicrobial. The main Gram-positive pathogens identified were *S. aureus* ($n=37$; 51.4%), including methicillin-resistant *S. aureus* (MRSA) ($n=14$; 19.4%), and coagulase-negative staphylococci ($n=32$; 44.4%).

The median (IQR) MICs of dalbavancin depending on the bacterial species were 0.064 (0.051–0.064) mg/L for *S. aureus* and MRSA, 0.047 (0.047–0.064) mg/L for methicillin-susceptible *S. aureus* (MSSA), 0.047 (0.025–0.064) mg/L for *Staphylococcus epidermidis* and 0.032 (0.023–0.064) mg/L for methicillin-resistant *S. epidermidis* (MRSE).

The median (IQR) MICs of vancomycin depending on the bacterial species were 1.0 (0.094–1.0) mg/L for *S. aureus*, 0.875 (0.173–1.375) mg/L for MRSA, 1.0 (0.297–1.0) mg/L for MSSA, 2.0 (1.125–2.0) mg/L for *S. epidermidis* and 2.0 (1.675–2.0) mg/L for MRSE.

Among the 75 patients, 74 (98.7%) had received prior antibiotic treatment, with a mean of 2.3 ± 1.2 lines (range, 1–8). The most common antimicrobials prescribed were rifampicin ($n=21$; 28.4%), daptomycin ($n=20$; 27.0%), linezolid ($n=19$; 25.7%), fluoroquinolones ($n=19$; 25.7%), vancomycin ($n=17$; 23.0%), clindamycin ($n=16$; 21.6%) and cefazolin ($n=16$; 21.6%). The median (IQR) duration of previous antibiotic therapy was 22.5 (14.3–39.8) days.

The main reasons for switching to dalbavancin treatment are also described in Table 1. Several dalbavancin treatment regimens were recorded and are presented in Table 2, with dosing regimens according to the site of infection.

Concomitant antibiotics were used with dalbavancin for 34 patients (45.3%). The most frequently antibiotics used were rifampicin ($n=12$; 35.3%), trimethoprim/sulfamethoxazole ($n=10$; 29.4%), fluoroquinolones ($n=6$; 17.6%) and tetracyclines ($n=6$; 17.6%).

Outcomes in total and according to type of infection are shown in Table 2. Overall, at the patient's last visit, with a mean follow-up duration of 87.8 ± 86.9 days, clinical cure with dalbavancin was observed in 54/68 patients and failure was observed in 14/68 patients. Nine patients received an antibiotic suppressive treatment after the end of their dalbavancin treatment. Two patients died from their infections. Also, two microbiological failures were reported, and one clinical failure was not microbiologically documented (endocarditis). Finally, four patients died from non-infectious causes, one patient was lost to follow-up and two patients were initially misdiagnosed and their antibiotic treatments were either altered or discontinued.

The main dalbavancin treatment regimens among cured patients were two 1500 mg i.v. injections with a 7-day interval ($n=26$; 48.1%) or a 14-day interval ($n=6$; 11.1%), and a single 1500 mg i.v. injection ($n=7$; 13.0%).

Table 1
Demographics and baseline characteristics and description of dalbavancin use in the study population ($N = 75$)

Characteristic	*n* (%) [a]
Age (years) (mean ± S.D.)	63.1 ± 17.0
Sex ratio (M/F)	2.26
Hospitalisation	
Length of stay (days) (mean ± S.D.)	25.2 ± 25.8
Hospital ward	
ICU	4 (5.3)
Medicine	62 (82.7)
Surgery	6 (8.0)
Other	3 (4.0)
Co-morbidities	
Chronic respiratory failure	6 (8.0)
Heart failure	28 (37.3)
Chronic renal failure	10 (13.3)
Liver failure	7 (9.3)
Neurological disease	15 (20.0)
Immunosuppression	25 (33.3)
Blood disorder	3 (4.0)
Chemotherapy	4 (5.3)
Immunosuppressive treatment	5 (6.7)
Corticosteroid use [b]	2 (2.7)
Diabetes mellitus	19 (25.3)
Organ transplant	1 (1.3)
Renal clearance (mL/min) (mean ± S.D.)	90.8 ± 42.5
Antibiotic allergy	9 (12.0)
History before hospitalisation	
Outpatient [c]	56 (74.7)
Institutionalised	6 (8.0)
Other hospital	11 (14.7)
Site of infection	
Disseminated disease [d]	19 (25.3)
BJI	48 (64.0)
Endocarditis	19 (25.3)
Native valve	9 (12.0)
Prosthetic valve	10 (13.3)
SSTI	13 (17.3)
Vascular infection	5 (6.7)
Catheter line infection	4 (5.3)
Bloodstream infection	3 (4.0)
Mediastinitis	2 (2.7)
Disease severity	
Septic shock	6 (8.0)
ICU admission during episode	7 (9.3)
Mechanical ventilation	2 (2.7)
Vasopressor requirement	2 (2.7)
Volume expansion	5 (6.7)
Before dalbavancin treatment	
Biological analyses (mean ± S.D.)	
White blood cell count ($\times 10^3$/L)	9.4 ± 4.4
Haemoglobin (g/dL)	10.7 ± 1.9
Absolute neutrophil count ($\times 10^3$/L)	6.6 ± 3.3
Eosinophil count ($\times 10^3$/L)	0.3 ± 0.4
C-reactive protein (mg/L)	81.3 ± 81.9
Surgical treatment	47 (62.7)
DAIR	12
Previous antibiotic treatment	74 (98.7)
Number of lines (mean ± S.D.)	2.3 ± 1.2
Duration (days) [median (IQR)]	22.5 (14.3–39.8)
Microbiology analysis	
Documented infections	72 (96.0)
Polymicrobial infections	25 (34.7)
Staphylococcus spp.	69 (95.8)
Staphylococcus aureus	37 (51.4)
MRSA	14 (19.4)
CoNS	32 (44.4)
Staphylococcus epidermidis	24 (33.3)
MRSE	15 (20.8)
Enterococcus faecalis	5 (6.9)
Corynebacterium spp.	5 (6.9)
Reason for dalbavancin use	
Clinical failure of previous antibiotic treatment	16 (21.3)
Microbiological failure of previous antibiotic treatment	4 (5.3)
Adverse event of previous antibiotic treatment	26 (34.7)
Multidrug-resistant bacteria	17 (22.7)
Impossible venous access	18 (24.0)
Patient autonomy	29 (38.7)
Early hospital discharge	26 (34.7)
Better compliance	21 (28.0)

S.D., standard deviation; ICU, intensive care unit; BJI, bone and joint infection; SSTI, skin and soft-tissue infection; DAIR, debridement, antibiotics and implant retention; MRSA, methicillin-resistant *S. aureus*; CoNS, coagulase-negative staphylococci; MRSE, methicillin-resistant *S. epidermidis*.

[a] Data are *n* (%) unless otherwise stated.

[b] If daily dose >20 mg of prednisolone equivalent.

[c] Data were missing for two patients.

[d] Disseminated disease was considered when at least two different sites were infected.

Following discharge from hospital, dalbavancin was administered as outpatient parenteral antimicrobial therapy (OPAT) in 37 patients (49.3%).

Only five adverse drug reactions were reported, without any dalbavancin treatment discontinuation. Two adverse drug reactions concurred with hypersensitivity to dalbavancin (erythematous rash, chills and fever after the first infusion). One patient suffered from headaches. An increase in eosinophils level was also reported, which was self-resolving. Lastly, one patient had local inflammatory signs after a single i.v. infusion of 1500 mg dalbavancin.

4. Discussion

Dalbavancin is a novel antibiotic with a long half-life, which received its approval for SSTI. A few recent studies have presented experience of dalbavancin in some specific indications, e.g. osteomyelitis and endocarditis [5,7]. One study focused on real-life experience of dalbavancin, but not at a national scale and not since the very beginning of market access [8].

The originality of the current study is to describe the first use, since dalbavancin was available, in real life, at a national level.

The study results show high off-label use, with only 4/75 patients (5.3%) receiving dalbavancin as approved. The results suggest that dalbavancin is a well-tolerated and effective treatment for different Gram-positive infections, especially those with off-label indications. The global cure rate was high (79.4%) despite dalbavancin being mostly used as salvage therapy.

A substantial proportion of patients presented with BJI. Regarding BJIs, a randomised controlled trial recently compared dalbavancin versus standard of care and reported good efficacy with two 1500 mg i.v. injections of dalbavancin [5]. In the literature, dalbavancin is associated with a high rate of clinical success (78–97%) in this indication, as also observed in the current study [5,8–12].

This study also included 19 cases of endocarditis with a 73.2% cure rate. A recent study showed high efficacy of dalbavancin as first-line or salvage therapy during endocarditis [7]. However, it should be noted that most of these patients (88.9%) received dalbavancin as salvage therapy.

Overall, the optimal administration regimen is still under debate in literature the [5,7–14]. The most prescribed regimen in the current study was 1500 mg on Day 1 and Day 8, but it appears that other regimens, such as 1500 mg twice with a 14-day interval or a single 1500 mg injection, are also effective whatever the indication. These dosages (1500 mg) are higher than those used in the pivotal trial that included only SSTIs [15]. Indeed, data on 1500 mg dosages at Days 1 and 8 were supported by clinical studies on BJI [5]. None the less, more data on optimal dosages are still warranted.

Table 2
Dalbavancin dosing regimen and patient outcome, in total and according to site of infection

	Total ($n=75$)	BJI ($n=48$)	Endocarditis ($n=19$)	SSTI ($n=13$)	Vascular infection ($n=5$)	CLI ($n=4$)	BSI ($n=3$)	Mediastinitis ($n=2$)
Dalbavancin dosing regimen (n)								
1 dose	15	5	2	5	1	3	2	0
1 g	2	1	0	1	0	1	0	0
1.5 g	13	4	2	4	1	2	2	0
2 doses	44	34	11	7	2	1	1	1
Unknown	2	0	2	0	0	0	0	0
7-day interval								
1 g, 0.5 g	1	0	0	0	1	0	0	0
1 g × 2	1	1	0	0	0	0	0	0
1.5 g × 2	31	29	5	5	0	0	1	1
14-day interval								
1.5 g, 1 g	1	1	1	0	0	0	0	0
1.5 g × 2	7	2	3	2	1	1	0	0
21-day interval								
1.5 g, 0.5 g	1	1	0	0	0	0	0	0
3 doses	2	1	1	0	0	0	0	0
7-day interval								
1.5 g, 0.5 g × 2	1	0	1	0	0	0	0	0
1.5 g × 3	1	1	0	0	0	0	0	0
4 doses	4	3	1	1	0	0	0	0
7-day interval								
1.5 g × 4	1 [a]	0	0	0	0	0	0	0
14-day interval								
1 g, 0.5 g × 3	2	2	0	0	0	0	0	0
1.5 g × 4	1	1	1	1	0	0	0	0
>4 doses (max. 10)	5	3	1	0	2	0	0	0
7-day interval								
1 g, 0.5 g × N	1	1	0	0	0	0	0	0
1.5 g, 0.5 g × N	1	1	0	0	0	0	0	0
14-day interval								
1 g, 0.5 g × N	2	1	1	0	1	0	0	0
1.5 g × N	1	0	0	0	1	0	0	0
Suppressive	3	2	1	0	0	0	0	1
21-day interval								
1.5 g, 0.5 g × N	1	1	0	0	0	0	0	0
1.5 g × 3, 0.5 g × N	1	1	0	0	0	0	0	0
1.5 g × N	1	0	1	0	0	0	0	1
Outcome at last visit [b] [n (%)]								
Cure	54/68 (79.4)	35/46 (76.1)	13/18 (72.2)	9/11 (81.8)	5/5 (100)	2/2 (100)	1/1 (100)	1/2 (50.0)
Failure	14/68 (20.6)	11/46 (23.9)	5/18 (27.8)	2/11 (18.2)	0 (0)	0 (0)	0 (0)	1/2 (50.0)
Delay since first dose (days) (mean ± S.D.)	87.8 ± 86.9	80.0 ± 73.9	97.9 ± 99.7	102.8 ± 96.6	88.0 ± 81.1	36.0 ± 26.9	82.5 ± 27.6	182

BJI, bone and joint infection; SSTI, skin and soft-tissue infection; CLI, catheter line infection; BSI, bloodstream infection; S.D., standard deviation.
[a] One patient with other indication.
[b] Patients who were lost to follow-up, died from non-infectious causes or were misdiagnosed were excluded.

Also, in this study dalbavancin was used in combination in 34 cases with a low cure rate (66.7%), whereas the cure rate was 91.4% when it was used as monotherapy. The need for combination during dalbavancin treatment is still discussed in the literature. One previous study reported that >35% of patients received combination treatment with a worse clinical course than in the current study [8]. This could be due to the severity of disease, thus physicians are more prone to prescribe combination therapy.

In an experimental foreign-body infection model with MRSA, the activity of dalbavancin in combination with rifampicin was superior to dalbavancin alone and prevented from emergence of rifampicin resistance [16]. Thus, the benefit of combination therapy with dalbavancin, according to indication and micro-organism involved, needs to be further evaluated with interventional clinical studies.

The median MIC for staphylococci to vancomycin and dalbavancin ranged from 0.875–2.0 mg/L and 0.032–0.064 mg/L, respectively. This underlines its efficacy even in cases of bacteria resistant to vancomycin.

Lastly, the number of reported adverse drug reactions in this study was similar to that found in the literature [5,7–14]. Therefore, in this study dalbavancin demonstrated an excellent safety profile, which is consistent with the results from a previous safety analysis [17].

There are several limitations of this study, including the small number of patients, the retrospective nature of the analysis and the absence of long-term follow-up.

5. Conclusions

In our experience, dalbavancin was used mainly in off-label indications and often as rescue therapy for severe infections. Even in these situations, dalbavancin appears safe and effective.

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