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Original Research Article

Drug utilization evaluation of ceftazidime-avibactam in a tertiary care hospital

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ABSTRACT

Background: The World Health Organization considers antimicrobial resistance a major global threat, and ceftazidime-avibactam (CAZ-AVI) is a treatment for multidrug-resistant Gram-negative infections. The FDA approved its use in 2015 for infections with limited treatment options.
Methods: A retrospective study was conducted in a hospital in India to analyse the use of CAZ-AVI formulation in patients. Data was collected from electronic records and included information on patient demographics, clinical and microbiological profiles, antibiotic treatment, and patient outcomes for those in the ICU.
Results: A total of 110 patients were included in the study. On assessing the results of this study, it was found that, the median age of population who received CAZ-AVI was 63 years and hypertension, diabetes mellitus were the common comorbidities present in the patients. Out of 110 subjects, 66 (60%) patients were started with a high-end antibiotic as an empirical therapy. While analysing the resistance pattern, it was found that 22 (20%) were resistant and 84 (76%) of the study subjects were sensitive to ceftazidime-avibactam. There was higher clinical success for BSI, CUTI, VAP amongst the indications of CAZ-AVI and combination of CAZ-AVI with aztreonam has given the most successful treatment outcome. The combination of CAZ-AVI with one or two high end antibiotics was observed as a common clinical practice.
Conclusions: The analysis of results showed encouraging clinical cure rates. Our study results suggest that ceftazidime-avibactam could be an effective standard therapy for managing MDR Gram -negative organisms.

Keywords: Antimicrobial resistance, Aztreonam, Ceftazidime-avibactam

INTRODUCTION

Antimicrobials have aided in the treatment of disease; however incorrect usage of these antimicrobials has brought new challenges. Antibiotic resistance refers to bacteria's capacity to protect themselves against the effects of an antibiotic. The proper and inappropriate use of antibiotics in recent years has resulted in a rise in the prevalence and spread of antibiotic-resistant bacteria.[1] The rising frequency of drug-resistant organisms such as carbapenem resistant Enterobacterales, methicillin-resistant *Staphylococcus aureus* (MRSA), and others has fuelled this trend. Carbapenem resistance is widespread in India, with up to 30% of bacteria developing carbapenemases.[2] While polymyxins are the preferred agents for empiric therapy, they have limited use in renally impaired and polymyxin B cannot be used in the urinary tract infections. The rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period, and at the lowest cost to them and the community. This study

retrospectively evaluated the prescribing patterns, clinical outcomes of CAZ-AVI use in various clinical syndromes with multidrug resistant (MDR) infections with limited therapeutic options (LTO)[3]

Combination of beta lactam antibiotic with Beta lactamase inhibitor

Currently the use of β-lactamase inhibitors [clavulanic acid (clavulanate), sulbactam, tazobactam] is the most successful strategy to restore the efficacy of β-lactam antibiotics. Cephalosporins (a β-lactam antibiotic) are efficacious and safe antibacterial agents with broad-spectrum activity and favourable pharmacokinetic and pharmacodynamic profiles. However, increasing resistance to cephalosporins and the expression of ESBL β-lactamases have limited the utilization of the cephalosporins. The first-generation β-lactamase inhibitors (clavulanic acid, sulbactam and tazobactam) are all β-lactam derivatives and work primarily by inactivating class A and some class C serine β-lactamases. The newer generations of β-lactamase inhibitors including avibactam and vaborbactam are based on non-β-lactam structures and their spectrum of inhibition is extended to KPC as an important class A carbapenemase.[4] Despite these advances several class D and virtually all-important class B β-lactamases are resistant to existing inhibitors. Ceftazidime and avibactam exhibit numerous similarities in pharmacokinetic properties: both have short plasma half-lives, low plasma protein binding, and similar volumes of distribution (V_d) and epithelial lining fluid (ELF) penetration ratios. Vaborbactam is active against ambler class A, whereas avibactam and relebactam have activity against ambler A, C and to some extent, class D. But, relebactam has a half-life of 1.8 hours, which makes avibactam the superior alternative amongst the non-suicidal beta-lactamase inhibitors.[5] Multi-drug resistant gram-negative infections are becoming increasingly difficult to treat, prompting increased focus on antimicrobial stewardship. Previous literature studies on CAZ-AVI have described the patterns of its use in treating a specific indication or its effectiveness in treating a particular species of MDR organism. Although, antimicrobial fixed dose combinations (FDCs) have been critical in improving clinical outcomes among patients with certain infections, the use of such FDCs for few bacterial infections is inappropriate as it drives AMR by selecting co-resistant microorganisms.

Thus, the present study aimed at understanding the patterns of use of CAZ-AVI as an FDC in all its indications, outcome evaluation, and antibiotic stewardship.

METHODS

This was a single-center retrospective study conducted on ICU patients who received CAZ-AVI from January 2022 to December 2022. The Protocol was approved by the ethics committee (#CHL 03022023-015).

Study location

This was a tertiary care hospital-based study at Continental Hospital, financial district, Gachibowli, Nanakramguda, Telangana, India.

Sample size

110 patients using simple random sampling method.

Inclusion criteria

Subjects of both the genders who were treated with CAZ/AVI for various indications.

Exclusion criteria

Subjects who have not been given CAZ/AVI, subjects who are of age <3 months, pregnant women.

Statistical method

The data was analyzed using Microsoft Excel and student t-test was used for analysis of clinical evaluation of outcomes.

Parameters and data collection

Ceftazidime-avibactam was given as a 2.5 gm i.v. infusion over 120 minutes (2 hours) thrice a day in a patient with normal creatinine clearance, dose adjustments for renally impaired patients was made based on the manufacturer's recommendations and the patient's clinical condition. Positive cultures were identified and antimicrobial susceptibility was processed using the VITEK-2 system. The data was collected from electronic medical records and parameters were reviewed by study coordinators, which included socio demographic and clinical characteristics of study participants (before and after treatment with CAZ-AVI), indication and prescribing patterns of CAZ-AVI, evaluation of rationality of prescriptions, sensitivity and resistance pattern of isolates, opportunistic infections obtained post CAZ-AVI therapy, CAZ-AVI as discharge medication and indications for CAZ-AVI as discharge medication, clinical evaluations of outcomes of CAZ-AVI in various indications.

RESULTS

A total of 110 patients who received CAZ-AVI within the study period and fit the study criteria were included. The study population had a median age of 63 years and mostly comprised males (80%, 88 out of 110).[6] The majority 26 (24%) of the subjects fall in the age group of 61-70, followed by 24 (22%) in 71-80 and 22 (20%) in 51-60. Hypertension followed by diabetes were the most

common co-morbidities seen among the population. Antimicrobial therapy characteristics that were collected for the study included indication for initiation of CEF-AVI, microbiological characteristics.[6] From a total of 110 isolates from different clinical samples, with 37 (33%) from blood, 32 (29%) from urine, 23 (23%) from sputum, 14 (13%) from ET secretions and 2 (2%) from wound swabs. Amongst the collected data, 89% of the bacteria isolated were Gram negative in nature and 11% were Gram positive. The most frequently isolated organisms for which CAZ-AVI can be a therapeutic option are *Klebsiella pneumoniae* 47 (39%), *Pseudomonas aeruginosa* 24 (20%), followed by *Escherichia coli* 22(18%). The "other" organisms include *Streptococcus pneumoniae*, *Proteus Mirabilis*, *Streptococcus agalactiae*, *Enterobacter cloacae*, *Enterococcus*, *Pneumocystis carinii*, *Burkholderia cepacian*.[7]

Table 1: Baseline patient characteristics for any patient who received ceftazidime-avibactam (n=110).

Variable	Values (%)
Age, median (min, max) years	63 (11, 98)
Sex	
Female	22 (20)
Male	88 (80)
Comorbid conditions	**Percentage**
Hypertension	39 (35)
Diabetes mellitus	30 (27)
Coronary artery disease	10 (9)
Hypothyroidism	7 (6)
Stroke	1 (1)
Chronic kidney disease	7 (6)
Asthma	4 (4)
Transplant	3 (3)
Malignancy	2 (2)
Others[a]	7 (7)

[a]The "other" comorbidities include epilepsy, rheumatoid arthritis, peptic ulcer disease, Whipple's disease, interstitial lung disease, cellulitis, hepatitis C.

Among 110 isolates, 21 (20%) of the cases showed resistance to CAZ AVI and 84 (76%) showed sensitive to CAZ-AVI. Out of which, 21 60% of cases were sensitive to CAZ-AVI in which *Klebsiella pneumoniae* was isolated and 22.86% of cases were found to be sensitive to CAZ-AVI among which *E. coli* was isolated, followed by 8.57% of cases are sensitive to CAZ-AVI in which *Pseudomonas aeruginosa* was isolated. There was observed resistance of 66 (78%) to *Klebsiella pneumoniae*, 15 (17%) to *Acinetobacter baumanii*, 4 (5%) to *E. coli*.[8]

The most common clinical syndrome for which CAZ-AVI was used was bloodstream infections (35%) and followed by cUTIs (29%) and cIAIs (12%). It was observed that CAZ-AVI was prescribed for off label indications like surgical prophylaxis in a pediatric patient, acute toxin induced hepatic injury wherein cultures are sterile and in infections caused by *Burkholderia cepacia* as well as *Pneumocystis carinii* infection (PCP).[9,10] Eighty-five percent (94 out of 110) of the indications for initiating CAZ-AVI were directed and 16% (16 out of 110) were for empirical reasons. From the data collected, meropenem (31%), colistin (29%) were prescribed empirically the most. 62 out of 110 isolates (56%) were CR0. Most are CRE (44 out of 110 isolates; 40%) and CRPA (14 out of 110; 13%).[11]

Table 2: Latest microbiological evaluation before start of ceftazidime-avibactam therapy, susceptibility of multidrug-resistant pathogens to antibiotics.

Most frequently isolated organisms	
Pathogens (n=120)	**N (%)**
Klebsiella pneumoniae	47 (39)
Pseudomonas aeruginosa	24 (20)
Escherichia coli	22 (18)
Acinetobacter baumannii	7 (6)
[b]MRSA	7 (6)
Others	13 (11)
Carbapenem resistant organisms (n=44)	**N (%)**
Klebsiella	22 (50)
Enterobacter	8 (18)
E. coli	12 (27)
Proteus	2 (5)
Culture report (n=110)	**N (%)**
Sensitive	84 (76)
Resistant	22 (20)
No culture report	4 (4)
Total	110 (100)
Isolated organisms (n=35)	**% of cases sensitive to CAZ-AVI**
Pseudomonas aeruginosa	3 (8.57)
E. coli	8 (22.86)
Klebsiella pneumoniae	21 (60)
Proteus mirabilis	1 (2.86)
Burkholderia cepacia	1 (2.86)
Pneumocystis carinii	1 (2.86)
Isolated organisms (n=85)	**% of cases resistant to CAZ-AVI**
Klebsiella pneumoniae	66 (78)
E. coli	4 (5)
Acinetobacter baumannii	15 (17)

[b]MRSA methicillin resistant staphylococcus aureus.

We have analyzed the culture reports to assess for susceptibility of the organisms to high end antibiotics. *Klebsiella pneumoniae* has shown higher resistance to the antibiotics such as meropenem (number of cases =37), imipenem (number of cases =34), gentamicin (number of cases =23).[6,12] Cases in which *E. coli* was isolated showed increased resistance to antibiotics such as meropenem (number of cases =17), imipenem (number of cases =15), gentamicin and aztreonam (number of cases =11).

Cases in which *Pseudomonas aeruginosa* was isolated showed increased resistance to gentamicin and imipenem (number of cases =11), meropenem (number of cases =10).[6]

In this study, the total duration of CAZ-AVI therapy while hospital stays and which was given as discharge medication was found to be highest in HAP (66.67%) for a period of 11-15 days amongst the indications of CAZ-AVI whereas the course of CAZ-AVI therapy was found to be 80% amongst the Off-label indications for a duration of 1-5 days.

66% of cases had a combination of CAZ-AVI with other reserved antibiotics (aztreonam 45%, colistin 32%, tigecycline 12%).[6] We have observed that in most of the patients, CAZ-AVI is given in combination with one or two high end antibiotics, there was a case of surgical prophylaxis wherein it was given as monotherapy, and a case where it was given with clindamycin.[13] The highest percentage of mortality was seen in cIAI (100%) when CAZ-AVI is prescribed along with other two high-end antibiotics followed by BSIs (37.5%) with the concomitant use of one high-end antibiotic along with CAZ-AVI when compared to the other indications of CAZ-AVI.

Table 3: Percentage distribution of duration of CAZ-AVI therapy.

Duration of CAZ-AVI therapy	Indications (n=110) N (%)						
Number of days	**BSI**	**CIAI**	**CUTI**	**CAP**	**HAP**	**VAP**	**Off label**
1 to 5	9 (25)	1 (25)	8 (25.8)	12 (57.1)	0	4 (40)	4 (80)
6 to 10	19 (52.7)	2 (50)	20 (64.5)	7 (33.3)	1 (33.3)	5 (50)	0
11 to 15	2 (5.5)	1 (25)	2 (6.4)	1(4.7)	2 (66.6)	1 (10)	0
16 to 20	3 (8.3)	0	0	1 (4.7)	0	0	1 (20)
21 to 25	1 (2.7)	0	0	0	0	0	0
26 to 30	2 (5.5)	0	0	0	0	0	0
31 to 35	0	0	1(3.2)	0	0	0	0

Table 4: Mortality rate of the combinations of CAZ-AVI + high end antibiotic according to indication.

Indication	% mortality rate CAZ-AVI + high end antibiotic			
	1+1	**1+2**	**1+3**	**1+4**
BSI	9 (37.5)	4 (50)	1 (50)	0
CUTI	5 (22)	1 (33.3)	2 (40)	0
CIAI	1 (33.3)	1 (100)	0	0
VAP	4 (100)	2 (50%)	0	0
CAP	2 (15.38)	2 (50)	0	0
Off label	1 (25)	0	0	0

The highest percentage of shift from ICU to Ward among the FDA approved indications for CAZ-AVI is seen in CAP (52%) followed by cUTI (48.39%) whereas the lowest percentage is seen in cIAI where all the patients with cIAI had a sole ICU stay.[14] The patients with HAP (48%) had a lesser percent of a sole ICU stay, 63.6% (n=70/110) were found to be discharged for whom CAZ-AVI is given as a part of therapy to treat infections along with their underlying respective comorbid conditions and a small group of individuals were found to be dead (n=40/110, 36.4%) despite giving CAZ-AVI therapy.[6] 38% of the subjects were given CAZ-AVI as discharge medication for CUTI, 28% for HAP, 17% for CAP and VAP.

The rationality of prescription was checked in accordance with National Antibiotic Policy and Hospital Antibiotic Policy.[15,16] Among the total prescriptions (n=110), 82.9% of the prescriptions were rationale and met the right dosing criteria, 50.9% of the prescriptions shown to receive right duration of therapy and only 38.1% of the prescriptions were prescribed with right frequency of the drug and 61.8% of prescriptions were not found to be given at right frequency of the drug. There was an equal percentage of prescriptions (50%) that were shown to have right de-escalation of the drug with those that did not have right de-escalation of the drug and found to be irrational. Among the 6 cases with CKD, 67% cases, the dose of CAZ-AVI was adjusted and in 33% of the cases the dose was not adjusted. Among the study subjects, 23 cases were seen with the occurrence of opportunistic infections post CAZ AVI therapy, out of which 9% were clostridium difficile diarrhea.

We have observed that 63% of the patients were discharged and 36% of the patients were dead. We have also observed that among the deaths, the utilization of CAZ-AVI was more in BSI, CIAI, VAP.[12] When

considering death across various Indications, 67% of deaths had an indication of BSI, 13% had cIAI and VAP. Diabetes mellitus represented the most common comorbidity, with a high prevalence among patient, especially in those who died.

Table 5: Prescribing pattern evaluation of CAZ-AVI (n=110).

	Characteristic	N (%)
Right dose	Met	91 (82.9)
	Not met	19 (17.1)
Right duration	Met	56 (50.9)
	Not met	54 (49)
Right frequency	Met	42 (38.1)
	Not met	68 (61.8)
Right de-escalation	Met	55 (50)
	Not met	55 (50)

Outcomes

We have observed that there is higher clinical success observed for BSI, CUTI, VAP amongst the indications of CAZ-AVI. The assessment of clinical outcome was done using the following indicators such as sterile cultures, laboratory parameter (WBC), Shift to medical ward from ICU, no. of cases of discharge versus death. Paired t-test results: The two-tailed p value was less than 0.0001. By conventional criteria, this difference is extremely statistically significant. It also gives an insight on the burden involved in eradicating and treating the infections by the health care system. Combination of CAZ-AVI with aztreonam has given the most successful treatment outcomes. Combination of CAZ-AVI with meropenem was observed to have higher clinical failure among the study population.

Table 6: Clinical evaluation outcome (success, failure, indeterminate) by indication and combination with high end antibiotics. Overall outcome of ceftazidime-avibactam (any therapy), n (%).

Characteristic	BSI (n=30)	CIAI (n=2)	CUTI (n=23)	CAP (n=22)	VAP (n=9)	HAP (n=14)
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Clinical success	23 (77)	1 (50)	21 (91)	19 (86)	8 (89)	10 (71)
Clinical failure	4 (13)	1 (50)	1 (5)	2 (9)	1 (11)	4 (29)
Indeterminate	3 (10)	0	1 (4)	1 (5)	0	0
Combination		**Total cases**		**%CF**		**%SCO**
CAZ-AVI aztreonam		45		7 (17.5)		38 (54)
CAZ-AVI colistin		24		9 (22.5)		15 (21)
CAZ-AVI meropenem		21		14 (35)		7 (10)
CAZ-AVI tigecycline		10		6 (15)		4 (6)
CAZ-AVI vancomycin		10		4 (10)		6 (9)

DISCUSSION

This was a retrospective study conducted on patients who received CAZ-AVI in a tertiary care center in India. Out of the 43 patients who were culture positive, 32 patients had CRE or CRPA infections. Thirty isolates from the study were CRE and five were CRPA. CEF-AVI testing was done in 27 isolates (25 patients), out of them nine showed resistance.[17]

In this study, we have checked whether the prescribing regimen is in lines with the National Antibiotic Policy and Hospital Antimicrobial Stewardship Policy, according to which only 38.1% of the prescriptions were prescribed with right frequency of the drug and 61.8% of prescriptions were not found to be given at right frequency of the drug.[16] A retrospective study by Nagvekar et al in India used CEF-AVI for the treatment of CRE infections and depicted a mortality rate of 21% similar to the present study.[18] 66% of cases had a combination of CAZ-AVI with other reserved antibiotics (aztreonam 45%, colistin 32 %, tigecycline 12%) similar to a study Soriano.[6] Most of the study population had bloodstream and septic shock being the cause of death in 89% of the study population. Septic shock is associated with high mortality and the pharmacokinetics of most drugs cannot be relied upon in this situation.

Being a retrospective study there were a lot of limitations with various variables not analysed. The study did not thoroughly evaluate adverse drug events or clostridium difficile-associated diarrhea in the patients. Even though over 56% of isolates from these patients were CRE or CRPA, data on CAZ-AVI sensitivity or synergy testing with aztreonam was limited.

CONCLUSION

The analysis of results showed encouraging clinical cure rates. Our study results suggest that ceftazidime-avibactam could be an effective standard therapy for managing MDR Gram-negative organisms. Further research needs to be carried out in our country for various clinical and microbiological indications for CEF-AVI. Studies on the evaluation of drug resistance development in strains where Oxa-48 and NDM resistance genes are prevalent need to be conducted. Even in this study, molecular analysis was not done on the CEF-AVI-

resistant strains. We encourage DUE studies on high-end antibiotics to know their usage, which reduces the economic burden on both patients and the healthcare system. Conducting the DUE studies, especially regarding the use of antibiotics which helps to understand the drug resistance and enables to identify the measures to prevent it by enabling to frame stewardship guidelines. Systematic monitoring and productive strategies must be applied to enhance patient compliance to attain a better therapeutic outcome. Adherence to the guidelines promotes the rational use of drugs and improves the quality of life.

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