



Original Article

## Clinical Insights on Ceftriaxone-Based Antibiotic Combinations in Combating Antimicrobial Resistance: A National Cross-Sectional Study in Indian Clinicians

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### ABSTRACT

**Background:** Antimicrobial resistance (AMR) is an escalating global health challenge, particularly in low- and middle-income countries such as India. Ceftriaxone-based antibiotic combinations incorporating beta-lactamase inhibitors and antibiotic resistance breakers have emerged as potential therapeutic strategies for managing resistant bacterial infections. This study aimed to evaluate clinicians' perceptions, prescribing practices, and awareness regarding ceftriaxone-based combinations in the management of multidrug-resistant (MDR) infections.

**Methods:** A descriptive, cross-sectional, questionnaire-based study was conducted among clinicians attending the 80th Annual Conference of the Association of Physicians of India (APICON). A structured 10-item questionnaire assessed knowledge of  $\beta$ -lactamase inhibitors, prescribing preferences, utilization of ceftriaxone-based combinations, perceptions regarding EDTA, approaches to MDR infections, factors influencing therapeutic decisions, awareness regarding novel antibiotic combinations, and educational needs. Responses were collected electronically and analyzed using descriptive statistics.

**Results:** A total of 399 evaluable responses of 412 collected responses were analyzed after data cleaning and duplicate removal. Among 399 respondents, 86.2% were from Internal/General Medicine. Awareness regarding differences between sulbactam and tazobactam was high, with 34.3% identifying superior ESBL inhibition by tazobactam and 29.9% recognizing sulbactam's activity against *Acinetobacter* spp. Nearly half of clinicians (48.8%) reported regular use of CSE, while an additional 32.6% used it occasionally. Local resistance patterns (32.1%) and infection severity (30.8%) were the primary determinants of antibiotic selection. Severe hospital-acquired infections including sepsis, hospital-acquired pneumonia, and ventilator-associated pneumonia were the most common indications for considering CSE (42.9%). The most frequently perceived benefit of EDTA was restoration of ceftriaxone activity against ESBL- and MBL-producing pathogens (46.7%). While 58.1% felt adequately informed regarding newer antibiotic combinations, 33.2% reported a need for greater awareness. A large majority (82.8%) expressed definite interest in further educational initiatives focused on resistant infections and novel antimicrobial combinations.

**Conclusion:** Indian clinicians demonstrate substantial awareness and utilization of ceftriaxone-based antibiotic combinations, particularly ceftriaxone-sulbactam-disodium EDTA. The findings highlight growing acceptance of carbapenem-sparing strategies, recognition of resistance-modifying approaches, and increasing stewardship-oriented prescribing practices. Continued educational efforts and real-world clinical research are warranted to optimize the use of these therapies in the era of escalating antimicrobial resistance.

## INTRODUCTION

Antimicrobial resistance (AMR) has emerged as one of the greatest threats to global public health, compromising the effectiveness of antibiotics that form the cornerstone of modern medical practice. The World Health Organization (WHO) recognizes AMR as a major global health challenge with the potential to reverse decades of therapeutic progress in infectious disease management. The Global Research on Antimicrobial Resistance (GRAM) study estimated that bacterial AMR directly caused approximately 1.27 million deaths and contributed to nearly 4.95 million deaths globally in 2019, making it one of the leading causes of mortality worldwide.<sup>1</sup>

India bears a disproportionately high burden of AMR owing to its large population, high prevalence of infectious disease, widespread antibiotic utilization, and increasing circulation of multidrug-resistant (MDR) pathogens. Recent estimates suggest that nearly 2,97,000 deaths in India were directly attributable to AMR in 2019, while more than one million deaths were associated with resistant bacterial infections.<sup>2</sup> The increasing prevalence of extended-spectrum  $\beta$ -lactamase (ESBL)-producing Enterobacterales, carbapenem-resistant *Enterobacterales* (CRE), multidrug-resistant *Acinetobacter baumannii*, and *Pseudomonas aeruginosa* has significantly complicated the management of both community-acquired and hospital-acquired infections.<sup>3</sup>

Third-generation cephalosporins, particularly ceftriaxone, have remained among the most widely prescribed injectable antibiotics for more than three decades. Ceftriaxone possesses broad-spectrum activity against numerous Gram-negative and Gram-positive pathogens, favorable pharmacokinetic properties, extensive tissue penetration, and a prolonged half-life that allows convenient once-daily administration.<sup>4</sup> Owing to these characteristics, ceftriaxone is routinely utilized in the treatment of respiratory tract infections, urinary tract infections, intra-abdominal infections, skin and soft tissue infections, bloodstream infections, and bacterial meningitis.<sup>5</sup> However, the widespread use of ceftriaxone has contributed to increasing selective pressure and the emergence of resistant pathogens capable of producing  $\beta$ -lactamase enzymes that hydrolyze third-generation cephalosporins.<sup>6</sup>

To overcome  $\beta$ -lactamase-mediated resistance, ceftriaxone has been combined with  $\beta$ -lactamase inhibitors such as sulbactam and tazobactam. These inhibitors protect the  $\beta$ -lactam antibiotic from enzymatic degradation and thereby restore antibacterial activity against susceptible resistant organisms. Sulbactam is unique among conventional  $\beta$ -lactamase inhibitors because, in addition to inhibiting  $\beta$ -lactamases, it exhibits intrinsic antibacterial activity against *Acinetobacter* species through direct binding to penicillin-binding proteins.<sup>7</sup> Tazobactam, on the other hand, is a potent inhibitor of several class A  $\beta$ -lactamases and has demonstrated substantial activity against ESBL-producing organisms when combined with  $\beta$ -lactam antibiotics.<sup>8</sup>

The emergence of metallo- $\beta$ -lactamase (MBL)-producing pathogens has created additional therapeutic challenges because conventional  $\beta$ -lactamase inhibitors are largely ineffective against these enzymes. Consequently, novel approaches aimed at restoring antibiotic susceptibility have gained considerable attention. One such strategy involves the incorporation of disodium ethylenediaminetetraacetic acid (EDTA), a metal-chelating agent capable of binding zinc ions that are essential for MBL activity. Beyond its inhibitory effect on MBL enzymes, EDTA has also been shown to disrupt bacterial biofilms, inhibit bacterial adhesion, and reduce horizontal transfer of resistance determinants, thereby functioning as an antibiotic resistance breaker (ARB).<sup>9</sup>

Ceftriaxone-sulbactam-disodium EDTA (CSE-1034), commercially available in India, was developed to address these resistance mechanisms. Several *in vitro* and clinical studies have demonstrated promising activity of this combination against ESBL-producing and MBL-producing Gram-negative organisms. In surveillance studies, CSE-1034 has demonstrated higher susceptibility rates against MDR pathogens compared with several commonly used antibiotics, including carbapenems in selected settings.<sup>10,12</sup> Furthermore, a randomized clinical trial comparing CSE-1034 with meropenem in complicated urinary tract infections demonstrated non-inferior clinical and microbiological outcomes, supporting its potential role as a carbapenem-sparing therapeutic option.<sup>13</sup> Such findings have generated growing interest regarding the clinical utility of ceftriaxone-based combinations in the era of escalating AMR.

Despite increasing availability and utilization of these agents, there remains limited information regarding clinicians' perceptions, prescribing patterns, and practical considerations surrounding ceftriaxone-based antibiotic combinations. Most published literature has focused on microbiological efficacy and clinical outcomes, whereas real-world prescribing behavior and clinician perspectives remain inadequately explored. Understanding these perspectives is important for guiding antimicrobial stewardship initiatives, identifying educational gaps, and optimizing the use of existing therapeutic options in resistant infections.

Therefore, the present study was conducted to evaluate clinicians' knowledge, attitudes, and prescribing practices related to ceftriaxone-based antibiotic combinations, including ceftriaxone-sulbactam, ceftriaxone-tazobactam, and ceftriaxone-

sulbactam-EDTA. The study further sought to assess factors influencing treatment selection, perceptions regarding the role of EDTA in combating resistance, and the need for additional educational initiatives focused on novel antimicrobial strategies.

## METHODOLOGY

### *Study Design and Participants*

A descriptive, cross-sectional, questionnaire-based study was conducted amongst clinicians attending the 80th Annual Conference of the Association of Physicians of India (APICON). The questionnaire was designed to evaluate clinicians' knowledge, attitudes, and prescribing practices regarding ceftriaxone-based antibiotic combinations in the management of infections, particularly those involving multidrug-resistant (MDR) pathogens.

The target population included clinicians involved in the diagnosis and management of infectious diseases across various specialties. Participation in the study was voluntary, and responses were collected anonymously. No personally identifiable information was included in the analysis. Completion of the questionnaire was considered as implied consent for participation.

### *Study Instrument*

A structured questionnaire consisting of 10 multiple-choice questions was developed. The questionnaire was designed to assess clinicians' perspectives on differentiation between sulbactam and tazobactam in clinical practice, preferred  $\beta$ -lactamase inhibitors for hospital-acquired MDR infections, utilization of CSE, factors influencing the choice of ceftriaxone-based antibiotic combinations, prescribing preferences in community-acquired infections, clinical scenarios in which CSE would be considered, perceived benefits of the EDTA component, awareness regarding recent developments in antibiotic combinations, approaches to management of MDR infections, and an interest in further educational initiatives related to novel antimicrobial combinations. The questionnaire included both single-response and multiple-response questions.

### *Data Collection and Data Cleaning*

The responses were collected electronically through a secure digital platform. A total of 412 responses were received. Data cleaning was performed prior to analysis. Duplicate entries were identified using respondent identifiers and verified before removal. Records with incomplete demographic information were retained whenever valid responses were available for individual questions. For each questionnaire item, analyses were performed using the number of valid responses available for that specific question. Following data cleaning and removal of verified duplicate entries, 399 responses were included in the final analysis.

### *Statistical Analysis*

Data were analyzed using descriptive statistical methods. Categorical variables were summarized as frequencies and percentages. For questions allowing multiple selections, percentages were calculated using the total number of respondents who answered the respective question as the denominator. Results were presented in the form of tables and graphical representations to facilitate interpretation. As this study was exploratory and descriptive in nature, no formal hypothesis testing or inferential statistical analyses were performed.

## RESULTS

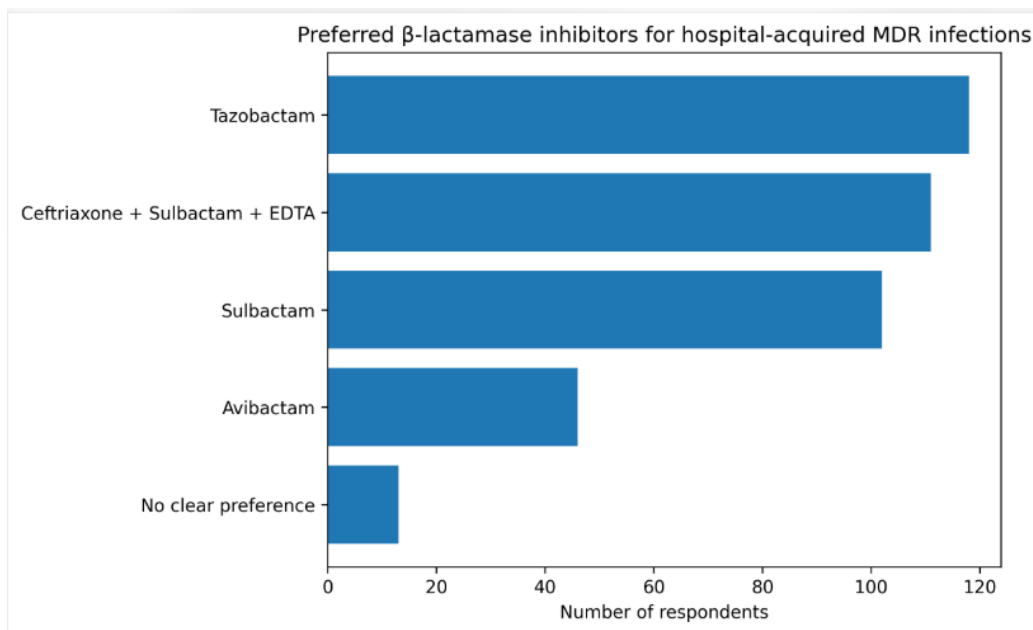
### *Respondent Characteristics*

A total of 412 responses were received. Following data cleaning and removal of verified duplicate entries, 399 responses were included in the final analysis. Respondents represented a broad range of clinical specialties. Internal/General Medicine constituted the largest group, accounting for 344 (86.2%) participants. Other specialties included Diabetology [7(1.8%)], Cardiology [5(1.3%)], Critical Care [3(0.8%)], Pulmonology [1(0.3%)], Nephrology [1(0.3%)], Surgery [1(0.3%)], and Pediatrics [1(0.3%)]. Thirty-six respondents (9.0%) belonged to other specialties (Table 1).

### *Knowledge Regarding Sulbactam and Tazobactam and Utilization of CSE*

Clinicians demonstrated good awareness regarding the differences between sulbactam and tazobactam. The most commonly selected response was that tazobactam shows better inhibition of ESBLs, reported by 133 respondents (34.3%). Sulbactam's specific utility against *Acinetobacter* species was recognized by 116 respondents (29.9%). Additionally, 56 respondents (14.4%) identified tazobactam as being more effective against class A, C, and some class D  $\beta$ -lactamases, while 83 respondents (21.4%) considered both agents equally effective across most indications.

When asked about the most effective  $\beta$ -lactamase inhibitor for hospital-acquired MDR infections, tazobactam was selected by 118 respondents (30.3%), followed closely by EDTA-enhanced combinations such as ceftriaxone + sulbactam + EDTA [111 respondents (28.5%)] and sulbactam [102 respondents (26.2%)]. Avibactam was selected by 46 respondents (11.8%), whereas only 13 respondents (3.3%) reported no clear preference (figure 1).

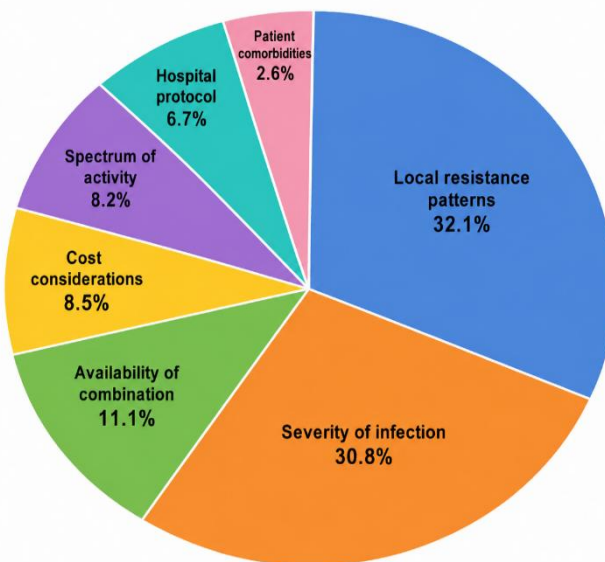


**Figure 1. Preferred  $\beta$ -lactamase inhibitors for hospital-acquired MDR infections**

Regarding utilization of ceftriaxone + sulbactam + EDTA (CSE), 190 clinicians (48.8%) reported regular use and 127 (32.6%) reported occasional use. In contrast, 57 respondents (14.7%) did not use the combination, while only 15 respondents (3.9%) had never heard of it.

**Factors Influencing Treatment Selection and Prescribing Preferences**

The most important factors influencing the choice of ceftriaxone-based antibiotic combinations were local resistance patterns [125 responses (32.1%)] and severity of infection [120 responses (30.8%)]. Other influencing factors included availability of the combination [43 responses (11.1%)], cost considerations [33 responses (8.5%)], spectrum of activity [32 responses (8.2%)], hospital protocol [26 responses (6.7%)], and patient comorbidities [10 responses (2.6%)] (figure 2).



**Figure 2. Factors Influencing Selection of Ceftriaxone-Based Combinations**

For community-acquired infections, ceftriaxone + sulbactam was the most frequently prescribed combination, selected by 132 respondents (34.1%). Piperacillin + tazobactam was preferred by 112 respondents (28.9%), followed by ceftriaxone + sulbactam + EDTA [94 respondents (24.3%)]. Ceftriaxone + tazobactam and meropenem were selected by 32 (8.3%) and 15 (3.9%) respondents, respectively.

**Clinical Scenarios for Considering CSE**

The most common clinical scenario for considering CSE was severe hospital-acquired infection including sepsis, hospital-acquired pneumonia (HAP), and ventilator-associated pneumonia (VAP), selected by 165 respondents (42.9%). This was

followed by infections caused by ESBL/MBL-producing MDR organisms [91 respondents (23.6%)] and community-acquired pneumonia [72 respondents (18.7%)].

Other scenarios included critically ill ICU patients [22 respondents (5.7%)], complicated urinary tract infections including pyelonephritis [11 respondents (2.9%)], post-surgical infections [8 respondents (2.1%)], uncomplicated urinary tract infections [6 respondents (1.6%)], bone and joint infections [4 respondents (1.0%)], and complicated skin and soft tissue infections [3 respondents (0.8%)] (table 1).

**Table 1. Clinical Scenarios for Considering Ceftriaxone + Sulbactam + EDTA (CSE)**

Clinical Scenario	n (%)
Severe hospital-acquired infections (Sepsis/HAP/VAP)	165 (42.9)
ESBL/MBL-producing MDR infections	91 (23.6)
Community-acquired pneumonia	72 (18.7)
Critically ill ICU patients	22 (5.7)
Complicated UTI/Pyelonephritis	11 (2.9)
Post-surgical infections	8 (2.1)
Uncomplicated UTI	6 (1.6)
Bone and joint infections	4 (1.0)
Complicated skin and soft tissue infections	3 (0.8)

### **Perceived Role of EDTA**

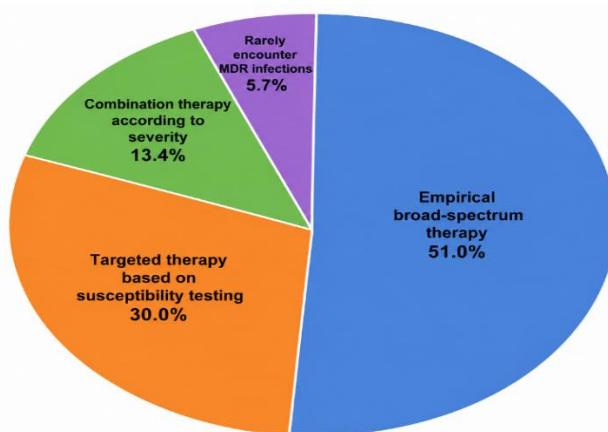
The most frequently perceived benefit of EDTA was its role as an antibiotic resistance breaker capable of restoring ceftriaxone activity against ESBL- and MBL-producing Gram-negative pathogens, selected by 175 respondents (46.7%). Additionally, 109 respondents (29.1%) selected ‘all of the above,’ indicating recognition of multiple mechanisms of action. Sixty-three respondents (16.8%) identified inhibition of bacterial adhesion and biofilm development as the principal benefit, while 24 respondents (6.4%) recognized inhibition of resistant plasmid transfer. Only four respondents (1.1%) believed that CSE offered no additional benefit over ceftriaxone + sulbactam alone.

### **Awareness, MDR Management Practices and Educational Needs**

A majority of clinicians reported feeling adequately informed regarding recent developments in antibiotic combinations [212 respondents (58.1%)]. However, 121 respondents (33.2%) felt that greater awareness was needed, while 32 respondents (8.8%) were unsure about recent developments.

Regarding management of MDR infections (figure 3), 187 respondents (51.0%) reported empirical use of broad-spectrum antibiotics such as meropenem or piperacillin-tazobactam based on clinical judgement. Targeted therapy guided by antimicrobial susceptibility testing was preferred by 110 respondents (30.0%), while 49 respondents (13.4%) reported using combination therapy based on infection severity. Twenty-one respondents (5.7%) reported rarely encountering MDR infections.

Interest in continuing medical education was high, with 312 respondents (82.8%) expressing definite interest in educational programs focused on resistant infections and novel antibiotic combinations. An additional 57 respondents (15.1%) indicated possible interest depending on the topic, while only 8 respondents (2.1%) reported no interest.



**Figure 3. Approach to MDR Infections**

## DISCUSSION

Antimicrobial resistance (AMR) continues to challenge clinicians globally, threatening the effectiveness of many commonly used antibacterial agents. The landmark GRAM analysis estimated that bacterial AMR was directly responsible for approximately 1.27 million deaths and associated with nearly 4.95 million deaths worldwide in 2019, underscoring the urgent need for effective therapeutic and stewardship strategies.<sup>1,2</sup> The increasing prevalence of ESBL-producing Enterobacterales, carbapenem-resistant Gram-negative pathogens, multidrug-resistant *Acinetobacter baumannii*, and *Pseudomonas aeruginosa* has substantially reduced the utility of several conventional antibiotics and has contributed to increasing reliance on broader-spectrum agents such as carbapenems.<sup>2</sup>

The present study provides important real-world insights into clinicians' perceptions and utilization of ceftriaxone-based antibiotic combinations in India. The findings suggest a relatively high level of awareness regarding  $\beta$ -lactamase inhibitor therapy and demonstrate substantial adoption of ceftriaxone-based combinations, particularly ceftriaxone-sulbactam-disodium EDTA (CSE), in routine clinical practice.

A notable observation was the clinicians' understanding of the differences between sulbactam and tazobactam. Approximately one-third of respondents recognized tazobactam's superior activity against ESBL-producing organisms, while nearly 30% identified sulbactam's unique activity against *Acinetobacter* species. These responses are consistent with existing pharmacological evidence. Sulbactam differs from conventional  $\beta$ -lactamase inhibitors by possessing intrinsic antibacterial activity against *Acinetobacter baumannii* through binding to penicillin-binding proteins, whereas tazobactam primarily functions through  $\beta$ -lactamase inhibition and is particularly effective against several class A  $\beta$ -lactamases.<sup>3-5</sup> The observed awareness among clinicians is encouraging because understanding the mechanistic differences between these agents is essential for rational antimicrobial selection.

Another important finding was the preference for tazobactam and EDTA-enhanced combinations for hospital-acquired MDR infections. Although carbapenems continue to be used for many serious ESBL-associated infections, increasing carbapenem use has contributed to the emergence of carbapenem-resistant organisms worldwide. Consequently, antimicrobial stewardship programs increasingly advocate carbapenem-sparing approaches whenever clinically appropriate.<sup>6</sup> In the present study, nearly one-third of clinicians considered CSE among the most effective options for hospital-acquired MDR infections, reflecting growing confidence in alternative strategies that may help reduce carbapenem utilization.

The substantial utilization of CSE observed in this study is particularly noteworthy. More than 80% of respondents reported either regular or occasional use of the combination. Furthermore, severe hospital-acquired infections, including sepsis, urinary tract infections, hospital-acquired pneumonia, and ventilator-associated pneumonia, emerged as the most common scenarios in which clinicians would consider CSE therapy. These findings suggest that many clinicians perceive CSE as a therapeutic option for infections in which resistance mechanisms are suspected or documented. The perceived utility of CSE is supported by emerging clinical evidence. The PLEA trial, a randomized, double-blind, non-inferiority study comparing CSE with meropenem in complicated urinary tract infections and acute pyelonephritis, demonstrated that CSE achieved clinical and microbiological outcomes comparable to meropenem. Importantly, the investigators concluded that CSE could serve as a carbapenem-sparing alternative for infections caused by resistant Gram-negative pathogens.<sup>7</sup> Such evidence is particularly relevant in countries like India, where carbapenem stewardship remains a critical public health priority.

The study also highlighted widespread recognition of the role of EDTA as an antibiotic resistance breaker. Nearly half of the respondents identified restoration of ceftriaxone activity against ESBL- and MBL-producing organisms as the principal benefit of EDTA, while an additional 29% acknowledged multiple beneficial mechanisms. This finding is consistent with experimental studies demonstrating that EDTA acts as a metal chelator capable of binding zinc ions required for metallo- $\beta$ -lactamase activity. In addition, EDTA has been shown to disrupt biofilm architecture, reduce bacterial adhesion, and potentially inhibit horizontal transfer of resistance determinants.<sup>8-10</sup> The broad awareness of these mechanisms among clinicians suggests increasing familiarity with resistance-modifying therapeutic approaches beyond conventional  $\beta$ -lactamase inhibition.

An important stewardship-related observation was that local resistance patterns and infection severity were the dominant factors influencing antibiotic selection. This finding is encouraging because contemporary stewardship principles emphasize the importance of microbiological epidemiology and patient-specific clinical factors in guiding antimicrobial therapy.<sup>11</sup> The relatively lower influence of cost considerations and availability suggests that clinicians are increasingly prioritizing resistance-related factors when selecting therapy for serious infections.

Despite this encouraging awareness, the study identified opportunities for further education. Approximately one-third of respondents believed that greater awareness regarding newer antibiotic combinations is required. Moreover, although targeted therapy guided by susceptibility testing was preferred by 30% of respondents, empirical use of broad-spectrum antibiotics remained common. These findings highlight the continuing need for educational initiatives focused on

antimicrobial stewardship, interpretation of susceptibility reports, and optimal utilization of emerging antimicrobial options. Such initiatives may facilitate more judicious use of broad-spectrum agents and improve alignment with stewardship recommendations.

The high level of interest in continuing medical education observed in the study further reinforces this need. More than four-fifths of clinicians expressed definite interest in additional educational programs related to resistant infections and novel antibiotic combinations. Similar observations have been reported in physician study evaluating antimicrobial prescribing practices, where clinicians consistently identify ongoing education as a key requirement for addressing evolving resistance patterns.<sup>12</sup>

The present study has several limitations. It relied on self-reported responses and therefore may be subject to recall and reporting bias. Participants were recruited from a national conference and may not fully represent prescribing practices across all healthcare settings in India. In addition, the study assessed clinician perceptions rather than objective prescribing data or patient outcomes. Nevertheless, the study provides valuable insights into real-world clinical attitudes regarding ceftriaxone-based antibiotic combinations and identifies important areas for future research and educational intervention.

This national cross-sectional study demonstrates substantial awareness and utilization of ceftriaxone-based antibiotic combinations among Indian clinicians managing resistant bacterial infections. Clinicians showed good understanding of the mechanistic differences between sulbactam and tazobactam, and widely recognized ceftriaxone-sulbactam-disodium EDTA (CSE) as a valuable option for severe hospital-acquired and ESBL-/MBL-associated infections. Local resistance patterns and infection severity were the primary drivers of treatment selection, reflecting stewardship-oriented prescribing practices. The widespread use of CSE, recognition of EDTA's role in overcoming resistance, and strong interest in continuing medical education support the potential role of ceftriaxone-based combinations in antimicrobial stewardship while emphasizing the need for ongoing clinician education and further real-world evidence.

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