LETTER TO THE EDITOR

Author Response

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We express our gratitude to Riddhi Kundu and Sumit Roy Chowdhury for demonstrating a keen interest in our research.[1] We value their invaluable insights. Our study findings concluded that the ceftazidime–avibactam with or without aztreonam (CAZ-AVI ± AZT) group exhibited a statistically significant clinical response compared to the polymyxin monotherapy for carbapenemase-producing *gram-negative* organisms. However, the study did not find any survival benefit, microbiological response, or side effects between the two groups.

We acknowledge the perceptive observation made by readers regarding higher baseline SOFA scores in the polymyxin group compared to the CAZ-AVI ± AZT group (6 vs 9; $p = 0.09$). This distinction could have potentially contributed to a more favorable clinical success outcome in the CAZ-AVI ± AZT group. It is essential to underscore the nature of our study as a prospective observational one, lacking randomization of baseline characteristics across comparative groups. Observational studies, particularly prospective cohorts, are susceptible to undetected confounding variables or omissions, potentially influencing study outcomes.[2] The external validity or generalizability of prospective studies may be limited, as the characteristics of study participants may not fully represent the diversity observed in real-world clinical scenarios.

Nevertheless, our study revealed no statistically significant differences in SOFA scores among the study groups. The composite outcome was subjected to rigorous testing using the Cox multivariate regression model, accounting for baseline SOFA scores and prevailing comorbidities. Unlike univariate methods, the Cox model allows simultaneous assessment of multiple factors, enabling a comprehensive evaluation of their impact on survival time.[3]

We concur with the readers' perspective on the necessity of a large-scale randomized controlled study. Our study, while providing valuable insights, has inherent limitations, and we welcome further investigations to strengthen the evidence base in this complex clinical context. We anticipate that forthcoming large prospective Indian studies on this topic will contribute valuable insights and further enrich the scientific understanding of these complex clinical scenarios.

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References

1. Kundu R, Chowdhury SR. Management of CRE infections: High time for an RCT? Indian J Crit Care Med 2024;28(5):511.
2. Rochefort-Maranda G. Inflated effect sizes and underpowered tests: How the severity measure of evidence is affected by the winner's curse. Philosophical Studies 2021;178:133–145. DOI: 10.1007/s11098-020-01424-z.
3. Deo SV, Deo V, Sundaram V. Survival analysis—part 2: Cox proportional hazards model. Indian J Thorac Cardiovasc Surg 2021;37(2):229–233. DOI: 10.1007/s12055-020-01108-7.