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Authors' response

We thank the author of the letter to editor¹ for reading our research work on the association between maternal SARS-CoV-2 infection and clinical outcomes in infants and raising pertinent queries on the methodological aspects.²

The author has highlighted that the comparison group in our study was classified on the basis of assumed negativity. We clarify that the selection of women in our comparison cohort was based on documented negative report for SARS-CoV-2 molecular based test or rapid antigen test.³ History of high-risk exposure and COVID-like symptoms was obtained from the women in the comparison group, in case of which their COVID-19 test reports following the exposure or illness were verified. Subsequently, the women were included in the cohort only upon verification of a negative test report. It may be possible that the pregnant women had contracted asymptomatic COVID-19 infection during their pregnancy and did not get tested, and were subsequently included in our comparison cohort, owing to the large proportion of asymptomatic cases.^{3,4} Further, the possibility of false positive test cannot be ruled out because of differences in sensitivity and specificity of molecular and rapid antigen tests.^{5,6} Both of these may have led to differential misclassification, which we have acknowledged as limitation in our study. Future studies will benefit from ascertaining exposure through detection of IgG SARS-CoV-2 in patient blood samples.

The second concern raised regarding the paradoxical enrichment is based on the exclusion of symptomatic women without test documentation in the exposure cohort. In our study, symptomatic women in both exposure and comparison cohort were excluded in the absence of a COVID-19 test report (positive or negative).² This may have led to a change in the strength of the associations without affecting the directionality.

We classified the women (and their infants) in our study as exposed or unexposed based on COVID-19 infection during pregnancy. Classification of study participants into multiple exposure/ infection/ vaccination status categories had the potential for a

more nuanced analysis. However, sub-group analysis based on trimester of infection was not possible for the exposure cohort since most women included in the exposure cohort underwent testing at the time of delivery. The retrospective nature of the study also made it difficult to classify the severity of the infection. Though initially planned as an ambispective cohort study, due to the complexity of problem as well as operational feasibility and ethical considerations we recruited all study participants retrospectively. Despite these limitations, our study generated empirical evidence from India on birth outcomes among women infected with SARS-CoV-2 in pregnancy.

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