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Letter to the Editor

# Defining surgical rescue when assessing transcatheter aortic valve implantation without on-site cardiac surgery. Response

## *Definición del rescate quirúrgico al evaluar el implante percutáneo de válvula aórtica sin cirugía cardiaca* in situ. *Respuesta*

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**To the Editor,**

We thank Sarıoğlu for the thoughtful and constructive comments on our study.[1] The 2 points raised are methodologically important and provide an opportunity to clarify how our results should be interpreted.

Regarding the definition of emergency cardiac surgery (ECS), in our study we used the VARC-3 definition of ECS as unplanned cardiac surgery occurring before the patient leaves the procedural environment, corresponding to the VARC-3 intraprocedural conversion category.[2] We agree, however, that this endpoint does not fully address the clinical question of whether a program without on-site cardiac surgery can manage the full spectrum of complications that may ultimately require surgical rescue. Nevertheless, to date, and to standardize the reporting of complications and facilitate comparisons with other studies, VARC-3 remains the most useful endpoint.

The case referred to by the author—a patient with persistent pericardial effusion who underwent delayed exploratory surgery and died postoperatively—was reported in our results precisely because we considered it clinically relevant, even though it fell outside the VARC-3 intraprocedural conversion window and instead met the VARC-3 periprocedural conversion category.

We agree with Sarıoğlu's suggestion that future studies should report both the formal VARC-3 ECS rate and a broader, clinically oriented endpoint to ensure greater clinical relevance and transparency.

Regarding zero events and noninferiority, the author is correct that zero ECS events in 300 procedures does not imply a negligible true rate: the exact 95%CI for 0/300 extends to approximately 1.2%. We should have stated this uncertainty explicitly rather than reporting only the point estimate, and we acknowledge this as a limitation of our reporting.

Furthermore, we agree that our use of "noninferiority" was descriptive rather than statistical. Our study had no prespecified noninferiority margin, as required by CONSORT guidance for noninferiority trials.[3] Similar mortality point estimates vs the national registry should therefore be interpreted as reassuring and hypothesis-generating, rather than as evidence of statistical noninferiority.

These clarifications do not change our core message: TAVI without on-site cardiac surgery appears safe and feasible when performed by an experienced heart team, with a low rate of surgical rescue, which is consistent with a recent meta-analysis showing no significant difference in ECS incidence rate between centers with and without on-site surgical backup (RR, 0.8; 95%CI, 0.2–2.4).[4]

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## STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

The authors declare that no generative artificial intelligence (AI) tools or AI-assisted technologies were used in the conception, writing, editing, data analysis, or preparation of this manuscript. All content was produced by the authors, who take full responsibility for its accuracy and integrity.

## AUTHORS' CONTRIBUTIONS

R. Viana and A. Rocha de Almeida wrote the response. R. Fernandes and L. Patrício reviewed the manuscript. All authors approved the final version.

## CONFLICTS OF INTEREST

The authors declared no conflicts of interest whatsoever.

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