

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

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

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To the Editor,

I read with interest the study by Rocha de Almeida et al. describing 300 consecutive transcatheter aortic valve implantation (TAVI) procedures performed without immediate on-site cardiac surgery (CS) support.¹ The authors deserve credit for reporting a contemporary program that addresses a genuine problem of access to care and for providing detailed procedural and follow-up outcomes. Their experience is clinically important. However, 2 issues warrant clarification before these data are interpreted as evidence of noninferiority or as indicating that immediate surgical support has become largely unnecessary.

The first concerns what is classified as emergency cardiac surgery (ECS). The study defines ECS as unplanned open surgery required during or shortly after TAVI and performed before the patient leaves the procedural environment.¹ According to this definition, the ECS rate was 0%. However, 1 patient developed persistent pericardial effusion after cardiac tamponade and ultimately required delayed exploratory cardiac surgery, followed by postoperative death.¹ This event is particularly relevant to the question addressed by the study: whether a TAVI program without on-site CS can safely manage complications that may require surgical rescue. Excluding a delayed but procedure-related surgical rescue from the main ECS endpoint because it occurred after the patient had left the procedural environment risks making the endpoint less clinically aligned with the policy question being examined. Moreover, the Valve Academic Research Consortium 3 (VARC-3) provides standardized event definitions, but evaluations of models of care may require a broader measure of emergency or unplanned cardiac surgery attributable to the index procedure.² Reporting both the formal VARC-3 ECS endpoint and a clinically broader "procedure-related surgical rescue" endpoint would therefore be informative.

Second, the absence of ECS among 300 procedures should not be interpreted as evidence that the true need for surgical rescue is negligible. With zero observed events, the upper bound of the 95% exact binomial confidence interval is approximately 1%, meaning that a clinically relevant rescue rate remains compatible with the

data. Contemporary series likewise show that surgical bailout is uncommon but not eliminated and that outcomes after surgical conversion are poor.³ For a rare but high-consequence event, the evidentiary question is therefore not simply whether zero events occurred, but how precisely the event rate has been estimated and whether a regional rescue pathway can provide timely surgery when such an event does occur.

The same distinction applies to the authors' repeated use of the term "noninferiority." Noninferiority is a design-based conclusion requiring, at a minimum, a prespecified margin and a confidence interval demonstrating that the upper bound of the between-group difference excludes that margin.⁴ Similar observed mortality between this cohort and a national registry is reassuring, but it does not establish statistical noninferiority in the absence of a prespecified noninferiority framework.

These considerations do not detract from the value of this pioneering Portuguese experience. Rather, they refine its most important message. The study convincingly demonstrates feasibility and encouraging outcomes at an experienced center without on-site CS; whether it establishes equivalence or noninferiority, and whether zero formal ECS events equate to zero clinically meaningful surgical rescues, are separate questions. Future evaluations should prospectively define rescue endpoints extending beyond the procedure room and specify noninferiority margins before using this terminology.

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CONFLICTS OF INTEREST

I declare no conflicts of interest whatsoever.

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