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Reply: Transcatheter paravalvular leak closure – insights on selection criteria, imaging, and comparative outcomes

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We thank Güner et al for their interest in our prospective multicentre Fermeture de Fuite ParaProthétique (FFPP) registry evaluating transcatheter paravalvular leak closure (PVLc)[1] and for their thoughtful and constructive comments. We welcome the opportunity to clarify several methodological points raised in their correspondence.

We fully agree that PVLc management remains complex and that outcomes depend on multiple factors, including patient selection, anatomical characteristics, procedural strategy, and imaging assessment. In this context, we believe that the prospective design of the FFPP registry, its complete follow-up up to two years, and the use of clinically meaningful endpoints provide robust real-world evidence in a high-risk population undergoing transcatheter PVLc[2].

Several concerns deserve clarification. First, regarding endpoint definitions, we would like to emphasise that Academic Research Consortium (ARC) criteria were explicitly acknowledged and applied in our methodology. In the FFPP registry, echocardiographic assessment of PVL severity followed the Valve Academic Research Consortium expert consensus[3], as detailed in both the present manuscript and in the initial publication from the same prospective registry focusing on short-term outcomes[4]. Our definitions of technical and clinical success should therefore not be interpreted as a departure from expert recommendations but rather as a pragmatic operationalisation adapted to a multicentre real-world registry. While ARC frameworks provide an important standardisation reference, they remain expert consensus statements, and the incremental clinical validity of highly granular and complex composite definitions over pragmatic patient-centred outcomes has not been clearly demonstrated. In our cohort, early clinical success at one month showed strong prognostic value for adverse outcomes at two years, supporting the clinical relevance of this approach.

Second, the absence of a surgical comparator arm is acknowledged as a limitation, as already discussed in the manuscript. However, the objective of the FFPP registry was not to compare transcatheter PVLc with redo-surgery, but to evaluate durability and identify prognostic factors in patients specifically treated with a transcatheter approach. Importantly, patients included in the FFPP registry were selected for PVLc because they were considered at high or prohibitive surgical risk (median EuroSCORE II 6 [interquartile range 4-10]) or because a transcatheter strategy was deemed highly feasible. In this context, direct comparison with surgery in a non-randomised prospective registry would be highly susceptible to indication bias. Moreover, for this selected population, transcatheter PVLc has become the preferred therapeutic strategy, in line with contemporary European and American guideline recommendations.

Third, the decision to proceed with transcatheter PVLc rather than first-line surgical reintervention was made by the Heart Team of each participating centre, according to local practice and guideline recommendations. Patients were referred for PVLc if they were considered at high or prohibitive surgical risk, or if transcatheter closure was deemed a feasible alternative to surgery. Standard feasibility criteria including leak size, trajectory, and proximity to

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critical structures were systematically evaluated using echocardiography and multimodality imaging, thereby limiting excessive morphological heterogeneity among cases referred for catheterisation, as previously reported in FFPP publications[4,5]. In addition, variability related to operator experience was mitigated by the frequent involvement of the most experienced operators in procedures performed at lower-volume centres, minimising learning-curve bias.

Fourth, we agree that future studies would benefit from more granular anatomical and echocardiographic characterisation, as well as stronger standardisation of imaging follow-up, ideally including core laboratory adjudication. These limitations are inherent to pragmatic multicentre real-world registries and reflect routine Heart Team decision-making and heterogeneous follow-up pathways across centres. Importantly, the FFPP registry was built on structured methodological foundations, and detailed echocardiographic characterisation was already reported in the initial FFPP publication[4]. In that study, leak morphology and severity were extensively described but were not independently associated with clinical success. By multivariable analysis, technical failure, mechanical prostheses, and haemolytic anaemia were the main determinants of the absence of clinical success, while residual leak severity *per se* was not predictive once technical success was achieved. These findings support the primacy of clinically meaningful outcomes over excessive morphological granularity. In the present cohort, complex anatomies, including multiple PVLs and frequent use of multiple devices, were well represented, and despite this complexity, outcome-driven results remained robust, with early clinical success being the strongest predictor of long-term outcomes.

Finally, to address several of the limitations highlighted in this discussion, particularly the need for enhanced data standardisation and more detailed procedural and imaging characterisation, we implemented the European Multicentre Registry of Percutaneous Paravalvular Leak Closure (EuroPVL) in 2020, with the support of international experts. This registry is currently ongoing, open to the participation of additional centres, and aims to further refine prospective data collection (ClinicalTrials.gov: NCT05506293).

Overall, we believe that the comments by Güner et al underline important directions for future research and standardisation. At the same time, our data provide prospective multicentre evidence that identify key prognostic factors, mitral position, mechanical prostheses, and haemolytic anaemia – and demonstrate that early clinical success remains the strongest predictor of adverse outcomes at two years.

We hope that this scientific exchange will contribute to further optimisation of patient selection, procedural strategies, and long-term outcomes in transcatheter PVL closure.

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Conflict of interest statement

S. Hascoët reports proctoring for Abbott. G. Smolka reports proctoring and fees or honoraria for lectures, presentations, and educational events from Abbott. G. Albenque and B. Gérardin have no conflicts of interest to declare.

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