

3. Our single-procedure freedom from AF/AT (atrial tachycardia) in patients off AAD (antiarrhythmic drugs) is 56% and 54% in patients on AAD ($p = 0.7$). The inference of Gianni and colleagues of a 31% rate is a miscalculation relying on incorrect study design assumptions.
4. We have clearly acknowledged that our study is a nonrandomized pilot investigation. As such, the validation set was selected according to commonly accepted matching statistical methods. Notably, its success rate is on par with the ones reported in the literature (reference 1 in our article [1]).

Altogether, both the previously published literature and our study strongly support the implementation of novel mechanism-guided and nonextensive patient-tailored AF ablation approaches. As for any therapeutic intervention, the logics of history point toward lesser extensive and increasingly patient-tailored ablation approaches.

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The Feasibility of Transcatheter Mitral Valve Replacement for Patients With Symptomatic Mitral Regurgitation



We read with great interest the feasibility study of Muller et al. (1). The study results were impressive regarding the 30-day follow-up following the procedure (1). However, the selective nature of the cases in this study together with the nonblinded nature of the study lessens the reproducibility of these results. Feasibility studies tend to answer 3 main questions (2). 1) Can it work? 2) Does it work? 3) Will it work? However, the reported results should be taken with caution given multiple factors affecting the study design and results. We cannot generalize the success rate for both types of mitral regurgitation (MR) because only 10% of participants ($n = 3$) had primary MR, whereas about 75% had secondary MR. It is known that anatomic difference between primary and secondary MR differs significantly to the point that may affect the stability of the implanted device (3). The design of the study showed unequal distribution of patients with more male predominance 83%, which also limits the feasibility of the study results in women because sex difference may affect the results of certain interventions due to the different underlying pathology and disease complications as shown in women with mitral valve repair surgery (4). Another factor that may affect the results is that 10% of participants had left ventricular ejection fraction $<30\%$, whereas it was stated at the patient selection that the patients with left ventricular ejection fraction $<30\%$ have been excluded from the study, which may raise a concern about selecting those of favorable outcomes. Finally, we agree with the authors that further large randomized cohort studies are in need to assess long-term effects and other different complications of the procedure, especially the rate of infective endocarditis, which is one of the major in-hospital complications for percutaneous transcatheter procedures (5).

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REPLY: The Feasibility of Transcatheter Mitral Valve Replacement for Patients With Symptomatic Mitral Regurgitation



The authors thank Dr. Rasla and colleagues for their interest in our feasibility study (1). We agree that it is not possible to generalize the results of this consecutive series to the larger population of patients with mitral regurgitation. The patients treated were indeed carefully selected and the study was unblinded as would be expected in a first-in-human

feasibility trial. The limited number of women and patients with degenerative mitral regurgitation included in the study cohort is likely to reflect the exclusion of patients with small left ventricular dimensions and the potential for left ventricular outflow obstruction after this intervention. The inclusion of 3 patients with a left ventricular ejection fraction <30% was addressed in a recently published correction to the Methods section of the paper (1). These patients met the inclusion criteria (left ventricular ejection fraction >30%) at the time of their enrolment, but the left ventricular ejection fraction had fallen to <30% at the time of the intervention.

Finally, we agree that, as stated in the manuscript, broad application of this technology will require pivotal comparative trials to better define the role of the intervention in the management of patients with severe symptomatic mitral regurgitation. Ongoing observational registries will provide additional data to help design these trials.

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