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Reply to Letter to the Editor: "Critical Appraisal of Caval Valve Implantation Procedure in 7 Cases of Torrential Tricuspid Regurgitation"

LETTER TO THE EDITOR
REPLY

To the Editor,

We would like to sincerely thank you[1] for your thoughtful and constructive comments on our manuscript titled "Caval Valve Implantation (CAVI) Procedure in 7 Cases of Torrential Tricuspid Regurgitation and Step-by-Step Description of the Procedure."[2] Your suggestions have been greatly appreciated and have encouraged us to reflect further on the scope and limitations of our work.

We agree that incorporating objective measures such as exercise testing and standardized quality-of-life scores would have added value to the study. However, given that our paper comprises 7 patients and was retrospective in nature, we were unable to present objective before-and-after comparisons using such parameters.

The RA–IVC pressure gradient is one of the relevant indicators of procedural success. Unfortunately, due to the retrospective design, post-procedural catheterization was not performed, and thus follow-up hemodynamic data were not available. Similarly, follow-up assessments of NT-proBNP levels and quantitative echocardiographic markers were not included for the same reason.

At present, there is no universally accepted risk stratification tool specifically designed for patients undergoing transcatheter treatment for tricuspid regurgitation (TR). The TRI-SCORE, which consists of 8 parameters, is widely used to predict in-hospital mortality in patients undergoing isolated surgical treatment for TR.[3] Our aim was to use this score to demonstrate the surgical risk of our patients. We agree that meticulous patient selection is crucial. Unfortunately, we lost one patient who had a very high TRI-SCORE (48). This patient had significant renal and hepatic dysfunction; however, following improvement in renal function with medical therapy, the patient was considered suitable for the procedure.

Regarding the concept of futility, current data suggests that transcatheter interventions may be futile and should be avoided in cases with sPAP >65 mm Hg, severely impaired RV function (TAPSE <13 mm), or poor LV function (LVEF <35%). In addition, severe renal or hepatic dysfunction may further diminish procedural benefit.

There is currently no randomized controlled trial addressing this issue. Prospective single-arm studies such as TRICUS (n=9) and TRICUS EURO (n=35) collectively included only 44 patients.[4] The TricBicaval Registry represents the largest dataset to date in this field, including 204 patients across 26 centers in Europe and one center in Brazil. According to the registry's preliminary findings—presented at PCR London Valves 2024 but not yet published—patients demonstrated improvement in functional class, reduction in signs of right heart failure, fewer hospitalizations, and decreased need for diuretics.

Caval valve implantation is a relatively simple procedure with a short learning curve, typically reached after 4-5 cases. The procedure is performed under conscious sedation and local anesthesia, with an average duration of 30-50 minutes. A hospital stay of 3-5 days is generally sufficient. It carries a low risk of

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complications. Access-site bleeding may occur. Rare complications such as device migration or thrombosis have been reported, and these are discussed in the manuscript.[5,6] In the TricBicaval Registry, a second device was implanted in 7 patients due to malposition. No major complications occurred in our series.

Finally, we agree with your comment that long-term data are lacking and randomized controlled trials are needed in this field. The TRICAV-II trial (NCT06458907 ClinicalTrials.gov), which plans to enroll 400 patients, will provide much more robust evidence.

As Türkiye, we believe that future participation in such randomized trials and contribution to large registries should be a priority to advance the field and optimize patient care.

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