VOL. 16, NO. 21, 2023
ISSN 1936-8798/$36.00

Letters

RESEARCH LETTER

1-Year Comparison of PASCAL vs MitraClip for Mitral Valve Transcatheter Edge-to-Edge Repair

A Quasi-Randomized Study

Transcatheter edge-to-edge repair of the mitral valve (M-TEER) has become a widely accepted therapy for patients with clinically relevant mitral regurgitation (MR) and heightened risk for surgical interventions. We previously reported prospective short-term results showing that 2 widely used systems, the MitraClip (Abbott Vascular) and the PASCAL repair system (Edwards Lifesciences), had similar technical and procedural success rates.[1] We now report on the 1-year follow-up results assessing the durability of MR reduction and clinical benefits during follow-up.

In this prospective, comparative study, we enrolled 214 M-TEER patients treated with either the PASCAL or MitraClip system at our university hospital from June 2019 to August 2021. Patient assignment to each device was based on the next available implantation date, with alternating weekly time slots, resulting in a quasi-random allocation. Scheduling and system selection were independent of treating physicians. The study received approval from the local ethics committee of Heinrich Heine University and was registered at ClinicalTrials.gov (NCT05865938).

Echocardiographic assessment was conducted at the local echocardiography core laboratory during 30-day and 12-month follow-up. The primary endpoint was achieving MR <2+ at 12 months, while the secondary endpoint was a composite of all-cause death or hospitalization for heart failure.

In total, 102 patients were treated using the PASCAL system, and 112 patients were treated using the MitraClip system. The 2 groups had comparable baseline characteristics, comorbidities, and echocardiography-derived ventricular and valvular parameters.[1] Of the 212 patients, 171 had evaluable MR severity at 1 year. Data were missing for 41 patients because of death (n = 26), mitral valve surgery (n = 5), or missed visits (n = 10).

M-TEER reduced MR with durable results over 1 year (Figure 1A). In the PASCAL group, no reduction in MR could be achieved in 4 patients (5%); in 7 patients (9%), MR was reduced by 1 grade, and in 69 patients (86%), MR was reduced by 2 grades compared with baseline. In the MitraClip group, in 6 patients (7%), MR was not reduced; in 8 patients (9%), MR was reduced by 1 grade; and in 77 patients (85%), MR was reduced by 2 grades compared with baseline ($P = 0.198$, PASCAL vs MitraClip). In summary, in the PASCAL group, 93% of patients (74 of 80), and in the MitraClip group 90% of patients (82 of 91), had MR grade ≤2+ ($P = 0.899$, PASCAL vs MitraClip) at 12 months. Optimal residual MR grade ≤1+ after 12 months was present in 59 patients (74%) treated with the PASCAL and in 64 patients (70%) treated with the MitraClip ($P = 0.619$).

In both groups, NYHA functional class improved in most patients. Twelve months after M-TEER, NYHA functional class I or II was present in 77.5% of patients (n = 62) in the PASCAL group and 74.7% of patients (n = 68) in the MitraClip group ($P = 0.577$).

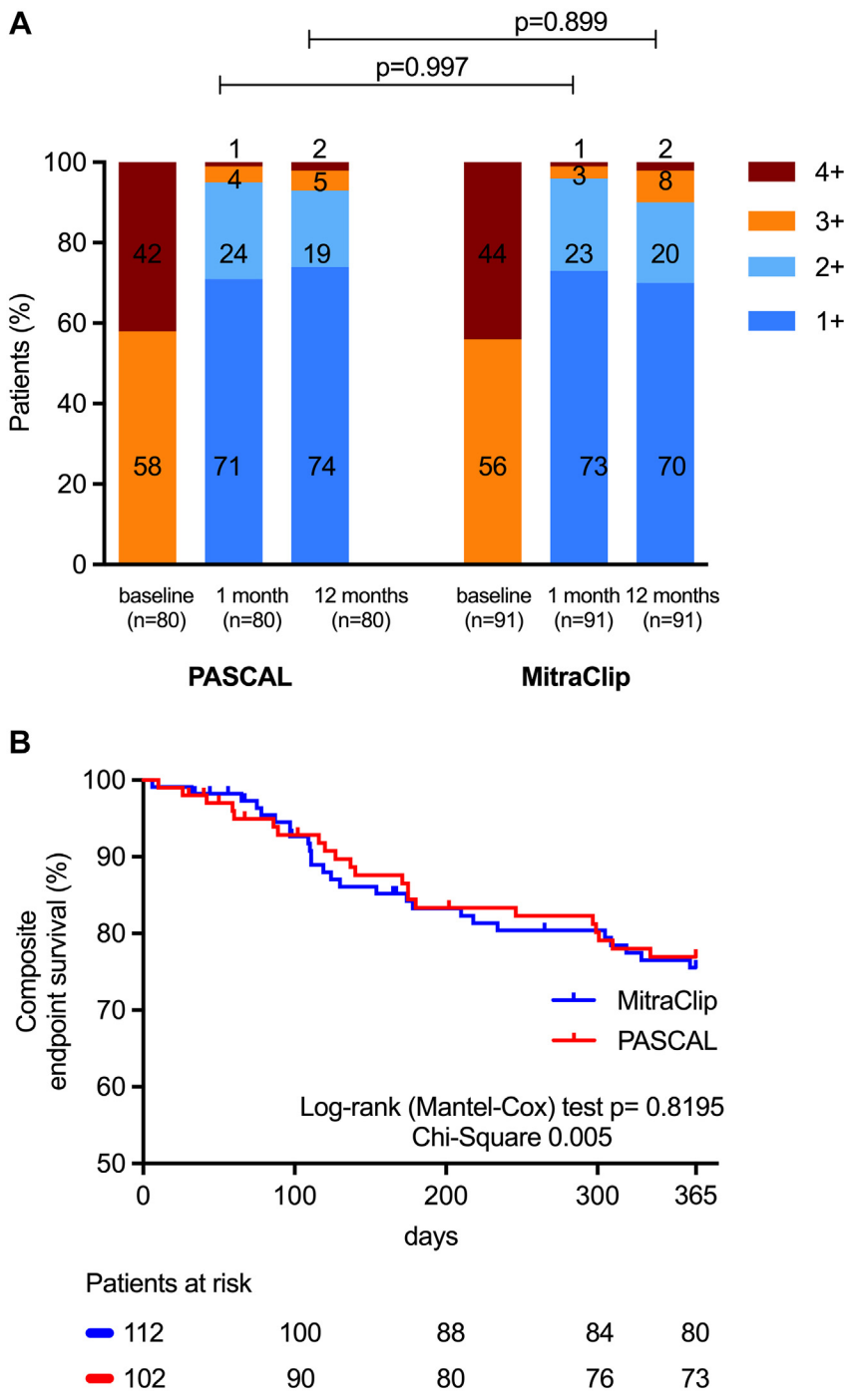
The composite endpoint of all-cause death or hospitalization for heart failure did not differ between the groups; in the PASCAL group, 28.4% of patients (29 of 102) and in the MitraClip group 28.6% of patients (32 of 112) died or were hospitalized for heart failure in the first 12 months after M-TEER ($P = 0.982$) (Figure 1B).

This study represents the first prospective quasi-randomized controlled study to report on the 1-year outcomes of M-TEER using the PASCAL in comparison with the MitraClip repair system. Our findings indicate that both M-TEER systems resulted in stable reductions of MR over the 1-year period and did not differ in terms of the composite endpoints of heart failure hospitalization and death.

These findings are consistent with those of previous retrospective studies[2,3] and the sole available randomized controlled trial, CLASP IID (Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial), which focused on degenerative MR.[4]

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 21, 2023
NOVEMBER 13, 2023:2687-2689

FIGURE 1 **1-Year Comparison of the PASCAL vs MitraClip for Transcatheter Edge-to-Edge Repair of the Mitral Valve in a Quasi-Randomized Controlled Study**



(A) Mitral regurgitation severity was reduced at 30 days and 12 months after transcatheter edge-to-edge repair using the PASCAL and MitraClip. (B) Survival data of the composite endpoint of all-cause death or hospitalization for heart failure over 1 year after transcatheter edge-to-edge repair of the mitral valve did not differ between the PASCAL and MitraClip groups.

When evaluating the efficacy of devices, it is important to consider the device generation used in the studies. In our prospective quasi-randomized study, we used the first-generation PASCAL platform without the ACE implant device and used the fourth-generation of the MitraClip system in only 20% of the patients belonging to the MitraClip group.

The use of more contemporary generations of both devices may lead to further improved results; however, more elaborate long-term data from a multicenter randomized comparison with a larger number of patients are required, such as the enrolling PASCAL CLASP IID/IIF Pivotal Clinical Trial (NCT03706833).

Jafer Haschemi, MD
Jean Marc Haurand, MD
Daniel Oehler, MD
Georg Wolff, MD
Maximilian Spieker, MD
Amin Polzin, MD
Malte Kelm, MD
***Patrick Horn, MD**

*University Hospital Düsseldorf
Division of Cardiology, Pulmonology and Vascular Medicine
Moorenstrasse 5
40225 Düsseldorf, Germany
E-mail: patrick.horn@med.uni-duesseldorf.de

https://doi.org/10.1016/j.jcin.2023.08.003

Dr Horn has received travel support and educational grants from Abbott Medical and Edwards Lifesciences; and has received an unrestricted research grant from Edwards Lifesciences. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.
The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

REFERENCES

1. Haschemi J, Haurand JM, Bonner F, Kelm M, Westenfeld R, Horn P. PASCAL vs MitraClip for mitral valve transcatheter edge-to-edge repair: a single-center real-world experience. *J Am Coll Cardiol Intv*. 2022;15(9):1002–1004. https://doi.org/10.1016/j.jcin.2022.02.019

2. Geis NA, Schlegel P, Heckmann MB, et al. One-year results following PASCAL-based or MitraClip-based mitral valve transcatheter edge-to-edge repair. *ESC Heart Fail*. 2022;9(2):853–865. https://doi.org/10.1002/ehf2.13849

3. Schneider L, Markovic S, Mueller K, et al. Mitral valve transcatheter edge-to-edge repair using MitraClip or PASCAL: a multicenter propensity score-matched comparison. *J Am Coll Cardiol Intv*. 2022;15(24):2554–2567. https://doi.org/10.1016/j.jcin.2022.10.028

4. Lim DS, Smith RL, Gillam LD, et al. Randomized comparison of transcatheter edge-to-edge repair for degenerative mitral regurgitation in prohibitive surgical risk patients. *J Am Coll Cardiol Intv*. 2022;15(24):2523–2536. https://doi.org/10.1016/j.jcin.2022.09.005