Novel self-expanding ALLEGRA transcatheter aortic valve for native aortic stenosis and degenerated bioprosthesis

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Abstract

Objectives: To investigate the safety and efficacy of the ALLEGRA valve in routine use.

Background: The ALLEGRA aortic valve is a self-expanding transcatheter heart valve (THV) with bovine pericardial tissue and was CE approved in March 2017. Its unique design was developed to provide low prosthesis gradients.

Methods: We analyzed patients receiving an ALLEGRA THV between May 2017 and March 2021 at our center for treatment of aortic valve stenosis or degenerated valve prosthesis. Hemodynamic results and clinical outcome according to the Valve Academic Research Consortium-2 consensus criteria were evaluated at discharge and three months post transcatheter aortic valve replacement (TAVR) procedure. 93 patients with a mean age of 82.5 ± 4.8 years and a median EuroScore II of 4.7 ± 3.4 were treated, 15 of them were valve-in-valve procedures.

Results: Implantation was successful in 97.8% (91/93) and VARC-2 defined device success was achieved in 94.6% (88/93). In-hospital all-cause mortality was 2.2% (2/93). Life-threatening bleeding, major vascular complications and strokes were 3.2% (3/93), 2.2% (2/93) and 3.2% (3/93), respectively. Paravalvular leakage was none to trace in 60.4%, mild in 38.5% and moderate in 1.1%. Permanent pacemaker implantation in pacemaker naive patients was necessary in 9.5% (8/84). Mean gradient at discharge was 8.2 ± 4.3 mmHg for all patients; 7.1 ± 2.6 mmHg in patients treated for stenosis of the native aortic valve and 13.8 ± 6.3 mmHg in patients treated valve-in-valve.

Conclusions: The ALLEGRA THV provides excellent hemodynamic results and a good safety profile with a low complication rate.

KEYWORDS
Allegra, aortic stenosis, transcatheter aortic valve replacement, transcatheter heart valve

INDEX MEDICUS: aortic stenosis, TAVR, valve-in-valve
1 | INTRODUCTION

Over the last decade a plethora of different transcatheter heart valve (THV) systems for the treatment of severe aortic valve stenosis has been developed. The novel self-expanding ALLEGRA THV by New Valve Technology (NVT AG, Morges, Switzerland and Biosensors, Singapore, Singapore) was CE approved in March 2017. It provides a unique design comprising a bovine pericardial trileaflet with a supra-annular position in a nitinol stent. The frame design allows a variable radial force along the stent. The concave stent shape and tip deflection during diastole is aimed to a reduction of stress on the leaflet, possibly improving long term durability. Due to the diamond-shaped configuration with variable cell sizes of the nitinol stent frame, coronary perfusion is improved, and coronary arteries remain accessible for percutaneous interventions, while the ventricular portion of the prosthesis includes a 12 mm sealing skirt, diminishing paravalvular leakages. The delivery system named PermaFlow® maintains left ventricular outflow. Furthermore, the three-step release mechanism

![Figure 1 Image of the Allegra TVH showing its key features.](Color figure can be viewed at wileyonlinelibrary.com)

![Figure 2 Implantation procedure of a 27 mm NVT ALLEGRA valve in an 82-year-old patient.](Color figure can be viewed at wileyonlinelibrary.com)
provides prolonged complete retrievability throughout the procedure and six radiopaque gold markers enable an optimal positioning of the valve prosthesis (see Figure 1). All available prosthesis sizes (23, 27, and 31 mm) are delivered through a 18F sheath.\textsuperscript{3,4}

Most data on the ALLEGRA THV are derived from small clinical studies or case reports.\textsuperscript{3–7} We therefore analyzed our experience in routine practice with the ALLEGRA system at our center to provide real-world experience with focus on short-term clinical and echocardiographic follow-up.

## MATERIALS AND METHODS

### 2.1 Patients

The ALLEGRA device system received CE mark in March 2017 and the first implantation at the Hannover Medical School was performed on May 29th, 2017. All patients treated with an ALLEGRA THV in aortic position at our center between May 2017 and March 2021, were analyzed, including valve-in-valve (ViV) procedures in patients with degenerated valve prostheses and patients treated in the early phases of our learning curve. All patients gave written informed consent for the procedure. The study procedure is in accordance with the ethical guidelines of the 1975 declaration of Helsinki. In Germany retrospective analyses of institutionally assessed anonymized patient data do not require an ethics statement.

### 2.2 Diagnosis of aortic stenosis, implantation procedure and follow-up

All patients were assessed by our institutional Heart Team. Evaluation of aortic stenosis and eligibility for a transcatheter aortic valve replacement (TAVR) procedure had been carried out at our center or in associated clinics according to the guidelines.\textsuperscript{8} Coronary angiography, transthoracic echocardiography and computed tomography for TAVR planning was done prior to implantation in all patients. 3mensio\textsuperscript{®} software (Maastricht, Netherlands) was used for sizing and pre-procedural planning. Sizing details for the ALLEGRA THV are provided in Supplemental Table S1.

Implantation procedures were conducted by the same interventionist, predominantly assisted by the same team. All patients received analgosedation throughout the TAVR procedure by an experienced cardio-anesthetist. Access was established transfemorally.
with an 18F Adelante Magnum sheath (Oscor Inc. Palm Harbor, FL) in all cases and percutaneous closure of the femoral access site was achieved using the suture-based closure devices ProStar or ProGlide (Abbott Vascular, Chicago, USA). In few cases the Manta devices (Tel-eflex, Wayne, Pennsylvania) was used. Fluoroscopic images of implantations are shown in Figures 2 and 3, the latter in a VV-patient. Systems for neuroprotection were not used. Following the TAVR procedure, patients were monitored in our intensive/intermediate care unit for at least 24 h. Post-procedural patients received single anti-platelet therapy with aspirin, unless dual anti-platelet therapy or oral anticoagulation was indicated. Other preexisting medication was continued or adjusted to current guidelines, respectively. Echocardiographic examination evaluating THV and left ventricular function were performed prior to hospital discharge. Routine follow-up including clinical examination, as well as transthoracic echocardiography was carried out three months after discharge in our out-patient clinic. Follow-up was incomplete in two patients, since at the time of data acquisition the TAVR procedure was less than 12 weeks ago, while another five patients did not attend the follow-up visit and could not be reached by phone. Mean clinical follow-up was 145.2 ± 142.1 days post-implantation, while complete follow-up including echocardiography was obtained in 71 patients.

### 2.3 Statistics

All data were collected and analyzed following the valve academic research consortium-2 (VARC-2) criteria and analyses were done using GraphPad Prism (Version 6.05; GraphPad Software, Inc, San Diego, CA, USA). Continuous values are presented as mean ± standard deviation, while categorical information is displayed as proportions of the total.

| TABLE 1 General traits (n = 93) | Unit | Value/Mean | SD |
|---------------------------------|------|------------|----|
| Age                             | Years | 82.5       | 4.8|
| Gender                          | %    | 62.4       |    |
| EuroScore II                    | %    | 4.7        | 3.4|
| Aortic valve disease            |      |            |    |
| Stenosis                        | %    | 22.6       |    |
| Combined                        | %    | 75.3       |    |
| Gradient max                    | mmHg | 74.1       | 19.5|
| Gradient mean                   | mmHg | 45.2       | 13.0|
| Orifice Area                    | cm²  | 0.7        | 0.2|
| Mitral valve disease            |      |            |    |
| Additional mitral valve disease | %    | 68.8       |    |
| Moderate/severe stenosis        | %    | 7.52       |    |
| Moderate/severe regurgitation   | %    | 51.6       |    |
| Ventricular function            |      |            |    |
| LVEF                            | %    | 56.1       | 11.7|
| TAPSE                           | cm   | 2.0        | 0.6|
| Comorbidities                   |      |            |    |
| Arterial hypertension           | %    | 95.7       |    |
| Diabetes                        | %    | 15.1       |    |
| Prior heart surgery             | %    | 20.4       |    |
| Coronary artery disease         | %    | 49.5       |    |
| Prior PCI                       | %    | 14.0       |    |
| COPD                            | %    | 6.5        |    |
| Pulmonary hypertension          | %    | 43.0       |    |
| H/O CVD                         | %    | 20.4       |    |
| H/O PAD                         | %    | 18.3       |    |
| Chronic kidney disease          | %    | 62.4       |    |
| Creatinine                      | µmol/l | 101.5   | 50.7|
| Prior ICD or PM                 | %    | 8.6        |    |
| NTproBNP                        | ng/l | 3678       | 6526|

Abbreviations: COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; D, standard deviation; LVEF, left ventricular ejection fraction; H/O, history of; ICD, implantable cardio defibrillator; NTproBNP, N-terminal pro brain natriuretic peptide; PAD, peripheral artery disease; PM, pacemaker; PCI, percutaneous coronary intervention; TAPSE, tricuspid annular plan systolic excursion.
3 | RESULTS

We treated 93 patients at our center with the ALLEGRA THV via transfemoral access. During the study period a total of 959 patients received a transfemoral THV at our center. Patient demographics and baseline data are depicted in Table 1. In brief, mean age was 82.5 ± 4.8 years, 62.4% were female and 62.4% described severe clinical symptoms graded as NYHA-Class III or IV. EuroSCORE II was 4.7 ± 3.4. Coronary artery disease (CAD, with stenosis >50% and/or previous myocardial infarction) was present in 49.5% of all patients. Overall, eight patients (8.6%) had a permanent pacemaker prior to TAVR, six of them with native aortic valve stenosis and two patients had previously undergone surgical aortic valve replacement. The majority of patients (83.9%) presented with severe stenosis of their native aortic valve, while 15 patients were treated with a VI-V-procedure for degenerated aortic valve prosthesis. Most VI-V-procedure were done in degenerated stenotic bioprosthesis. However, particularly patients with Mitroflow®-prostheses, often showed severe regurgitation or combined stenosis and regurgitation (Table 2).

3.1 | Implantation procedure and hospital stay

Balloon dilatation before the prothesis implantation was performed in all patients with native aortic valve stenosis and in two patients undergoing VI-V-procedure. The distribution among the used THV sizes was 31.5% for the 23 mm, 47.8% for the 27 mm and 20.7% for the 31 mm. Postdilatation was necessary in 48.9%. 140.4 ± 65.1 mL of contrast agent was used. Fluoroscopy time reached 822.5 ± 433.6 sec resulting in a dose-area product of 2216 ± 13,382 cGy*cm². Procedural characteristics are depicted in Table 3.

TABLE 2  Degenerated valve prosthesis types

| Typ        | Size | Stenosis Grade | Regurgitation Grade | Surface [cm²] | Gradient pre VI-V | Gradient post VI-V |
|------------|------|----------------|---------------------|---------------|------------------|-------------------|
| Mitroflow  | 19 mm| 3              | 2                   | 0.7           | 58/31            | 34/20             |
|            | 21 mm-1| 3              | 3                   | 0.6           | 53/32            | 20/10             |
|            | 21 mm-2| 0              | 3                   | n/a           | 30/17            | 14/7              |
|            | 23 mm-1| 2-3            | 3                   | 1.3           | 74/40            | 19/9              |
|            | 23 mm-2| 2              | 3                   | 1.3           | 56/34            | 44/23             |
|            | 23 mm-3| 2              | 3                   | 1.5           | 55/31            | 28/14             |
|            | 23 mm-4| 3              | 3                   | 0.8           | 88/53            | 28/16             |
| Carpentier-Edwards | 23 mm-1| 3              | 0                   | 0.8           | 86/53            | 48/27             |
|            | 23 mm-2| 3              | 1                   | 0.6           | 80/51            | 20/12             |
|            | 23 mm-3| 3              | 1                   | 0.7           | 100/57           | 25/15             |
|            | 25 mm  | 3              | 0                   | 0.9           | 54/30            | 9/5               |
|            | 27 mm  | 3              | 1                   | 0.9           | 35/25            | 16/8              |
| Medtronic Hancock II | 21 mm| 3              | 2                   | 0.9           | 44/20            | 24/15             |
| Perimount Magna Ease | 25 mm| 3              | 0                   | 0.8           | 49/30            | 36/18             |
| Mosaic     | 29 mm  | 0              | 3                   | n/a           | 47/26            | 11/7              |

Abbreviations: n/a, not available; VI-V, valve-in-valve; Gradients presented as Pmax/mean [mmHg].

TABLE 3  Procedural characteristics

| Unit          | Value/ Mean | SD  |
|---------------|-------------|-----|
| THV size      | 23 mm %     | 31.5|
|               | 27 mm %     | 47.8|
|               | 31 mm %     | 20.7|
| Postdilatation | %          | 48.9|
| Fluoroscopy time | sec      | 822.5| 433.6|
| Dose-area product | cGy*cm² | 2216.8| 1338.2|
| Contrast agent | ml         | 140.4| 65.1 |
| Recapture maneuver | % | 7.5 |

Abbreviations: THV, transcatheter heart valve.

VARC-2 defined device success could be achieved in 94.6%, while implantation procedure was successful in 97.8% of all patients. In one case the ALLEGRA THV was implanted in a high but still by fluoroscopy and echocardiography acceptable position. After several hours respiratory distress occurred and a CT scan was performed revealing a position partly above the annulus. Transthoracic echocardiography still showed a low aortic gradient (mean 8 mmHg) and good LV function, so no further action regarding valve was taken. The patient developed a sepsis of unknown focus and ultimately died in multi organ failure after 13 days. In another patient the ALLEGRA THV could not be positioned successfully and therefore a different THV (CoreValve®, Medtronic, Dublin, Ireland) was implanted. This particular patient was excluded from further analyses concerning THV-function. All-cause in hospital mortality was 2.2%. One patient died the day after the procedure due to pericardial tamponade following transvenous pacemaker application. In-hospital life threatening bleeding...
occurred in 3.2% and major vascular complications in 2.2% of patients. Two patients experienced minor strokes, while one patient was left disabled from a major stroke. Implantation of a permanent pacemaker (PPI) in pacemaker naïve patients was required in 9.5%, in patients with native aortic valve stenosis in 11.3%, whereas no pacemaker was needed in the valve-in-valve cases. Detailed results of the implantations procedures are shown in Table 4.

At discharge, in most patients (60.4%) paravalvular regurgitation (PVR) was none to trace, while a mild PVR was apparent in 38.5%. Only one patient showed a moderate PVR (Figure 4). Mean transvalvular gradient was 8.2 ± 4.3 mmHg in the overall cohort. In patients treated for native aortic valve stenosis, the ALLEGRA prosthesis resulted in mean gradient of 7.1 ± 2.6 mmHg. ALLEGRA THV-implantation in patients with a ViV-procedure led to a mean gradient of 13.8 ± 6.3 mmHg (Figure 5). Transvalvular gradients remained stable during the follow-up period (Figure 5). Detailed information on mean transvalvular gradients by prosthesis size and indication is shown in Supplemental Table S22.

At three months post-implantation most patients (79.5%) reported improved functional capacity defined as a reduction in NYHA class of at least one grade (Figure 6).

**FIGURE 4** Paravalvular Regurgitation – Classification of echocardiographically assessed paravalvular regurgitation at discharge

### TABLE 4 Procedural outcomes

|                                | Percentage | Absolute value |
|--------------------------------|------------|----------------|
| Implantation procedure         | Technical success | 97.8 | 91/93 |
|                                | Device success (VARC-2) | 94.6 | 88/93 |
|                                | Dilation post implantation | 48.9 | 45/92 |
|                                | ViV-Procedures | 16.1 | 15/93 |
| Mortality (in hospital)        | Cardiovascular | 1.1 | 1/93 |
|                                | All-case | 2.2 | 2/93 |
| Stroke                         | Total | 3.2 | 3/93 |
|                                | Disabling | 1.1 | 1/93 |
|                                | Non-disabling | 2.2 | 2/93 |
| Permanent Pacemaker            | in pacemaker naïve patients | 9.5 | 8/84* |
| VARC-defined Complications     | Life-threatening bleeding | 3.2 | 3/93 |
|                                | Major bleeding | 5.4 | 5/93 |
|                                | Minor bleeding | 4.3 | 4/93 |
|                                | Major vascular complication | 2.2 | 2/93 |
| Improvement NYHA-Class ≥1     | at Follow-up | 79.5 | 66/83*bc |

Abbreviations: NYHA, New York Heart Association; VARC, Valve Academic Research Consortium; ViV, valve-in-valve.

*aPositioning of one NVT Allegra THV failed and therefore another valve prosthesis type was implanted. This patient was excluded from all analyses concerning prosthesis function.

*bAt the time of data acquisition two patients had not completed their follow-up, respectively 5 not attend the follow-up visit or could not be reached by telephone.

*cMean FU duration 146.7 days.

In our single-center experience the NVT ALLEGRA THV was a safe and reliable system for the treatment of severe aortic stenosis, as well as for ViV-procedures of degenerated valve prosthesis, providing excellent hemodynamic results.

The main findings are: 1. Technical success could be reached in 97.8% and VARC-2-defined success in 94.6% of all cases. 2. All-cause in-hospital mortality as well as rates of adverse events such as stroke, vascular complications or bleeding remained low. 3. Hemodynamic outcome concerning PVR and transvalvular gradients reached excellent results.

### DISCUSSION

In our single-center experience the NVT ALLEGRA THV was a safe and reliable system for the treatment of severe aortic stenosis, as well as for ViV-procedures of degenerated valve prosthesis, providing excellent hemodynamic results.
Our data derives from a fairly large patient cohort including a high proportion of ViV-cases, especially when considering the single center design. Two small single center studies exist, though involving no ViV cases.3,5 Even earlier multi center registries did not involve a considerably higher number of patients.4,6,10 Parallel to our study period another group analyzed data from a multi-center registry, including more patients. The report shows a similar clinical outcome to our registry as far as comparable, since our patient cohort comprises three times more ViV-cases. Beyond that, we gathered more procedural data.11 In addition we provide in hospital and three month follow-up echocardiographic data, while most former studies and registries included only a 30-day follow-up, some lacking echocardiographic analyses.3–5,10

All-cause in hospital mortality as well as periprocedural and in-hospital complications were comparable to former reports on TAVR procedures. In our series, only two patients died (2.2%), while one patient suffered from a disabling stroke (1.1%). When compared with early studies investigating TAVR in a high risk population, stroke occurred in about 5% of all cases (5.0% major strokes in PARTNER trial with Edwards Sapien12; 4.9% stroke in CoreValve High Risk Study with Medtronic CoreValve13). Over the last years, complication rates dropped due to increasing clinical experience and improved devices. A meta-analysis of observational and randomized studies showed a mortality of 5.01 ± 4.09% (first generation THV CoreValve) and 1.15 ± 1.13% (second generation THV CoreValve EvolutR) in patients receiving these most widely used self-expanding THVs.2 In this meta-analysis stroke occurred in 2.6 ± 2.15% (CoreValve) and 1.82 ± 2.11% (CoreValve EvolutR).2 Furthermore, data from the German Institute for Quality Assurance and Transparency in Healthcare showed an in-hospital mortality of 2.3% in 2019, assessing the situation in a real world setting in Germany.14

Major vascular complication occurred in two cases (2.2%), while three patients (3.2%) developed VARC-defined life-threatening bleeding, but all patients were suffering from chronic anemia. These outcomes reflect again the low adverse event rates in our cohort. In a report on the comparison of two closure devices regarding vascular complications after TAVR, Dimitriadis et al. found a major VARC-2 complication rate of 8%.15 In the multicentric S3U-registry of transfemoral TAVR using the new Edwards Sapien 3 Ultra balloon-expandable prosthesis, major vascular complications and life-threatening bleeding occurred in 2.2%.16 In the CHOICE randomized clinical trial, life-threatening bleeding occurred in as much as 12.0% after use of a self-expandable THVs.17

High pacemaker rates, especially after self-expanding TAVR device are still an issue. In our cohort using the ALLEGRA THV in a real world setting, the frequencies of permanent pacemaker necessity in pacemaker naïve patients receiving TAVR-procedure for native aortic stenosis, was acceptably low (11.3%) when compared with earlier data from large studies with self-expanding THVs (CoreValve High Risk Study 19.8%13). In the CHOICE randomized clinical trial, rates of placement of new permanent pacemaker even reached 37.6%, when a self-expandable valve was used.17 In other registries, reported pacemaker rate was 16.6% in the German Aortic Valve Registry (GARY)18 and similar after use of the EvolutPro THV in the United Kingdom and Ireland Implanters’ registry.19 In contrast to data from the Spanish ALLEGRA valve-in-valve (SAVIV) registry, none of our patients requiring a ViV-procedure for degenerated aortic valve prosthesis developed pacemaker dependency.10

The hemodynamic outcome with a significant reduction in transvalvular mean gradients from 45.2 ± 13.0 to 8.2 ± 4.3 mmHg was at least in range of former reports on TAVR with supraanular design, if not even better.20,21 Though, ViV-procedures in general lead to higher
transvalvular gradients compared to TAVR procedures for native aortic stenosis. In our 15 ViV-cases with the ALLEGRA valve, the mean gradient by echocardiography could be decreased to 13.8 ± 6.3 mmHg. This is comparable to the post ViV gradients seen in a first report on ALLEGRA use in ViV procedures, the VIVALL study. In the recent published data from the SAVIV registry, even lower mean gradients were observed, which might be explained by somewhat different patient population and treatment approach. In two cases of our series VARCH-2 defined device success could not be obtained, because mean gradient reached values >20 mmHg. In one case a 27 mm ALLEGRA valve was implanted in a 23 mm CE prosthesis of a 1.86 m tall male patient, who already suffered from moderate prosthesis mismatch. In the other case ViV-procedure was performed in a patient with a history of David-procedure firstly, and secondly surgical aortic valve replacement using a 23 mm Mitroflow prosthesis. On this specific anatomy in these two cases aggressive postdilation or cracking the valve prosthesis, which potentially have reduced the transvalvular gradient, was not performed. Considering the over-all cohort, these two patients remained the only ones in whom VARC-2 device success could not be reached because of elevated transvalvular gradients. In all other ViV cases a sufficient decline in transvalvular gradient was reached. We therefore did not see a need for bioprosthetic valve fracture maneuvers to further lower transvalvular gradients. Of interest, in the SAVIV registry also no valve cracking was done in any case, indicating that in most cases excellent gradients can be reached in ViV procedure using the Allegra valve even without bioprosthetic valve cracking.

Echocardiographically assessed PVR showed excellent results at discharge, since no patient suffered from severe and only one patient showed a moderate PVR, while almost two third of all cases presented with none to trace of PVR. In early TAVR studies like the CoreValve U.S. Pivotal Trial PVR was moderate or severe in 9.9%. In a recent published propensity score-matched comparison of balloon-expanding versus self-expanding TAVR based on data from the FRANCE-TAVI nationwide registry, moderate or severe PVR was reported in 15.5% of all cases treated with self-expanding THV. An analysis of different generations of the Medtronic self-expanding THV derived from data from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry revealed a declining rate of more than mild PVR with each newer generation in a matched population (8.3% CoreValve, 5.4% Evolut R, and 3.4% Evolut PRO), but rates remained higher than in our cohort even with the newest Medtronic THV generation.

Improvement in quality of life and functional capacity following TAVR-procedure is of substantial importance. Almost all patients reported improved functional capacity assessed by NYHA class three months after TAVR-procedure, which stands in line with data from the GARY, reporting improvement of NYHA functional class one year after TAVR.

4.1 Limitations

The study encompasses data derived from a single center and the patient cohort remains limited, especially since not all patients attended the follow-up visit. Therefore, hard clinical endpoints during the follow-up could not be analyzed and need to be evaluated in larger studies. Furthermore, all procedures were performed by an experienced operator at a high-volume center and therefore data on outcome and complications can only be transferred with caution to smaller centers with less experience. However, our data includes the operator’s learning phase with the new device. Therefore, our results confirm the safety and efficacy of the ALLEGRA THV, even under these circumstances.

5 CONCLUSION

Treatment of patients suffering from severe aortic valve stenosis with the ALLEGRA THV system provides a good safety profile concerning implantation procedure and results in an excellent hemodynamic outcome at three months post implantation with low transvalvular gradients, a low rate of relevant PVR and low pacemaker rate.

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CONFLICT OF INTEREST

Julian D. Widder is a consultant for NVT and Medtronic. Johann Bauersachs reports personal fees from Novartis, Vifor, Bayer, Servier, Aibomed, Pfizer, Boehringer Ingelheim, AstraZeneca, Cardior, Daichii Sankyo, CVRx, BMS, MSD, Amgen, Corvia; research grants: Zoll, CVRx, Vifor, Aibomed; all outside the submitted work. Tibor Kempf has been a paid consultant for and/or received honoraria payments from AstraZeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Novartis, Pharmacosmos, and Vifor. Tibor Kempf reports research support from Vifor, the German Heart Research Foundation and the German Research Foundation. All outside the submitted work. Jonas Neuser declares no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION
Additional supporting information may be found in the online version of the article at the publisher’s website.

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