

Feasibility of a MPR-based 3DTEE guidance protocol for transcatheter direct mitral valve annuloplasty

Martin Geyer MD¹  | Efthymios Sotiriou MD¹ | Karsten Keller MD¹ |
 Alexander R. Tamm MD¹ | Tobias F. Ruf MD¹ | Felix Kreidel MD¹ |
 Andres Beiras-Fernandez PhD² | Angela Kornberger MD² | Yang Yang MD³ |
 Tilman Emrich MD³ | Eberhard Schulz MD¹ | Thomas Münzel MD^{1,4} |
 Ralph Stephan von Bardeleben MD¹

¹Center for Cardiology, Cardiology I, University Medical Center Mainz (Johannes Gutenberg-University Mainz), Mainz, Germany

²Department for Thoracic and Cardiovascular Surgery, University Medical Center Mainz (Johannes Gutenberg-University Mainz), Mainz, Germany

³Department of Radiology, University Medical Center Mainz (Johannes Gutenberg-University Mainz), Mainz, Germany

⁴German Center for Cardiovascular Research (DZHK), Partner Site Rhine Main, Mainz, Germany

Correspondence

Dr. Med. Martin Geyer, University Medical Center Mainz, Center for Cardiology, Cardiology I, Langenbeckstr. 1, 55131 Mainz, Germany.
 Email: martin.geyer@unimedizin-mainz.de

Abstract

Objectives: Several interventional approaches have been established for the treatment of severe mitral regurgitation (MR) in patients at elevated risk for surgery. Direct annuloplasty is a relatively novel option in transcatheter mitral valve repair dedicated to reverse pathology in specific subsets of MR. With regard to echocardiographic guidance, this procedure presents with higher efforts in comparison with edge-to-edge therapy to enable safe and exact positioning of the device's anchors; evidence on optimal peri-interventional imaging is sparse. We tested a specific 3D-echo-guidance protocol implementing single-beat multiplanar reconstruction (MPR) and evaluated its feasibility.

Methods: Overall, 16 patients consecutively treated with transcatheter direct annuloplasty for severe MR (87.5% functional/6.3% degenerative/6.3% mixed pathology) were entered in this monocentric analysis. Of these, two patients received a combined procedure including edge-to-edge repair. For all implantations, a 3D-echo-guidance protocol inheriting MPR was employed.

Results: Periprocedural device time decreased continuously (overall mean 140 ± 55.1 minutes, 213 ± 38 minutes in the first 4 vs 108 ± 33 minutes in the last 4 procedures, $P = .018$) using the MPR-based echo protocol, going along with reduced fluoroscopy times and doses. Technical success rate was high (93.8%) without any serious cardiac-related adverse events. MR could be relevantly improved.

Conclusion: Echocardiographic guidance of transcatheter direct annuloplasty using a real time MPR-based protocol is feasible and safe. Optimized imaging might enable reduced implantation times and potentially increases safety.

KEYWORDS

3DTEE, multiplanar reconstruction, peri-interventional imaging, transcatheter mitral valve repair

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1 | INTRODUCTION

Mitral valve regurgitation (MR) is a common valvular disorder with an age-dependent prevalence of over 10% in the elder population beyond 75 years in industrialized countries.¹ With respect to its pathomechanism, functional or secondary MR (FMR), caused by a pathologic annular deformation, has to be discriminated from degenerative or primary MR (DMR) due to a leaflet pathology. In this context, it is well known that FMR is an independent predictor for a limited prognosis in concomitant heart failure.^{2,3} As MR patients are often affected by an elevated risk for perioperative mortality at mitral valve surgeries due to age and comorbidities, several interventional approaches (transcatheter mitral valve repair (TMVR)) with a transvenous approach have been implemented over the last years. While most evidence has been gained by the technique of edge-to-edge repair with Abbott MitraClip® (Abbott Vascular) comprising about 100 000 implantations up to now, direct mitral annuloplasty with Edwards Cardioband® (Edwards Lifesciences) aims on reversing the specific pathomechanism of annular dilatation in anatomically suitable subsets of FMR. The device is implanted by a transvenous, transeptal approach and consists of a flexible Dacron band, fixated by 12 to 17 metal anchors deployed by a steerable catheter system. Similar to other forms of TMVR, guidance of implantations demands on simultaneous visualization by 3D transesophageal echocardiography (TEE) and fluoroscopy. By final dynamic reduction of the implant's length, the system diminishes annular diameters. A feasibility trial was published recently reporting on a relevant reduction of MR severity⁴ by remodeling of the annulus⁵ and facilitating significant clinical benefit during a follow-up of up to 1 year.^{6,7}

While recommendations regarding echocardiographic imaging for percutaneous edge-to-edge repair are accepted and well-established (eg,^{8,9}), evidence and recommendations on optimal guidance for direct transcatheter annuloplasty are widely lacking. We developed a specific echocardiographic protocol, inheriting real time multiplanar reconstruction (MPR) for 3DTEE allowing optimal visualization of the anchoring points (for details, see Ref.10). In this monocentric analysis, we aimed to investigate the feasibility of this echo protocol for guidance of direct annuloplasty procedures and discuss potential benefits and challenges in comparison with "conventional" modes of 3DTEE visualization.

2 | METHODS

All patients consecutively treated by transcatheter direct annuloplasty (device: Edwards Cardioband®, Edwards Lifesciences) in our Heart Center from December 2015 to September 2017 were included in this monocentric observational analysis. Patients were adult individuals with symptomatic severe MR despite optimal medical treatment and, when appropriate, cardiac resynchronization therapy. MR severity and etiology were assessed according to standards of the EACVI recommendations¹¹ in four grades: 0

for no or trace MR, 1 for mild, 2 for moderate, and 3 for severe MR. Judgment on elevated individual risk for valve surgery by an interdisciplinary heart team board at baseline was based on established scoring systems (eg, logistic EuroSCORE I) as well as other individual factors like frailty or relevant comorbidities. Anatomical eligibility for percutaneous direct annuloplasty was evaluated by a protocol including TEE and CT scan and was approved by the manufacturer before implantation. All procedures were performed under general anesthesia.

Implantations were guided by experienced interventional echocardiographers. Recent echo scanners by GE (Vivid E95, GE Healthcare), Philips (EPIQ 7C(i), Philips Healthcare), and Siemens (Acuson SC2000 Prime, Siemens Healthcare) were employed. We used a dedicated 3DTEE protocol inheriting real time multiplanar reconstruction developed in our center and published recently (for details, see Ref.10 as well as Figures 1 and 2) for echocardiographic guidance of all procedures. In brief, the main steps of the echocardiographic protocol comprise the following:

- Guidance of the transeptal puncture: As in all transeptal procedures, identification of the fossa and determination of the optimal puncture height are the essential tasks; as in edge-to-edge repair

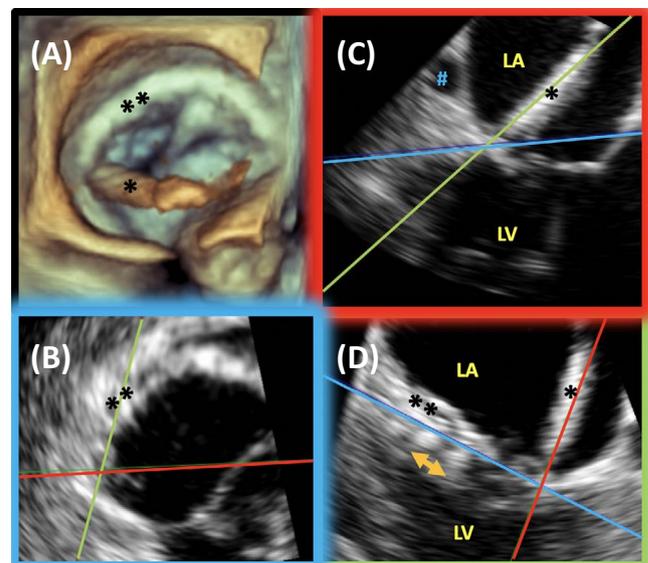


FIGURE 1 Real time 3DTEE guidance of a direct annuloplasty procedure using multiplanar reconstruction at an early stage of the implantation. (A) Real time 3D aspect, (B-D) derived 2D MPR planes: (B) "annular" plane through the mitral annulus; (C): centripetal plane; and (D): tangential plane, "cut" through the implantation catheter (*) during anchor implantation. The MPR-based protocol allows full orientation around the mitral annulus (B): "cutting" of the other MPR planes visible; LA = left atrium; LV = left ventricle as well as identifying optimal tissue contact (C) avoiding damage of leaflets and the coronary sinus (#). Furthermore, the previously implanted part of the device (marked by **, distance between implanted anchors is depicted by arrow in (D)) can be displayed, enabling a continuous control of a successful implantation. For further details, see text and Ref.10

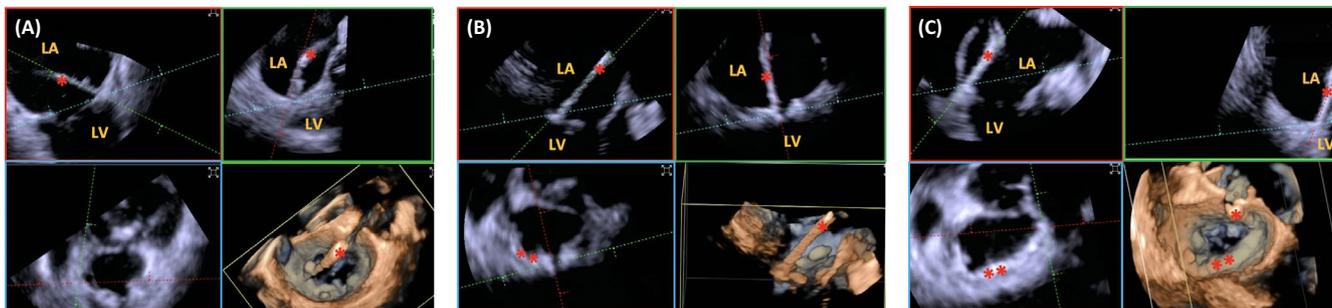


FIGURE 2 MPR-augmented TEE guidance during different stages of anchor implantation. Implantation of the devices-anchors at different stages of the procedure: (A) Implantation of the first anchor starting at the lateral segment of the posterior annulus. (B) Implantation of an anchor in the P2 region. (C) Placement of one of the final anchors in the septal region of the posterior annulus. LA = left atrium; LV = left ventricle; *: displayed parts of the implantation catheter; **: displayed parts of the implanted device. For further details, see Figure 1, text, and Ref.10

procedures, imaging in several 2D planes is satisfactory at this stage for most procedures.

- Guidance of the implantation catheter in the left atrium by real time MPR: After generating an optimal real time/single-beat 3D volume consisting of a “sufficient” compromise regarding optimal volume size (relatively large “atrial view,” including “near field” to visualize the catheter and the complete mitral annulus), and satisfactory temporal and spatial resolution, three individually adjustable 2D MPR planes are applied in a predefined manner. One plane is positioned on the height of the mitral valve annulus as orientation plane and remains unchanged during the whole deployment process; the other two planes are allocated on the momentaneous implantation site “cutting” through the implantation catheter (one plane orientated tangentially, the other centripetally in relation to the mitral annulus) and moved after each anchor implantation to the next target site of anchor implantation until all anchors are deployed. This approach of MPR-based guidance allows to visualize the annulus and all adjacent structures (coronary vessels) and the catheter in orthogonal views for each implantation site in an anatomically correct manner.

Primary efficacy endpoints of the retrospective analysis of our patient cohort after transcatheter direct annuloplasty included the following:

1. Technical success, as defined by MVARC (recommendations by the Mitral Valve Academic Research Consortium¹²): ability to deploy the device as intended (advancing the steering device in the anchoring positions, implanting the anchors to the tissue avoiding adjacent coronary vessels, and reducing the size of the mitral annulus by the dynamic reduction of the device) as well as successful retrieval of the delivery system without periprocedural mortality or need of emergency surgery or intervention.
2. Successful reduction of MR after implantation of the device at the end of the procedure, as assessed by echocardiography.

2.1 | Ethical aspect

Since the study involved an anonymized, retrospective analysis of diagnostic standard data, ethics approval was not required according to German law.

2.2 | Statistical analysis

Statistical analysis was conducted using SPSS software version 23 (SPSS Inc). Continuous variables are presented as mean (\pm standard deviation) or as median values (with interquartile range); categorical variables are expressed as percentages. Continuous variables, in which normal distribution was confirmed with the modified Kolmogorov-Smirnov test, were compared using Student's *t* test or in variables, in which normal distribution was denied, the Wilcoxon-Whitney U test was used for comparison. Categorical variables were tested with Fisher's exact or chi-square test, as appropriate. Only *P*-values $<.05$ were considered to be statistically significant.

3 | RESULTS

3.1 | Patients' baseline characteristics

Overall, sixteen patients (44% females) consecutively treated with transcatheter direct annuloplasty at the Heart Center University Medical Center Mainz until September 2017 were included in the present analysis. Leading etiology of MR was FMR (87.5%); additionally—and after approval of eligibility by the manufacturing company—one patient with a degenerative and one with a mixed pathomechanism were also included in the study. Median age at implantation was 79.6 years (IQR 58-86), and all patients were assessed to be at elevated risk for valve surgery (mean logistic Euroscore $22.0 \pm 13.4\%$); further baseline characteristics are shown in **Table 1**. All patients received Cardioband® devices of sizes C to F, each of

these fixated by 15 anchors in mean; one patient with a mixed and one with a functional pathomechanism were primarily treated by a combined therapy approach including an interventional edge-to-edge repair (both Abbott MitraClip®).

3.2 | Success rate and reduction of MR

Periprocedural technical success rate of transcatheter direct annuloplasty was high (93.8%). The device was successfully implanted in 15 patients. One implantation failed due to peri-interventional detachment of several anchors during an advanced stage of the procedure. As this patient was anatomically not eligible for another interventional treatment option like edge-to-edge repair and assumed to be at very high risk for an operative therapy, the loose end of the band was sutured on the septal side to avoid potential complications caused by a floating band and the patient was continued to be managed with optimal medical treatment. Starting all from severe MR pre-interventionally, MR could be significantly reduced to mild to intermediate MR on average by the procedure (statistical “mean” MR 1.22 ± 0.75 , see Figures 3 and 4). Two patients—those with not exclusively FMR etiology—were additionally treated with MitraClip® directly after the annuloplasty procedure to achieve further reduction of the MR, which remained peri-interventionally still mid- to severe MR grade after dynamic reduction of the device.

TABLE 1 Patients' baseline characteristics

Variable	Value
Age at procedure	79.6 (73.8/82.6) y
Female gender	43.8% (7)
Leading etiology of mitral regurgitation	
Degenerative	6.3% (1)
Functional	87.5% (14)
Mixed	6.3% (1)
Anchors used for Cardioband	15 (15/16)
Device success	93.8% (15)
LVEF (%)	$34.6 \pm 14.1\%$
NYHA class III or IV	75.0% (12)
Logistic EuroSCORE I	$22.0 \pm 13.4\%$
COPD	37.5% (6)
Atrial fibrillation	87.5% (14)
Coronary artery disease	50% (8)
Prior coronary artery bypass grafting	18.8% (3)
Renal impairment	50.0% (8)
Diabetes mellitus	37.5% (6)

Note: Data are presented as percentages (absolute values in brackets) or median and interquartile range/mean and standard deviation

3.3 | “Learning curve” and evolution of implantation times

With increasing numbers of treated patients, procedural duration decreased significantly revealing a “learning curve” of the interventionalists. Device time (defined as time from transseptal puncture to cinching of the anchors) ranged from 75 to 240 minutes (mean 140 ± 55 minutes). While mean duration of the first 4 procedures was still 213 ± 38 minutes, mean device time decreased to 108 ± 33 minutes ($P = .018$) in the most recent four patients (Figure 3). Fluoroscopy times could also be significantly reduced (initially up to 90 minutes; mean 63 ± 20 minutes; 83 ± 14 in the first vs 45 ± 12 minutes in the last 4 patients, $P = .018$), whereas the decrease in overall fluoroscopy dose-area products was also pronounced, but did not reach statistical significance ($12\,119 \pm 2571$ in the first 4 vs 6300 ± 4787 cgy*dm in the last four patients, $P = .311$).

4 | DISCUSSION

Transcatheter direct annuloplasty with implantation of the Edwards Cardioband® is a novel and promising approach for treatment of symptomatic FMR in selected patients with a relatively high technical success rate and sufficient results in kind of MR reduction up to 1 year.^{4,6,7}

Guidance of each kind of TMVR is performed by a combination of fluoroscopic and echocardiographic imaging, usually performed using real time 3D modalities (Figure 5). Echocardiography enables the real time visualization of tissue structures and is considered to have at least the same relevance as fluoroscopy during interventional procedures.¹³ Optimal positioning and safe deployment of the device is the crucial step to achieve technical and procedural success for each kind of TMVR. While a distinct screening protocol has been elaborated by the manufacturing company, evidence as well as recommendations on optimal peri-interventional echocardiographic visualization and guidance for transcatheter direct annuloplasty is still lacking.

4.1 | Real time 3D MPR as augmentation of “conventional” 3DTEE—challenges and advantages in comparison with “conventional” echo guidance of TMVR

We developed and tested an advanced 3DTEE protocol inheriting the additional use of real time MPR to suit the specific needs for guidance of this kind of TMVR. Whereas MPR planes derived from 3D datasets are a widely used tool in diagnostic radiology, this feature has become available in most recent echo scanners, but still gained limited impact into daily practice of real time interventional guidance up to now. In comparison with other forms of TMVR, the intricacy of echocardiographic guidance for direct transcatheter annuloplasty is relevantly increased: Multiple anchors have to be

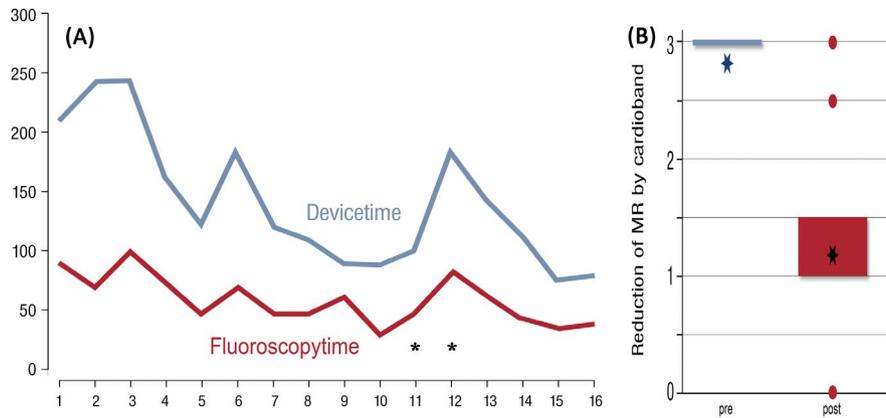


FIGURE 3 Development of device times and immediate reduction of mitral regurgitation. (A) Development of device times implementing the MPR-based 3DTEE protocol. Please note, for procedures 11 and 12, additional edge-to-edge repair was performed (*). A similar trend can be observed for the fluoroscopy times. (B) Reduction of mitral valve regurgitation (MR) by interventional direct annuloplasty; MR assessed in severity grades 0/no or trace to 3/severe as proposed by EACVI recommendations¹¹ before and after the procedure

positioned in an anatomically correct manner starting in the lateral posterior (P1) and advancing to the medial posterior (P3) segment of the mitral annulus (Figure 2) and fixated in the myocardial tissue

sparing neighboring structures like the coronary sinus and the circumflex artery. By dynamic reduction of the device, remodeling of the mitral annulus is achieved.⁵ The aim of echocardiographic guidance is enabling a safe positioning of the anchors in a “landing zone” predefined by the screening CT scan. Theoretically, an anatomically correct imaging including exact orthogonal views might be beneficial

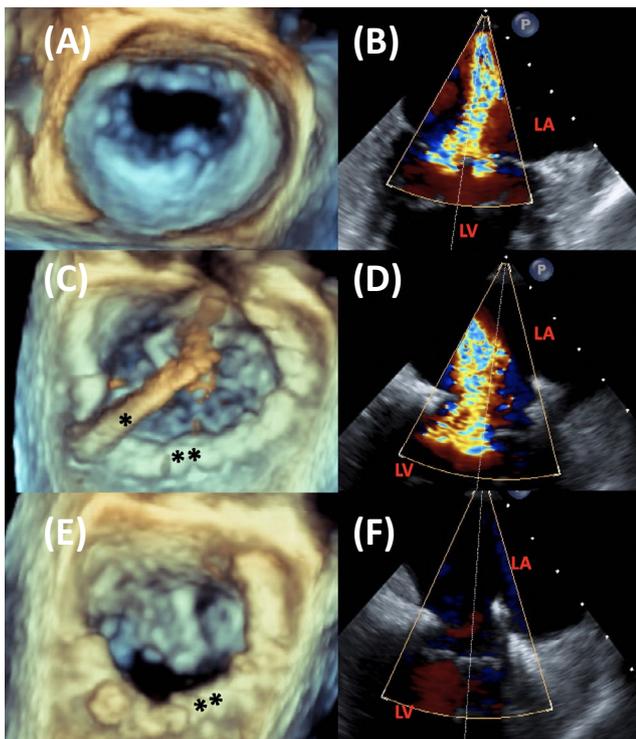


FIGURE 4 Successful implantation of a transcatheter direct annuloplasty and peri-interventional reduction of the mitral regurgitation. Three-dimensional overview (TEE) and color Doppler imaging of the grade of mitral regurgitation (MR) at different stages of the procedure: (A,B) Initial echocardiographic aspect of a severe functional MR, caused by annular dilatation. (C,D) Echocardiography after implantation of the devices' anchors before dynamic reduction of the band, still showing severe MR at this stage of the procedure. (E,F) Final result after dynamic reduction of the device: direct reduction from severe grade to trace MR by remodeling of the annulus. LA = left atrium; LV = left ventricle; * displayed parts of the implantation catheter; ** displayed parts of the implanted device

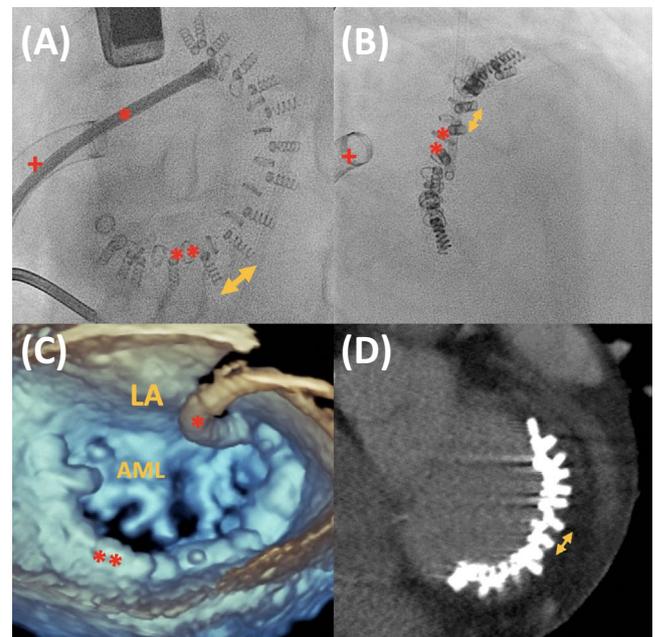


FIGURE 5 Aspects of a transcatheter direct annuloplasty procedure by different imaging modalities. Different imaging modalities of transcatheter direct annuloplasty. (A, B) Fluoroscopic aspects in different angulations (device catheter [marked by asterisk *] via transeptal sheath [+] still in situ in (A) showing the devices' anchors (distance of two anchors depicted by arrow, device marked by **) after implantation in the mitral annulus. (C) Echocardiographic aspect at this stage (3D overview; AML = anterior mitral leaflet; LA = left atrium). (D) Reconstruction from cardiac CT after devices' implantation showing the device and anchors in situ

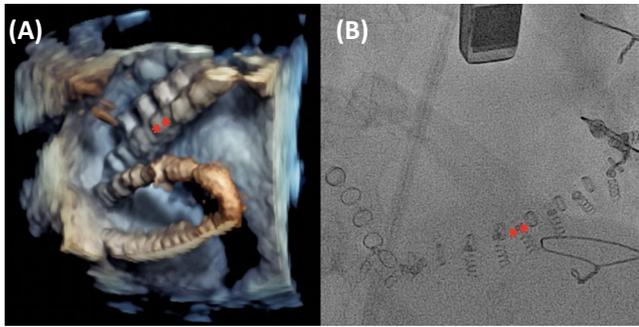


FIGURE 6 Technical device failure in one patient: Image of technical failure by detachment of anchors; the procedure was finalized by fixation of the “pendulating” part of the device (**) in the septum: echocardiographic (A) and fluoroscopic (B) aspect during the procedure (for details, see text)

compared to “conventional” techniques of two- and three-dimensional echocardiography.

These “conventional” modes, which are commonly used for the guidance of many forms of TMVR, comprise imaging of real time full 3D volumes as well as simultaneous visualization of two or more 2D planes, which are centripetally orientated to the probe center (eg, “biplane” mode). On the one hand, these two standard modalities have very limited options to exert true axis imaging—especially when the “object of interest” is situated rather “peripherally” of the volume, as the probe’s positioning is usually rather restricted by anatomical structures (esophagus, stomach in TEE). On the other hand, the still rather flexible orientation and its rapid and quite easy usage as well as the excellent temporal and spatial resolution of images (in, eg, biplane) enable a very steep learning curve and a substantial benefit even when used by echocardiographers with limited experience. Nevertheless, these restrictions of “conventional” forms of 3D imaging modalities are not problematic for several forms of TMVR including edge-to-edge repair, as here the devices are mainly placed very “central” in the atrial-orientated TEE view.

Yet, technically advanced procedures like transcatheter direct annuloplasty have different needs on TEE guidance, and here, “fixed” planes often do not entail true axis visualization with respect to the more “peripheral” structures like those situated around the mitral annulus. By MPR-based imaging as augmentation to “conventional” 3DTEE, anatomically correct visualization of the mitral annulus, mitral leaflets, and the delivery catheter is possible in order to assure perpendicularity and optimal tissue contact before starting anchoring (Figures 1 and 2). Of course, the sequence of adjusting MPR planes for true axis visualization has to be repeated for every single anchor. Certainly, this advanced protocol for 3DTEE guidance is accompanied by some additional endeavor even for experienced interventional echocardiographers at the beginning; nevertheless, in our cohort, we could show it is feasible and safe. After a phase of learning, an MPR-based protocol might even be able to expedite implantation times. Furthermore, an anatomically correct MPR-based imaging might be beneficial regarding safety of the procedure by optimal visualization of soft

tissue structures adjacent to the mitral annulus during every step of the procedure.

An expert consensus statement on core competencies in echocardiography for imaging in structural heart disease interventions published recently emphasizes the need for a distinct educational training pathway for interventional echocardiography specialists, being a fully integrated part of the procedural team to facilitate optimal results.¹⁴ Furthermore, availability of real time fusion imaging (integration of TEE or CT in fluoroscopic visualization) has enriched advanced guidance for transcatheter structural heart interventions (eg,^{15,16}). Nevertheless, implementation of MPR in 3DTEE might be the key to optimal true axis visualization of soft tissue structures in the context of these contemporary developments.

Thus, we think a profound knowledge of MRP-augmented imaging enhances the spectrum of advanced peri-interventional imaging tools to enable maximum accuracy and safety in centers offering all available forms of transcatheter therapies.

4.2 | Results of our monocentric experience with transcatheter direct annuloplasty inheriting advanced echocardiographic guiding with MPR

Showing a relevant reduction of MR by the device, the results of our initial implantation experience are similar to those of the feasibility trial.⁴ We observed a large reduction of procedure times employing the MRP echocardiographic modality starting from up to four hours to under two hours; mean procedure time was even shorter (140 ± 55 minutes) in our study than in the feasibility trial (165 ± 44 minutes⁴). Our success rate was 93.8% (comparable to 93.6% in Ref.4). One of our first patients encountered implantation failure by partial detachment of previously implanted anchors (Figure 6); in the early phase of device implantations, this technical problem has been reported by other centers as well and the manufacturer modified the implantation protocol in the meantime. No other relevant complications were observed; in all cases, echocardiographic guidance allowed safe release of the anchors without injury of adjacent structures like the coronary sinus or the circumflex artery.

4.3 | Limitations

The present study has several limitations, caused by its retrospective observational design. All implantations were performed under echocardiographic guidance according to the protocol described without the control group. Of course, a statistical quantification of potential superiority of 3D echo guidance implementing the additional feature of MPR against “conventional” 3DTEE remains putative until confirmation by a randomized study. Patients’ eligibility for the device implantation had to be approved by the manufacturing company for all procedures; thus, a selection bias cannot be excluded.

5 | CONCLUSIONS

Multipolar reconstruction has become available as additional feature on most recent TEE scanners. We demonstrated the feasibility and safety of the routine use of a real time MPR-based 3DTEE protocol for transcatheter direct annuloplasty and observed a substantial and continuous reduction in procedure time. As the variety of interventional devices dedicated to interventional valve repair or replacement is expected to increase, we propose that MPR-based echocardiography protocols will represent an important milestone to facilitate safe implantations for advanced procedures.

ACKNOWLEDGMENTS

Thomas Münzel is PI of the DZHK (German Center for Cardiovascular Research), Partner Site Rhine-Main, Mainz, Germany. The authors are responsible for the contents of this publication. We thank Margot Neuser for the support in realization of graphic illustration of the results.

CONFLICT OF INTERESTS

Felix Kreidel reports having received consultancy and lecture honoraria from Abbott, Cardiac Implants, and Edwards Lifesciences. Andres Beiras-Fernandez reports having received lecture honoraria from Edwards and consultancy from Abbott and NeoChord. Eberhard Schulz reports having received lecture honoraria from Edwards Lifesciences and Medtronic. Ralph Stephan von Bardeleben reports having received consultancy and lecture honoraria from Abbott Structural Heart, Boehringer Ingelheim, Cardiac Dimensions, Edwards Lifesciences, GE Health Systems, and Philips Healthcare. Martin Geyer, Efthymios Sotiriou, Karsten Keller, Alexander R. Tamm, Tobias F. Ruf, Angela Kornberger, Yang Yang, Tilman Emrich, and Thomas Münzel have no conflict of interest to declare.

ORCID

Martin Geyer  <https://orcid.org/0000-0002-9935-8293>

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How to cite this article: Geyer M, Sotiriou E, Keller K, et al. Feasibility of a MPR-based 3DTEE guidance protocol for transcatheter direct mitral valve annuloplasty. *Echocardiography*. 2020;37:1436–1442. <https://doi.org/10.1111/echo.14694>