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Research Article

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Clinical Evaluation of a Mitral Valve Simulation Application Used to Support Planning of Transcatheter Edge to Edge Repair Procedures

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Abstract

Background: Transcatheter mitral valve edge-to-edge repair (M-TEER) in the setting of severe mitral regurgitation (MR) has experienced increased usage in recent years. To select appropriate candidates and plan for these procedures, the cardiologist must predict likely procedural outcomes dependent on factors such as clip type, size, and position. We have proposed a method to utilize computed tomography (CT) images to generate a patient specific procedural simulation model that allows these variables to be tested to support clinical decision making in patients undergoing M-TEER procedures.

Objectives: To compare the mitral valve simulation (MVS) prediction with the prediction generated by expert cardiologists to assess whether MVS is comparable to expert cardiologist in predicting residual MR post M-TEER.

Methods: The severity of residual MR post M-TEER device implant was predicted by MVS and by expert readers, using either pre-procedural trans esophageal echocardiography (TEE) or CT imaging. The MVS and expert reader predictions were compared to a ground truth (GT). The accuracy between MVS and GT, and expert cardiologists and GT were calculated.

Results: We found that when comparing the error of predicted effective regurgitant orifice area (EROA) from MVS to GT, and expert readers to GT, the mean error is smaller between GT and MVS than between GT and expert readers. These results suggest that the accuracy of post-procedural EROA estimation by MVS is equivalent to the accuracy of expert cardiologists' predictions.

Conclusion: The predicted reduction in MR related to clip placement generated by the MVS software demonstrates a strong correlation to GT and suggests that results are comparable to the predictions by expert readers. The findings of this study suggest that the MVS application can generate a prediction of the residual MR that is accurate, and consistent.

Keywords

Valvular heart disease, Mitral regurgitation, Transcatheter mitral valve edge-to-edge, Procedural simulation, Automated measurements, Procedural planning

Introduction

The use of TEER of the mitral valve (MV) in the setting of severe MR has seen increasing usage in recent years [1, 2]. Currently the most frequently

used devices for MR are the MitraClip (Abbott Laboratories, Abbott Park, Illinois) [3] and the PASCAL transcatheter valve repair system (Edwards Lifesciences, Irvine, California) [4]. As the range of options for M-TEER interventions increase, with devices of various sizes and designs becoming available, the candidate pool for these procedures also continues to increase [5]. Candidate selection is based on clinical assessment and information provided by various diagnostic imaging modalities, such as CT and echocardiography [6]. At present, the heart team, imaging specialist, and interventionalist must consider imaging data from several sources, internalize this data, and determine a procedural plan based on variables such as device type, size, device placement, and patient specific anatomy and hemodynamics. The goal of this integrated approach is to achieve the lowest possible post-procedural residual MR.

We believe that tools designed to support planning of the M-TEER procedure by predicting procedural outcome based on device selection, the number of devices required and device placement in an accurate and reliable manner could provide significant benefit. If this tool provides accurate information pertaining to valve structure, function, and hemodynamics, it could be used as a test bed for clinicians to evaluate the impact of device sizing and positioning in a simulated model to optimize outcomes and circumvent potential problems such as residual MR or flow obstructions.

Our group has previously described the development of MVS tool, which is a simulation application based on a valve deformation model to simulate EROA and a lumped parameter model to simulate regurgitant volume (RVol) [7]. This *in silico* model is tailored to the individual patient's anatomy and pathophysiology. In this process, CT or TEE are used for a valve deformation model and CT is used for the lumped parameter model. We propose that MVS has the potential to allow the type of device, the size, and the placement to be tested in the model at the time of procedural planning to determine the efficacy and optimal approach to treat the individual patient.

The objective of this study is to compare the MVS prediction with the prediction generated by expert cardiologists to assess whether MVS is comparable to expert cardiologist in predicting residual MR post M-TEER.

Methods

Study population

In this study, two study populations with MR in need of M-TEER were recruited for validation of two MVS metrics. The study was conducted as an internal procedural quality assessment project, with anonymization of all patient identifications and according to contemporary practice at the time a waiver of informed consent in place.

Inclusion criteria of the first population for the study required that the patient had a pre-procedural TEE performed within one month of the M-TEER procedure that included an entire cardiac cycle and a frame rate >30 Hz. These patients also required a TEE study performed during the MitraClip procedure with pre and post clipping data that included three dimensional (3D) TEE, Doppler, and standard echocardiographic imaging, that captured the entire MV. These studies included the pre and post images for each device, if more than one device was used. We excluded the data in which the TEE images contained large artifacts. This study population included 6 patients that had undergone a total of 10 MitraClip (age 82 ± 5, 5 male) for treatment of severe MR, and that had a pre-procedural and intra-procedural TEE. Each case underwent one procedure which used one or two devices.

The second study population required pre-procedural full R-R cycle CT images in addition to the data required for the first study cohort. The inclusion criterion required an entire cardiac cycle and at least 20 phases and we excluded the data which the TEE images contained large artifacts. The study population included 4 patients that had undergone total of five MitraClip procedures (age 79 ± 4, 3 male) for treatment of severe MR.

Aside from these criteria, patient selection was based on retrospective data from patients reviewed by The Heart Team that were evaluated and referred for M-TEER using the institution's selection criteria. The Heart Team reviewed the diagnostic imaging studies in addition to the patient's history and clinical status to determine eligibility for the procedure.

Evaluation overview

The evaluation overview is shown in figure 1 and is conducted in five steps. 1) segment the MV and 4 chamber region from 3D images with approval of a physician external to the readers group, 2) identify the device placements for actual post-procedure by GT reader, who is an expert interventional cardiologist, 3) calculate the EROA based on post-procedural images as GT by GT reader, 4) predict post-procedural EROA and RVol by MVS and three readers based on pre-procedural information, and 5) analyze the prediction results from MVS and the three readers.

The MVS uses postprocedural EROA and RVol as evaluation metrics because they are quantitative indices of the MR grade defined in the American Society of Echocardiography [6] guidelines. The regurgitant fraction percentage (RF%) calculation by MVS was not included in

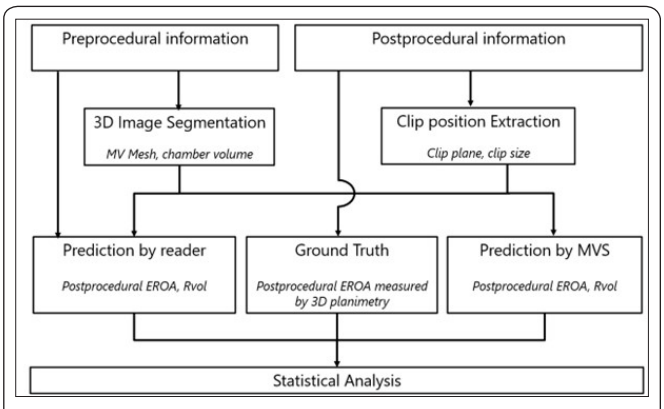


Figure 1: Evaluation overview in this study. MVS and reader predict EROA and Rvol using pre-procedural information, respectively. GT reader measured EROA by 3D planimetry method using post-procedural CT images.

this evaluation because the retrospective post-procedural data did not contain the information required to measure RF%.

In clinical practice, the severity of MR is often assessed using a 4-step grading schema that is based on multiparametric echo/Doppler measurements, rather than the quantitative EROA and RVol. For this reason, the results of the MVS measurement of EROA were converted to a corresponding MR grade.

3D image segmentation

As one of the pieces of information for prediction by MVS and readers, MV leaflets are manually segmented from pre-procedural 3D TEE imaging in both study populations. The four heart chambers are also segmented manually from pre-procedural CT in the second study population. These four heart chamber segmentations are used by MVS to decide the patient-specific simulation parameter to estimate the MV regurgitation volume. Furthermore, post-procedural MV leaflets are also segmented manually from post-procedural 3D TEE to be used for intermediate validation for performance of MVS. These segmentations were performed by engineers using in-house software and validated by a physician external to the readers group.

Device position extraction

We extracted the specific cross section as a device position. A schematic diagram to extract device position is shown in figure 2. The cross section in the post-procedural TEE image through the center of MitraClip and perpendicular to the gripping surface was created by an echo cardiologist and validated by the GT reader, that reviewed the pre-procedural, procedural, and post-procedural TEE study, the procedure reports, and follow up trans thoracic echocardiography (TTE). Moreover, the alignment of the pre-procedural MV geometry

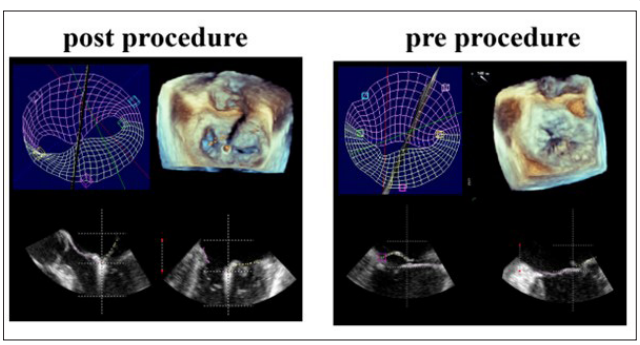


Figure 2: Method to extract device position. Left shows the cross-section set based on the device visualized in the post-procedural 3D TEE and the right shows the position of that cross-section converted to the pre-procedural 3D TEE.

to cross section is determined from the alignment of post-procedural MV geometry, pre-procedural MV geometry and post-procedural cross section.

GT creation

GT of EROA is established by the GT reader based on the pre-procedural, procedural, and post-procedural images. Due to difficulties in the calculation of proximal isovelocity surface area (PISA) with the retrospective data we had available, the planimetry method was used to measure EROA. According to previous studies, the measurement values obtained by the PISA method and the 3D planimetry method correlated with r = 0.93 [8]. With reference to previous research, in this study, the measurement values obtained by the 3D planimetry method were used directly as the EROA. There is a potential source of error associated with the planimetry method related to the selection of the orthogonal plane used to perform measurements, and the small size of the incompetent orifice being planimetered. Because the measurement results of the planimetry method can vary depending on the cross section measured. The cross section and measurements were carefully measured using both the cross-sectional 2D image and the color Doppler cross sectional area of the regurgitant jet at the narrowest level. Measurements were performed by an experienced cardiac sonographer and then accepted by GT reader.

Prediction by the MVS

The overview of our framework to predict the effect of edge-to-edge repair is shown in previously published paper [9]. In the first step, the patient-specific model is built utilizing the segmentation results. Segmented MV geometry at valve open phase is utilized for the MV dynamics model, which is the part of MVS, and simulation parameters are optimized using covariance matrix adaptation evolution strategy comparing segmented and simulated MV geometry at the valve closed phase. The simulated MV geometry of the closed phase is calculated using the finite element method, with the segmented geometry of the open phase setting to initial simulation time. The displacement of annulus in simulation is given as a constraint based on the one in the segmentation results. A lumped parameter model which is the second part of MVS uses the segmented chamber and RVol to optimize simulation parameters. In the second step, the post device simulation is carried out. We add the device conditions such as number of devices, position, and the device size to the pre-procedural model, which is personalized in the first step. After that, we conduct the valve deformation simulation to predict MV geometry with the device at closed phase and calculate EROA. Finally, RVol is estimated by inputting EROA calculated from valve deformation simulation to lumped parameter simulation.

Prediction by reader

Expert readers consisted of cardiologists (members of the heart team) with M-TEER experience that evaluate candidates for M-TEER procedures and were blinded to the MVS results and GT. This group had access to pre-procedural TEE and TTE studies, and pre-procedural patient files. They were informed of the device positions and device sizes set by the GT reader and the segmentation results extracted from the pre-procedural 3D TEE and CT, if present. They were asked to predict EROA, RVol, based on first and subsequent device placement(s). Prediction results were input by moving a slide bar utilizing an in-house prediction recording tool.

Statistical analysis

Continuous parameters were given as mean and standard error (±SE).

For EROA, first, the GT reader measures the post-procedural results to be used as GT. Next, the difference between the predicted results of MVS and GT is calculated, and the difference between the reader's predicted results and GT is also calculated. A one-sided t-test at a significance level of 0.05 is then performed on each of these differences.

Because it was not possible to obtain the echo/Doppler data required to measure the flow rate through the MV, which is used for measuring RVol, it was decided to calculate the correlation between the EROA measured by MVS and the readers. For verification, Pearson's correlation coefficient is used, with the significance level set at $p < 0.05$. All statistical analyses were performed using statistical package for the social sciences (SPSS) (IBM, New York, USA).

Results

The MV geometry of four representative cases in the closed phase, obtained from post-procedural 3D TEE or predicted by MVS, are shown in figure 3. Since the annulus shape is given as a boundary condition in MVS, the shape coincides with the segmented pre-procedural closed phase shape. In patient 1, the prolapse area remained on the septal side in both GT and MVS and near the center in patient 2. In patients 3 and 4, there is no outstanding prolapse region in any area for both MVS and GT. In patient 2, the prolapse area of both GT and MVS remained on the center, but the detailed prolapse position differs slightly in GT and MVS.

Table 1 shows the measurement or prediction of EROA for each subject. The mean value and standard deviation (SE) for GT is 15.84 ± 5.50, while for MVS it is 18.09 ± 3.93. The 95% confidence interval (CI) are 16.19 - 28.27 and 18.34 - 26.99, respectively, indicating a slightly higher trend for MVS. The mean values and SE for reader 1, 2, and 3 are 17.89 ± 2.30, 21.20 ± 2.53, and 12.30 ± 2.83, respectively. The mean value of reader 2's prediction is the highest, while reader 3 is the lowest.

Table 2 shows error in each patient for MVS and the reader. Mean error and SE for MVS is 6.90 ± 2.34, while for reader 1, 2, and 3 they are 13.95 ± 2.62, 15.23 ± 3.19, and 11.95 ± 2.84, respectively. MVS has the smallest error, and reader 2 has the largest error.

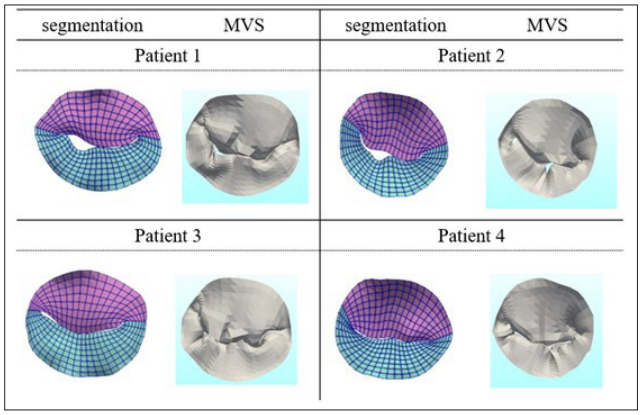


Figure 3: The MV geometry of four representative cases in the closed phase in each patient, GT created by manual segmentation is shown on the left and prediction by MVS is shown on the right.

Table 3 shows the statistical analysis of the difference between MVS error and reader's error, and figure 4 shows a box plot of the error in EROA. The box plot indicates that MVS had the smallest median error (MVS = 5.89, reader 1 = 12.30, reader 2 = 13.50, reader 3 = 8.00, respectively). The error of MVS is 6.16 ± 2.88 smaller than that of reader 1 and 7.28 ± 3.05 smaller than that of reader 2, and the error of MVS is significantly smaller than reader 1 and reader 2 ($p < 0.05$). The error of MVS is on average 4.80 ± 3.00 smaller than that of reader 3, but this difference is not statistically significant ($p = 0.071$).

The results of converting EROA to MR grade for each patient are shown in table 4. Reviewing the MR grades of GT, all patients undergoing two devices yielded the result of a moderate MR in first device and mild after deployment of the second device.

The agreement of MR grade with GT is shown in table 5. As a result, the agreement rate between the MR grade converted from GT and prediction from reader 1 and reader 3 are 80%, and expert reader 3 are 70%. On the other hand, the

Table 1: Measurement or prediction of EROA for each subject.

Patients	GT	MVS	Reader 1	Reader 2	Reader 3
Patient 1 (1st device)	22.74	26.01	24.00	26.00	5.00
Patient 1 (2nd device)	0.00	6.79	14.00	13.00	0.00
Patient 2 (1st device)	26.37	26.53	21.00	28.00	22.00
Patient 2 (2nd device)	0.00	0.90	14.00	14.00	5.00
Patient 3 (1st device)	0.00	22.87	20.00	22.00	18.00
Patient 4 (1st device)	31.61	23.18	21.00	22.00	26.00
Patient 4 (2nd device)	0.00	8.91	9.00	24.00	10.00
Patient 5 (2nd device)	38.79	33.79	8.00	9.00	9.00
Patient 6 (1st device)	38.85	30.92	32.00	36.00	22.00
Patient 6 (2nd device)	0.00	1.01	15.00	18.00	6.00
Mean ± SE	15.84 ± 5.50	18.09 ± 3.93	17.89 ± 2.30	21.20 ± 2.53	12.30 ± 2.83
95% CI	16.19 - 28.27	18.34 - 26.99	17.95 - 23.00	21.36 - 26.92	12.48 - 18.71

Note: The unit of each measurement is mm^2.

Table 2: Error in each patient for MVS and the reader. The error is calculated as the absolute error between GT and the prediction or MVS.

Patients	MVS error	Reader 1 error	Reader 2 error	Reader 3 error
Patient 1 (1st device)	3.27	1.26	3.26	17.74
Patient 1 (2nd device)	6.79	14.00	13.00	0.00
Patient 2 (1st device)	0.16	5.37	1.63	4.37
Patient 2 (2nd device)	0.90	14.00	14.00	5.00
Patient 3 (1st device)	22.87	20.00	22.00	18.00
Patient 4 (1st device)	8.43	10.61	9.61	5.61
Patient 4 (2nd device)	8.91	9.00	24.00	10.00
Patient 5 (2nd device)	5.00	30.79	29.79	29.79
Patient 6 (1st device)	7.92	6.85	2.85	16.85
Patient 6 (2nd device)	1.01	15.00	18.00	6.00
Mean ± SE	6.90 ± 2.34	13.95 ± 2.62	15.23 ± 3.19	11.95 ± 2.84
95% CI	1.61 - 12.19	8.02 - 19.88	8.01 - 22.46	5.53 - 18.37

Note: The unit of each measurement is mm^2.

Table 3: Statistical analysis of the difference between MVS error and reader error.

Difference	Mean ± SE	P-value
MVS error to reader 1 error	-6.16 ± 2.88	0.03*
MVS error to reader 2 error	-7.28 ± 3.05	0.02*
MVS error to reader 3 error	-4.80 ± 3.00	0.071

Note: The superscript * indicates that $p < 0.05$.

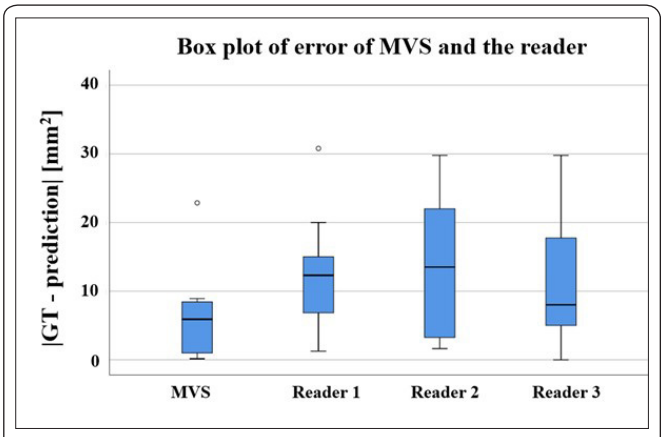


Figure 4: Box plot of the difference error of MVS and the reader. The error is calculated as the absolute error between GT and the prediction or MVS.

agreement rate between the MR grade converted from GT and prediction from the MVS is 90%, which is found to be higher than MVS and readers.

Table 6 shows that measurement or prediction of RVol for each subject. Reader 2 has the highest mean value and the widest confidence. MVS has the lowest mean value and a relatively narrow confidence interval, suggesting more consistent measurements compared to reader 2. Reader 1 and reader 3 have similar mean values and CI, indicating comparable performance in their measurements.

Table 7 shows statistical analysis of RVol of the difference between MVS error and reader error. There is a strong positive correlation between MVS and reader 1 ($r = 0.949$, $p < 0.005$). On the other hand, the negative correlation between MVS and reader 2 ($r = -0.492$) and the moderate positive correlation between MVS and reader 3 ($r = 0.685$) are not statistically significant ($p = 0.321$ and $p = 0.133$, respectively).

Regarding correlation between readers, the weak negative correlation between reader 1 and reader 2 ($r = -0.261$) and the

Table 5: Number of agreement of MR grade with GT. Total patients are 10.

	GT-MVS	GT- reader 1	GT- reader 2	GT- reader 3
Agreement of MR grade	90%	70%	80%	80%

Table 4: MR grade calculated from EROA in each patient by GT, MVS, and the reader.

Patients	GT	MVS	Reader 1	Reader 2	Reader 3
Patient 1 (1st device)	Moderate	Moderate	Moderate	Moderate	Mild
Patient 1 (2nd device)	Mild	Mild	Mild	Mild	Mild
Patient 2 (1st device)	Moderate	Moderate	Moderate	Moderate	Moderate
Patient 2 (2nd device)	Mild	Mild	Mild	Mild	Mild
Patient 3 (1st device)	Mild	Moderate	Moderate	Moderate	Mild
Patient 4 (1st device)	Moderate	Moderate	Moderate	Moderate	Moderate
Patient 4 (2nd device)	Mild	Mild	Mild	Moderate	Mild
Patient 5 (2nd device)	Moderate	Moderate	Mild	Mild	Mild
Patient 6 (1st device)	Moderate	Moderate	Moderate	Moderate	Moderate
Patient 6 (2nd device)	Mild	Mild	Mild	Mild	Mild

Table 6: Prediction of RVol for each patient.

Patients	MVS	Reader 1	Reader 2	Reader 3
Patient 1 (1st device)	18	17	15	2
Patient 2 (2nd device)	13	24	35	28
Patient 3 (1st device)	6	16	65	15
Patient 4 (1st device)	4	19	55	32
Patient 5 (1st device)	58	55	36	55
Patient 5 (2nd device)	37	33	2	33
Mean ± SE	22.67 ± 8.55	27.33 ± 6.09	34.67 ± 9.64	27.50 ± 7.33
95% CI	0.68 - 44.66	11.67 - 42.99	9.88 - 59.45	8.65 - 46.35

Note: The unit of each measurement is ml.

Table 7: Statistical analysis of RVol of the difference between MVS error and reader error.

Difference	r	P-valve
MVS to reader 1	0.949	<0.005
MVS to reader 2	-0.492	0.321
MVS to reader 3	0.685	0.133
Reader 1 to reader 2	-0.261	0.618
Reader 2 to reader 3	0.033	0.95
Reader 1 to reader 3	0.685	0.026

Note: r is the correlation coefficient.

negligible correlation between reader 2 and reader 3 (r = 0.033) are shown, but also not significant (p = 0.618 and p = 0.95, respectively). On the other hand, there is a moderate positive correlation between reader 1 and reader 3 (r = 0.685, p = 0.026).

These results indicate a strong correlation between MVS and reader 1, and a significant correlation between reader 1 and reader 3, while the other correlations are not statistically significant.

Discussion

In recent years, the commercialization of physical simulations for treatment planning in cardiovascular field has been actively progressing. For example, the DASI simulation has obtained Food and Drug Administration (FDA) approval [10] for precision transcatheter aortic valve implantation (TAVI™) which supports TAVI treatment planning, and FEops. FEops HEARTguide™ [11] which received FDA approval for left atrial appendage closure (LAAC) and cardiac echocardiography marks for both LAAC and TAVI [12, 13]. The number of hospitals introducing these products is increasing year by year. The MVS developed by our group is a simulation for M-TEER, so the target treatment differs from existing products, but it may be used in a similar way as existing products. We believe that with the complexity of the MV apparatus, the increasing number of devices and sizing options, and expanding procedural approaches available to treat MR, an accurate method of generating an individualized simulation model of the MV has the potential to improve efficacy and efficiency of TEER procedures.

In this study, we evaluate the performance of MVS, which is an *in silico* model for predicting post M-TEER status, by comparing its predictions with those generated by readers. To the best of our knowledge, this is the first study to validate an *in silico* model for predicting EROA and RVol through comparison with physicians.

In the post-procedural MV geometry in the closed phase shown in figure 3, it is visually confirmed that prolapse region roughly matched between GT and MVS in all cases. Furthermore, as shown in table 2, the mean error and SE of EROA calculated from the difference from MVS to GT is 6.90 ± 2.34 [mm^2]. It suggests that MVS can predict EROA with some degree of accuracy, which is an important prognostic indicator for M-TEER, as well as the geometry around the valve orifice which is used to calculate EROA.

Comparing the prediction results of MVS and readers, it is found that MVS has the smallest median error, 5% confidence limit, 95% confidence limit and SE. In addition, p-value of the difference between the MVS error and the error of reader 1 is under 0.05, for reader 2 it is also under 0.05, and for reader 3 it is 0.07. Our results suggest that when predicting the post-procedural residual EROA, the MVS error is smaller and exhibits less variability than the reader's error.

When the prediction is based on a standard grading system of MR severity rather than the EROA, the results of readers and MVS predictions are closer, though the error is still less for the MVS prediction. Although this study is a small single-center study with N = 10, it is possible that MVS may still demonstrate superiority when converted to MR grades commonly used in clinical practice, so it would be worthwhile to verify this index in a larger scale study.

For the predicted RVol for both readers and MVS shown in table 6, the prediction from reader 2 shows the highest mean and variability compared to the other readers and MVS. Furthermore, from table 7, it is found that MVS is highly correlated with reader 1 and reader 3, and that the correlation between reader 2 and MVS is similar to the correlation between reader 2 and other readers. From these results, it can be concluded that reader 2 exhibits greater variability compared to the other readers, and the evaluations by MVS tend to be closer to those of reader 1 and reader 3. In the results of MR severity converted from EROA, readers' predictions have an accuracy of 70% to 80%, so the consequence that two readers and the MVS showed similar trends suggests that the MVS can estimate RVol with similar accuracy as the physician.

Next, we discuss the applicability of MVS to clinical practice. In the clinical setting, prognosis after M-TEER is estimated using MR grade, which is predicated on multiple quantitative and qualitative indices. Due to the difficulty of interpreting qualitative indices in MVS algorithm and the calculation time, the indices calculated by MVS are only EROA and RVol. However, since MVS can predict EROA and RVol to the same extent as experienced cardiologists, MVS may have a certain degree of clinical usefulness.

Our intention moving forward is to a) refine the quantitative measurement of EROA and RVol after placement of the M-TEER device to improve quantitative assessment of residual MR, b) expand the study population in terms of number of procedures and diversity in patient populations, and c) achieve a better understanding of how patient and disease phenotypes influence outcomes predictions by MVS.

Limitations

Our study has several limitations. First, this is a retrospective, single-center study and subject to the inherent limitations of observational studies. In future evaluations we will expand this group to include a larger number of patients undergoing M-TEER with both a single device and multiple devices.

Furthermore, it should be noted that as four of these patients had multiple devices, the reading physicians could make inferences regarding the efficacy of the first device. For example, in patients with two devices placed, it can be inferred that MR severity does not sufficiently decrease with the placement of just one device. In addition, because all three readers who performed the predictions are highly skilled experts, the results of the comparison with doctors may not be generalizable. These limitations carry the risk of underestimating the performance of MVS.

As mentioned in the methods section, we faced difficulties in measuring EROA using PISA. To address these limitations with the PISA method, we also performed direct planimetry of the regurgitant orifice from the 3D TEE derived multiplanar reconstruction images. This approach was predicated on the ability to ascertain that the smallest orifice had been adequately visualized, and that the borders of these relatively small orifices could be accurately measured. It was operator dependent and very time consuming. As discussed, the reliance on PISA and direct planimetry is problematic in that they are both prone to measurement error and can be somewhat difficult to apply in certain conditions pre and post procedurally. It will be necessary to determine the most practical means of accurately determining EROA and RVol to achieve more precision in comparing prediction to outcome.

Because there were no suitable post-procedural images for RVol measurements, the RVol estimated from MVS were verified by comparing predicted RVol from readers. In future work, it is considered necessary to recruit a sufficient number of prospective cases and to carry out comparison with GT.

The validation of the segmentation results was conducted through a procedure in which a physician visually inspected the segmentation outputs and manually corrected them when discrepancies were identified. This process was carried out by a single physician, and no quantitative assessment was performed.

The potential advantages of MVS are that if the observations regarding the accuracy of MVS measurements are demonstrated in a larger and more diverse study population, the ability to automatically predict outcomes with the accuracy of a manual read faster and with less interobserver variability could positively impact pre-procedural planning for M-TEER.

Conclusion

In this study we demonstrated that the predicted reduction in MR based on EROA and MR grade related to device placement provided by the MVS software, has a strong correlation to GT and suggests that these results are comparable to the predictions by expert readers. These initial results indicate further evaluations in a larger patient population are warranted. If the post-procedural condition can be more accurately understood before treatment, there is a possibility of achieving more effective treatment, and the simulation techniques introduced in this paper could contribute to this.

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None.

Conflict of Interest

None.

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