



Egyptian Society of Cardiology
The Egyptian Heart Journal

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ORIGINAL ARTICLE

The value of three-dimensional color Doppler trans-esophageal echocardiography in predicting the number of MitraClip devices needed during the procedure



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Received 1 March 2017; accepted 21 March 2017

Available online 7 April 2017

KEYWORDS

Mitral regurgitation;
Three-dimensional
vena-contracta area;
Three-dimensional
vena-contracta length;
MitraClip

Abstract *Purpose:* During MitraClip procedure, one or more clips might be needed to effectively reduce the mitral regurgitation (MR). Three-dimensional vena-contracta (3D-VC) assessed by color Doppler three-dimensional trans-esophageal echocardiography (3D-TEE) was proven to be well correlated with MR severity. However, its role in predicting the number of MitraClip devices needed during the procedure was not fully determined. Aim of this study is to assess the predictive value of 3D-VC area & length in determining the number of clips needed during the procedure.

Methods: 3D-TEE with color Doppler was performed in 20 patients (age: 68.9 ± 2.5 years; 65% males; with functional severe/moderately severe MR) who underwent successful MitraClip procedure (reduction of MR to $< 2+$). Manual tracing and measurement of the 3D-VC area (3D-VCA) as well as the 3D-VC length (3D-VCL) was done. These values were compared between patients who received 1 clip ($n = 4$) and ≥ 2 clips ($n = 16$).

Results: Patients who received ≥ 2 clips had larger 3D-VC area compared to patients who received 1 clip (0.39 ± 0.23 cm² vs. 0.13 ± 0.03 cm², $p = 0.04$, $t = 2.22$). Patients who received ≥ 2 clips had bigger 3D-VC length compared to patients who received 1 clip (1.14 ± 0.33 cm vs. $p = 0.005$, $t = 3.25$). A cut-off values of 0.20 cm² & 1 cm for the VCA & VCL respectively, are

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Peer review under responsibility of Egyptian Society of Cardiology.

<http://dx.doi.org/10.1016/j.ehj.2017.03.004>

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suggestive that the patient will most likely require more than one MitraClip device to treat his mitral regurgitation.

Conclusions: The 3D-VCA & 3D-VCL using 3D TEE is helpful in determining the number of MitraClip devices needed during the procedure in functional mitral regurgitation.

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1. Introduction

Mitral regurgitation is known to be one of the most frequent valvular disorders that necessitates surgical treatment in Europe.¹

Conventional open heart surgery for mitral valve repair is considered to be the standard of care for mitral regurgitation, mainly in degenerative valve disease.²

However, due to prohibitive procedural risk related to multiple comorbidities, almost half of patients with symptomatic severe or moderately severe mitral regurgitation are not treated surgically.³

Therefore, alternative percutaneous therapies such as percutaneous mitral edge-to-edge repair “MitraClip” procedure have evolved to address this category of patients.⁴

One of the recently validated tools for the assessment of mitral regurgitation severity is the three-dimensional derived Vena-Contracta area (3D-VCA).⁵

2. Aim of the study

The aim of the study was to detect the value of the Vena-Contracta Area (VCA) and Vena-contracta length (3D-CVL) measured by Color-Three-Dimensional trans-esophageal echocardiography (3DTEE) in predicting the number of MitraClip devices needed during the MitraClip (percutaneous mitral edge-to-edge repair) procedure to treat the mitral regurgitation in a given patient.

3. Materials and methods

Twenty consecutive patients (mean age, 68.9 ± 2.5 years; 65% males) undergoing MitraClip implantation procedure for severe or moderately severe symptomatic functional mitral regurgitation were enrolled. Using a commercially available ultrasound system (Philips iE33; Philips Medical Systems, Andover, MA) with a matrix array 3D-TEE probe (X7-2t; Philips Medical Systems), echocardiographic studies were done pre-operatively to calculate the 3D-VCA and 3D-VCL by Color-3D-TEE.

Then the patients had MitraClip implantation procedure with one or more MitraClip devices.

The study protocol was approved by the local Institutional Review Board (IRB). Informed consents were taken from all patients involved in the study.

3.1. Inclusion criteria

Any patient undergoing MitraClip implantation procedure for severe or moderately severe symptomatic functional mitral regurgitation.

3.2. Exclusion criteria

- (1) Poor, suboptimal Echocardiographic views.
- (2) Degenerative mitral regurgitation, e.g. prolapse or Flail mitral valve.
- (3) Persistence of more than grade II residual MR after the procedure.
- (4) Significant mitral stenosis after the procedure (diastolic transmitral pressure gradient of more than 5 mmHg).

3.3. Echocardiography

Three-Dimensional Color Doppler Acquisition and Data Analysis: A full-volume 3D color Doppler acquisition (Fig. 1) was obtained from the mid-esophageal commissural view over 4 consecutive cardiac cycles with ECG gating, the narrowest sector possible to maximize the frame rate, and Nyquist velocities of 50–80 cm/s.

Each 3D-color MR jet dataset was analyzed using the Philips Q-lab 9.0 software. Two orthogonal image planes parallel to the regurgitant jet direction were manually aligned across the regurgitant jet; a third cropping plane, which was perpendicularly oriented to the jet direction, was moved along the jet direction until the cross-sectional area at the level of the vena contracta was visualized (Fig. 2). The frame with the largest VCA in systole was magnified, and VCA (Fig. 3) was measured by direct planimetry of the color Doppler flow signal.⁶ The curved length of the VC (3D-VCL) (Fig. 4) was also measured.⁷

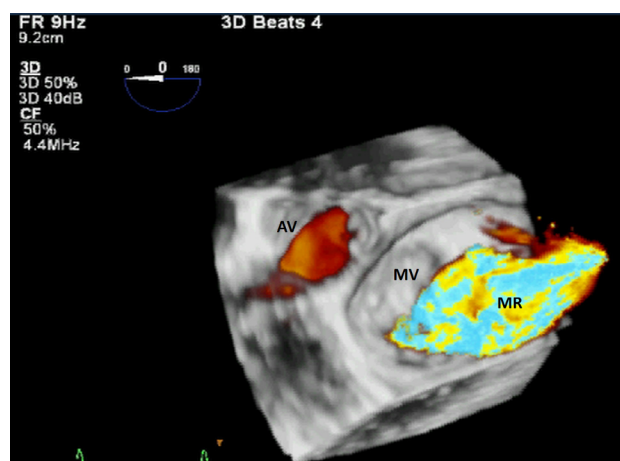


Figure 1 3D-Color full-volume of the mitral valve MV, showing severe mitral regurgitation MR. Av; aortic valve.

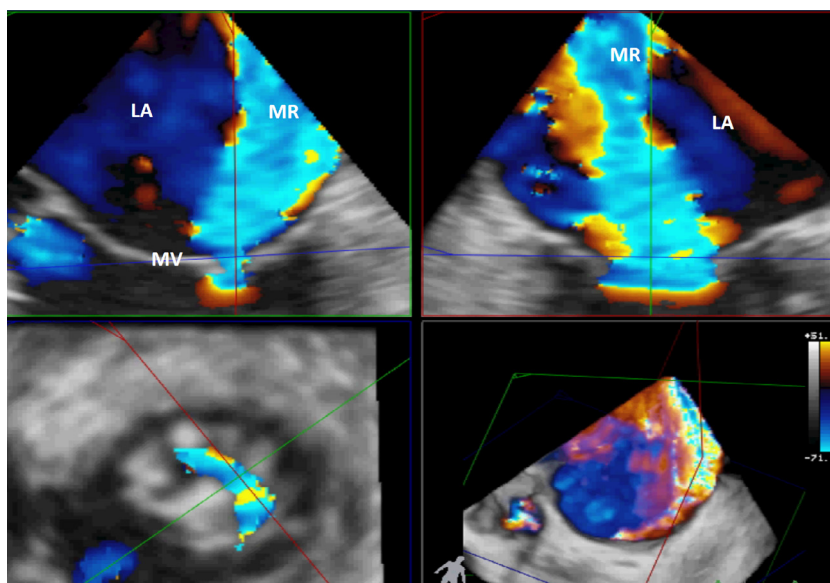


Figure 2 Multi-planar reformatting (MPR) mode of a 3D-Color full-volume of the mitral valve MV. MR; mitral regurgitation, LA; left atrium.

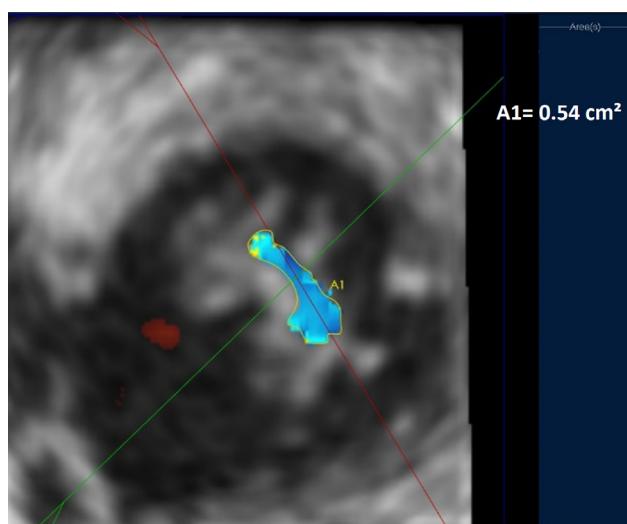


Figure 3 3D vena-contracta area (3D-VCA).

3.4. During the MitraClip procedure

The number of MitraClip devices implanted was calculated only after successful reduction in mitral regurgitation (\leq Grade II MR) without significant diastolic transmitral pressure gradient (> 5 mmHg).⁸

4. Results

The 3D-VCA and 3D-CVL could be calculated in all of the 20 patients included in our study.

The Three-dimensional Vena Contracta Area (3D-VCA) was Mean, 0.34 ± 0.23 cm², while the three-dimensional vena-contracta length (3D-VCL) was Mean, 1.03 ± 0.39 cm.

Regarding the number of MitraClip devices used, four patients (20%) needed a single MitraClip device, and twelve

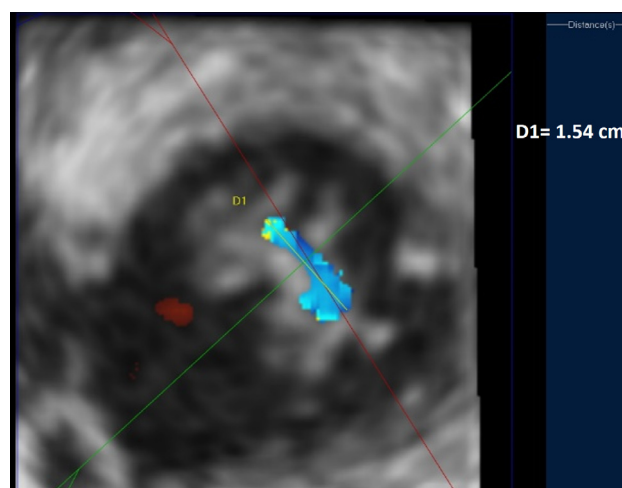


Figure 4 3D vena-contracta length (3D-VCL).

patients (60%) needed two devices while four patients (20%) needed three devices during the procedure.

Patients who needed a single MitraClip device had a mean 3D-VCA of 0.13 ± 0.03 cm², while those who needed more than one device had a 3D-VCA of 0.39 ± 0.23 cm², and the difference between the two groups is statistically significant ($p = 0.04$, $t = 2.22$).

As regards the 3D-VCL, patients who needed a single MitraClip device had a VCL of 0.57 ± 0.23 cm, while those who needed more than one device had a mean VCL of 1.14 ± 0.33 cm, and the difference between the two groups is statistically highly significant ($p = 0.005$, $t = 3.25$).

For patients who needed a single MitraClip device had an age of 70.5 ± 2 years, Vs 68.5 ± 2.4 years for those who needed more than one device, p value was 0.081.

As regards the Left ventricular ejection fraction (LVEF), those who needed a single device had an LVEF of 30

$\pm 5.7\%$ while those who needed more than one device had an LVEF of $32 \pm 3.6\%$, and p value was 0.386.

Descriptive statistics showed that the single clip group 3D echocardiographic measurements were significantly less than those of the multiple-clip group in terms of area and length of Vena Contracta.

Multifactorial regression analysis showed no impact of Age, Ejection fraction or etiology on the number of MitraClip devices required.

A cutoff values of 0.20 cm² and 1 cm for the VCA and VCL respectively, are suggestive that the patient will most likely require more than one MitraClip device to treat his mitral regurgitation.

5. Discussion

Over the past decade, we have noticed the advent of novel transcatheter therapies for valvular heart disease. The MitraClip (Abbott Laboratories, Abbott Park, Illinois) is a transvenous percutaneous device that creates an edge-to-edge repair for mitral regurgitation (MR).⁹

TEE has a critical role in accurate patient selection as well as guidance during the procedure knowing that fluoroscopy cannot visualize the MV leaflets.¹⁰

3D-TEE was shown to have an incremental value over 2D-TEE during MitraClip procedure,¹¹ as it can provide anatomically oriented en-face views of different cardiac structures such as the inter-atrial septum that facilitates guiding the trans-septal puncture.¹² 3D-TEE also provides en-face views for the MV thus enabling accurate assessment of MV anatomy which is critical for proper patient selection and guidance during the procedure as well as assessment of the results and complications.¹⁰

The assessment of the regurgitant orifice area using color 3D-Echocardiography was proven to be feasible and comparable to almost all of the ASE guidelines' recommended methods.^{13,5,14}

In our study, we measured the 3D-VCA and 3D-VCL before the procedure and then calculated the number of MitraClip devices needed per each patient to successfully treat his/her mitral regurgitation. We found that, measuring the 3D-VCA and 3D-VCL is feasible in all of our patients. And more importantly, we clearly noticed that the larger 3D-CVA and 3D-VCL were for a given patient, the more MitraClip devices the patient needed. We could also suggest cut-off values of 0.2 cm² and 1 cm for the 3D-VCA and 3D-VCL respectively, above which the patient will most likely require more than one MitraClip device to treat his/her MR.

These findings can really help in pre-procedural planning as regards the number of devices to be ready beforehand as well as optimizing the grasping point of the first device. As if more than MitraClip device will be used, it is going to be much easier for the interventionist to put the first device at the medial side of the VCA and then to put the other devices lateral to the first one.

6. Conclusion

Assessment of the regurgitant orifice area (ROA) using color 3D-TEE driven 3D-VCA and 3D-VCL is feasible. It can help

predicting the number of MitraClip devices to be required during the procedure.

Conflict of interest

All authors of this manuscript confirm that they have no conflict of interest.

Disclosure

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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