

The Value of the Left Atrial Appendage Orifice Perimeter of 3D Model Based on 3D TEE Data in the Choice of Device Size of LAmbré™ Occluder

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Preoperative optimal selection of the occluder size is crucial in percutaneous left atrial appendage (LAA) occlusion, and the maximal width of the LAA orifice is the main reference index, however it cannot fully meet the practical operation requirements. We retrospectively analyzed three-dimensional (3D) transesophageal echocardiography (TEE) and computed tomography (CT) imaging dataset of the 41 patients who underwent LAA occlusion with LAmbré™ system. The LAA orifice parameters were overall evaluated to determine their role in device size selection. Eight LAA 3D models of the four cases who had been replaced their device during the procedure based on TEE and CT were printed out to verify the optimal parameter decision strategy. There was a significant concordance of the results between 3D TEE and CT in the LAA orifice evaluation. The correlations between the perimeter and maximal width measurements by 3D TEE and the closure disk of the device were stronger than that between the area measurements and the closure disk ($r=0.93, 0.95, 0.86$, respectively and $p < 0.001$ all), and the result was similar to that by CT ($r=0.92, 0.93, 0.84$, respectively and $p < 0.001$ all). The ratios of the maximal width to the minimal width of the four cases were all higher than that of the rest 37 cases. Based on the comprehensive assessment of the LAA orifice perimeter and maximal width of the 3D printed models, the experiments were all succeed just for one try. The LAA orifice perimeter of 3D printed model based on 3D TEE may help in choosing the optimal device size of LAmbré™, especially for the LAA with flater ostial shape.

Transcatheter LAA occlusion is an effective treatment for

the prevention of atrial fibrillation-related stroke in patients with anti-coagulation contraindications or a high risk of embolism [1,2]. However, the anatomical morphology and the size of the LAA vary greatly, which makes percutaneous occlusion fairly challenging [3]. In early clinical trials of LAA occlusion, interventional physicians used an average of 1.8 occluders to achieve a satisfactory sealing effect, and frequent replacement of occluders can increase the risk of complications. Improper size of LAA occluder will lead to an increased time of replacement, and oversizing and undersizing of the LAA occluder have potential risks of complications, such as device migration or embolization, cardiac perforation, pericardial effusion and even cardiac tamponade. Thus, preoperative optimal selection of the device size is particularly important to increase the one-time success rate of occlusion [4-6].

Currently, the maximal width of the LAA orifice measured by peri-procedural two-dimensional (2D) TEE combining with fluoroscopy guidance is the main reference index for the clinical decision, while the anatomy of the LAA orifice cannot be accurately and comprehensively assessed just by this parameter [7]. For example, for the LAA whose opening shape is foot-like, the difference between the maximal and minimal width of the LAA orifice is large. Due to the occluders are all round-shape, as a result, the device would be more easily overestimated if only consideration of the maximal width, which may cause the difficulty of release and lead to the corresponding complications. Therefore, to improve this situation, our research group explored the value of other parameters of the LAA orifice.

Accurate measurement of the LAA ostial parameters depends on accurate and comprehensive display of the LAA orifice. Studies have shown that 3D TEE and cardiac CT are convenient for obtaining full volume data and presenting a full-view image of the LAA via specialized segmentation software. Using these methods, effective measurement was carried out, which was more accurate than 2D-TEE by virtue of the limited sections. And, more other parameters of LAA, such as perimeter, area, and the angle of the first bend, can be easily measured and evaluated, which cannot be reached by conventional 2D TEE and x-ray angiography. In recent years, 3D printing technology has rapidly developed in the field of cardiovascular medicine [8-13]. Patient-specific 3D printing LAA models based on 3D TEE and CT [14-18] have been successfully applied to the guidance of percutaneous LAA occlusion recently, and measurement and simulation can be easily operated on 3D Printing models, which makes the choice of occluder size more accurate.

In this study, we used the Materialize interactive medical image control system (Mimics; Leuven, Belgium) to post-process the digital imaging and communications in medicine (DICOM) data from forty-one patients who underwent successful LAA occlusion in our hospital based on 3D TEE and cardiac CT to obtain the 3D printing digital file of the LAA. The DICOM volume data were all at 75% of the R-R interphase of the cardiac cycle, which is the diastolic phase of the LA, in order to minimize its effects on the LAA parameters. The cases that we studied all used the LAmbré™ device [19], which is a nitinol-based, self-expanding device comprising a hook-embedded umbrella and a cover that is 4-6 mm larger in diameter than the umbrella. This type of occluder is available in 11 different sizes based on the lobe diameter, which is 16-36 mm, stepwise in 2 mm increments, and the corresponding size of perimeter is 50.3–113.1 mm, stepwise in 6.3 mm increments. Similar to ACP occluders [20], the LAmbré™ device has a double-disk structure, therefore, the definition of the landing zone diameters for endoluminal devices is similar to that for the LAmbré™ device. Consequently, the plane of the LAA orifice of 3D model in our research was reconstructed ~10 mm distally from the ostial plane into the lobe [21]. Then five LAA ostial parameters were measured and evaluated to determine their role in occluder size selection, including one qualitative parameter: opening shape, and four quantitative parameters: maximal width, minimal width, perimeter, and area. By comparing and evaluating these measurements based on these two 3D data sources, we found that 3D TEE and CT were in good concordance in assessing the LAA orifice. We know that CT is the mainstream approach of 3D printing data source, however, there are some associated risks to CT such as ionizing radiation and contrast agent allergies, images of some patients may not be obtained. Beyond that, the positive predictive value of CT is not

high in the preoperative detection of thrombus in the LAA. 3D TEE has no such limitations. The limitation of TEE is the attenuation of ultrasonic signals in the far field, but which had no influence on the evaluation of the LAA orifice. TEE is the foremost imaging method in preoperative screening, the choice of device type and size, intraoperative monitoring and postoperative follow-up. The study may lay a more solid imaging foundation for the complementary advantages of these two imaging methods.

On this basis, we innovatively analyzed the relationship between the measurements of each LAA ostial parameter based on 3D TEE and CT data and the actually implanted device size of LAmbré™. The shapes of the LAA orifice are mostly elliptical or irregular, however, the current occluders are all designed to be round [22]. Self-expansion of the LAmbré™ device may cause deformation of the LAA orifice; for example, the triangular shape becomes oval. After occluder implantation, the morphological deformation of the LAA orifice may lead to marked changes of LAA maximal width and minimal width, but not very noticeable changes of LAA perimeter. The trend and degree of the change in LAA maximal width and minimal width may be determined by the shape of the LAA orifice. Moreover, by virtue of the law that the area of the circle is largest under the condition of constant perimeter, the area of the LAA orifice would increase. Thus, the perimeter may be the most reproducible parameter for sizing devices. Since the minimal width of the LAA orifice is only related to the opening shape, the correlation between it and the device size was not analyzed. Our study found that the correlations between the perimeter and maximal width measurements by 3D TEE and the closure disk of the device were stronger than that between the area measurements and the closure disk ($r=0.93, 0.95, 0.86$, respectively and $p < 0.001$ all), and the result was similar to that by CT ($r=0.92, 0.93, 0.84$, respectively and $p < 0.001$ all), which indicates that these two LAA ostial parameters are both important parameters for the choice of occluder size.

Then we chose four cases who had been replaced devices during actual implantation and the number of device replacement in each case was once, the ratios of the maximal width to the minimal width of which were all higher than that of the rest 37 cases, whose actual intervention operations were all successfully performed just for once. By obtaining eight patient-specific life-sized 3D printed LAA models based on 3D TEE and CT with a rubber-like material, we intended to discuss the instruction value of LAA orifice perimeter for sizing an LAA occluder to verify the optimal parameter decision strategy especially for those cases with special ostia shape. Simulation operations with the LAmbré™ device were performed on the models by the assessment of the parameters of the LAA orifice. In our in vitro simulation experiments, the LAA occluder sizes of four models based

on 3D TEE dataset and two models based on CT dataset were both overestimated just by the analysis of the LAA ostial maximum diameter for the first time. In these six 3D printed models, the orifice shapes were long oval or water drop-like, and the minimal width was relatively small when compared with other ostial shapes. Additionally, in consideration of the above correlation analysis results, other parameters of the orifice should also be analyzed, especially the perimeter. After assistant analysis of the LAA ostial perimeter, this study successfully selected the optimal size of the occluders by simulating the occlusion in the 3D printed LAA models, which were the same as the choices of actual operation. In other two 3D printed LAA models based on CT, the device sizes selected by both the maximal width and perimeter of the LAA orifice were the same sizes as the actually inserted ones. The reason for the difference between 3D TEE and CT was the way these two imaging methods work. In conclusion, the in vitro release experiment of occluders showed that, when the ratio of the maximal width to the minimal width of the LAA orifice was high, in other words, when the shape of the LAA orifice is flatter, the comprehensive assessment of the maximal width and perimeter of LAA orifice based on both 3D TEE and CT may assist the choice of occluder size.

We report a single-center experience with a small sample size including only 41 individuals. A 3D LAA model was printed within 6 h using a 3D printer, which is time consuming. In addition, due to the selection method of device size, the results of good correlation between 3D TEE and actually inserted occluder size were a natural result. This is an inadequacy of the study.

At present, there are some new researches related to LAA occlusion, for example guiding role of 3D printed LAA models [23], fabrication of customized LAA devices [24,25], and the quantification of device-model interactions in vitro with the aid of software for 3D strain analysis [26]. The first one has been the most extensively studied field. However, current limitation of 3D printing includes the lack of validated technical standard, increased upfront costs of the technology, and scant evidence on the added clinical benefit. The accuracy of 3DTEE data in assessing the LAA orifice discussed in this study may provide some help for the early technical support and cost saving related to 3D printing. 3D-TEE could be the preferred method in the whole process of the future LAA occlusion. For patients with contraindications to TEE or unclear images acquired before surgery, CT can be considered for preoperative evaluation to guide the selection of occluders. Successful choice of the LAA device type depends on many factors, such as the ostial parameters, depth and angulation of LAA. We focused on discussing the value of different LAA orifice parameters especially perimeter for sizing an LAA occluder. Our main conclusion is that considering the deformation of the LAA orifice after occluder insertion, the assessment of the LAA ostial perimeter of 3D model

and the simulation on 3D printed model with rubber-like material may help to choose the optimal device size of LAmbré™ in increasing the one-time success rate of operation, especially for the LAA with flatter ostial shape. And our team is optimizing soft 3D printing materials that are closer to the mechanical properties of human myocardial tissue, and evaluating the accuracy and application value of the LAA models based on 3D TEE in dynamic fluid in vitro simulation of LAA occlusion, which may also be helpful in technical standardization.

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