SPECIAL REPORT

Optimising Left Atrial Appendage Occlusion (LAAO) Procedures For Patients at Risk of Stroke

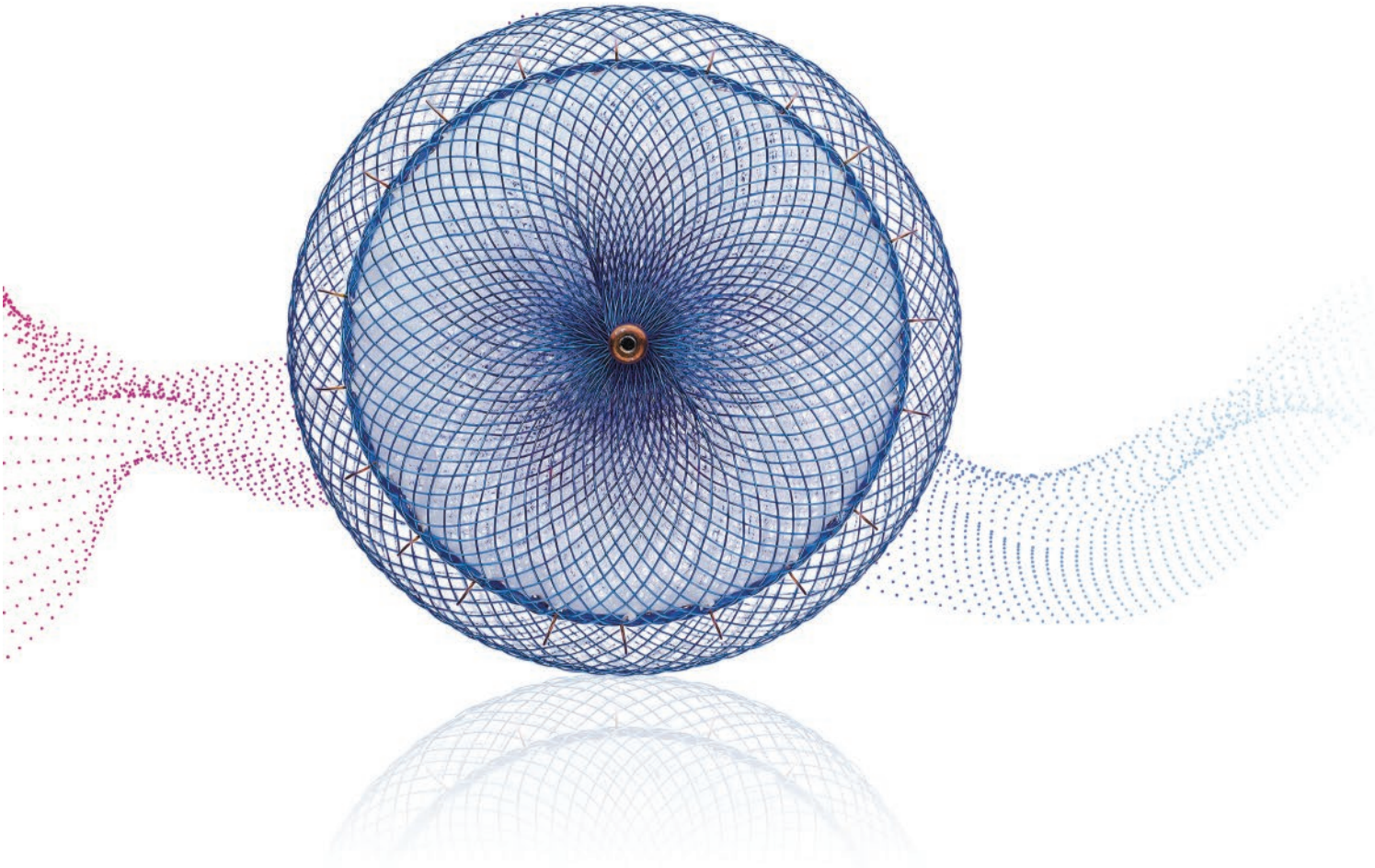
The Primary Results of the Amulet IDE Trial

Left Atrial Appendage Occlusion Versus Direct Oral Anticoagulation

The Novel Amplatzer Steerable Delivery Sheath for Left Atrial Appendage Occlusion

How to Visualize Anatomical Landmarks and Understand Device-host Interaction for Percutaneous Left Atrial Appendage Occlusion: Pre-procedural Planning with FEops HEARTguide

Intracardiac Echocardiography to Guide Left Atrial Appendage Occlusion



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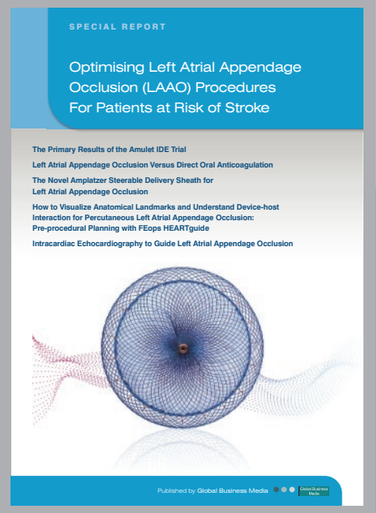

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Contents

Foreword

A trial fibrillation and cardiac arrhythmias are a significant cause of cardiovascular morbidity and mortality, and the number of men and women affected is expected to double over the next 20 years in developed nations. The resulting socioeconomic burden is felt not just by healthcare systems that must pay the additional costs associated with treatment, but also by patients with increased risk of stroke of systemic embolism who experience the morbidity and mortality associated with this condition. For both, implementing innovative approaches to address the socioeconomic burden of these conditions presents an increasingly pressing challenge. Further adding to this challenge is the fact that contraindications and bleeding risks may withhold physicians from a mainstream pharmaceutical approach for prevention of stroke and systemic embolism, i.e., long-term oral anticoagulation.

Through a series of evidence-based articles, this report highlights a device-based approach to this challenge: left atrial appendage occlusion (LAAO) procedures for patients at risk of stroke. The report begins in the first article, where Dr. Boris Schmidt reviews a prospective randomized multi-centre non-inferiority trial comparing two devices for left atrial appendage occlusion. The trials serve as a proof-of-concept study and provide further confirmation for interventional LAAO as an effective therapeutic option for stroke prophylaxis in patients who are unsuitable for long-term oral anticoagulation. This is followed by a second article, where Dr. Nielsen-Kudsk compares left atrial appendage occlusion to direct oral anticoagulation through a review of two studies. Although acknowledging an obvious need for more randomised studies comparing LAAO with DOAC, Dr. Nielsen-Kudsk nonetheless highlights the promising nature of the results.

The remaining articles examine different facets of LAAO. In article three, Dr. Cruz González and colleagues explore a novel steerable delivery sheath, arguing how it facilitates the procedure in all cases, but especially in complex anatomies, where it facilitates alignment and offers the possibility of releasing the device in perpendicular direction. This is followed in the fourth article by an overview of pre-procedural planning with cardiac computed tomography (CCT). In that article, Dr. De Backer considers how to use computational modelling based on CCT measurements to optimize LAAO. The report concludes in article five with a discussion of the use of intracardiac echocardiography to guide LAAO. In that piece, Dr. Nielsen-Kudsk explains how intracardiac echocardiography can be used instead of transoesophageal echocardiography to guide LAAO, thereby allowing the procedure to be carried out under local anaesthesia with the patient being awake, cooperating and capable of reporting any unexpected symptoms.

Taken together, these articles provide an exciting overview of the possibilities of LAAO, not only in terms of technological advances, but also with respect to patient outcomes. Indeed, as patients, clinicians, and the healthcare systems in which they operate see more widespread diffusion of this technology, we will likely witness a meaningful impact on the health and wellbeing of patients at risk for stroke from atrial fibrillation.

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OPTIMISING LEFT ATRIAL APPENDAGE OCCLUSION (LAAO) PROCEDURES FOR PATIENTS AT RISK OF STROKE

The Primary Results of the Amulet IDE Trial

A prospective randomized multicenter non-inferiority trial comparing Amulet and Watchman devices for left atrial appendage occlusion.

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BETWEEN 2016 and 2018 almost 40.000 left atrial appendage occlusion (LAAO) procedures using Watchman™ were performed in the United States according to the National Cardiovascular Data Registry.[1] In order to obtain FDA approval for the AMULET LAAO device a prospective randomized study has been performed and study results were presented on August 30th in the late breaking session of the 2021 European Society of Cardiology Meeting by the lead investigator Dr. Lakkireddy, Kansas City, USA.

The study was designed to prospectively compare the performance, the safety and the efficacy of the AMULET to the already approved Watchman device serving as a control group in patients with non-valvular atrial fibrillation with a high stroke risk defined by a CHA2DS2-VaSc score of 3 or more and an appropriate rationale to seek an alternative to long-term oral anticoagulation. In 108 centers world-wide a total of 1878 patients were randomized in a 1:1 fashion to receive either device and patients were followed for a maximum of 5 years.

In total, three different primary endpoints were assessed for non-inferiority: 1) Mechanism of action – defined by LAA occlusion with less than 5mm peri-device flow on transesophageal or transthoracic echocardiography at 45 days following the procedure. 2) Safety – defined as a composite of procedure-related complications, or all-cause death, or major bleeding (Bleeding Academic Research Consortium (BARC) ≥3) at 12 months. 3) Effectiveness – defined as a composite of ischemic stroke or systemic embolism through 18 months of follow-up.

Study Results

From September 2016 through March 2019, a total of 1878 patients at 108 sites were enrolled and randomly assigned to receive either an Amulet occluder (n=934) or Watchman device (n=944). Patients had a high risk for stroke and bleeding as reflected by the average CHA2DS2-VASc (4.5 and 4.7) and HAS-BLED (3.2 and 3.3). History of stroke was present in about 20% of patients (see Table 1).

The overall implantation success was very high in both groups (98.4% for AMULET vs 96.4% for Watchman). Per protocol patients implanted with an AMULET occluder were discharged more frequently on dual antiplatelet therapy (75.7%) as opposed to patients who had received a Watchman device who were mostly discharged on

The overall mortality rate was remarkably low at 3.9% and 5.1% for the AMULET and the Watchman group patients, respectively

Table 1: Amulet IDE Trial Demographics and Medical History

	Amulet (n=934)	WATCHMAN (n=944)
Age (years)	75.0 ± 7.6	75.1 ± 7.6
Female	41.2%	38.7%
BMI (kg/m2)	30.0 ± 6.3	30.0 ± 6.5
CHA2DS2-VASc	4.5 ± 1.3	4.7 ± 1.4
HAS-BLED	3.2 ± 1.0	3.3 ± 1.0
Prior AF ablation	30.4%	29.8%
Prior Bleeding	72.2%	71.5%
Prior TIA	10.7%	12.0%
Prior Stroke	18.0%	19.9%
Data are mean ± standard deviation or percentages of patients		

Device related thrombus formation remains one of the greatest challenges for LAAO since it has been shown to be a predictor for an increased stroke risk

oral anticoagulation and aspirin (82%).Outcomes for the primary study endpoints are summarized in Figure 1.

The first primary endpoint – LAAO with no or minimal flow – was more frequently achieved with the AMULET occluder (98.9% vs. 96.8%; difference=2.03, 95% confidence interval [CI], 0.41-3.66; p<0.001 for noninferiority; non-inferiority margin: 3%; p=0.003 for superiority).

According to the echo core lab complete occlusion (i.e. no residual jet around the device) was observed in only 63.0% of Amulet occluder patients and 46.1% of Watchman device patients.

The primary safety endpoint was met in 14.5% and 14.7 % of patients in the AMULET and Watchman group, respectively (difference=-0.14, 95% CI, -3.42-3.13; p<0.001 for noninferiority; non-inferiority margin: 5.8%).

Major bleeding and all-cause death was similar between groups (10.6% vs 10.0% and 3.9% vs 5.1%, respectively). Procedure-related complications were higher for the Amulet occluder (4.5% vs. 2.5%), largely related to more frequent pericardial effusion (2.4% versus 1.2%) and device embolization (0.7% versus 0.2%). Of note, the pericardial effusion events in the AMULET group occurred >2 days after the procedure in approximately half of the above-mentioned patients. A post-hoc analysis revealed that half of the patients with pericardial effusion after AMULET had received oral anticoagulation instead of dual antiplatelet therapy after the implant thereby increasing the risk from 1.8% to 5.3% (p=0.008).

The overall mortality rate was remarkably low at 3.9% and 5.1% for the AMULET and the Watchman group patients, respectively.

With regards to the primary effectiveness endpoint the AMULET proved to be non-inferior to the Watchman device in preventing stroke or systemic embolism at 18 months (2.8% vs. 2.8%; difference=0.00, 95% CI, -1.55-1.55; p<0.001 for non-inferiority; non-inferiority margin: 3.2%).

In the echocardiographic evaluation device related thrombus was detected in 3.3% and 4.5% of AMULET and Watchman patients, respectively.

In conclusion, all three co-primary endpoints met the predefined non-inferiority criteria, thus it was concluded that the AMULET may be considered non-inferior to the only currently FDA approved device. As a result, the AMULET device was approved for clinical use in the US by the FDA in August 2021.

Figure 1: Primary endpoint outcomes

Interpretation of the Results

The present study may be interpreted as another proof-of-concept study for interventional LAAO being an effective therapeutic option for stroke prophylaxis in patients who are unsuitable for long-term oral anticoagulation. In comparison to previous randomized studies (Protect AF and Prevail) and large scale registries the ischemic stroke rate was lower.[2-4] In both groups, the annual stroke rate was below 2% (1.67% and 1.94% for the AMULET and Watchman groups, respectively) despite a similar stroke risk. Of note, in a comparative age and risk group, rivaroxaban showed slightly higher stroke rates in the ROCKET AF study.[5]

From a technical perspective, it is reassuring, that the lobe-disc design occluder may be implanted in almost all patients successfully. The data suggests, that it even offers additional versatility in comparison to the standard plug type occluder in borderline anatomical situations. The number of patients who had been excluded for an unsuitable LAA anatomy were 50% lower in the AMULET group. The very high implantation success rate of 98.4% must be highlighted in the light of the involvement of many US centers that had no experience with the AMULET device before the study.

The latter may also partly explain the higher procedure related complication rate for pericardial effusion and device embolization. This assumption is supported by the observation, that the complications occurred early in the operator's learning curve and declined with an experience of 10 or more implants. On the other hand, device specific features such as different anchoring wires may also have contributed to this result. In this context, it should, however, be noted, that the post-procedural antithrombotic drug regimen in the AMULET group differed from the study protocol (i.e. dual antiplatelet therapy for 3 months) in approximately one quarter of patients and 20% of patients received oral anticoagulation plus aspirin. As mentioned above, this added to a higher pericardial effusion rate.

It has to be pointed out, that in comparison to contemporary registry studies the overall mortality was low. In the EWOLUTION registry, the mortality in the first year after LAAO was 9.8% and in the AMULET Global registry it was 8.4%.[6,7] This holds true despite very similar patient characteristics in terms of age, stroke risk and co-morbidities. It can be speculated that other, non-reported parameters, biased investigators towards in- and exclusion. Nevertheless, the low mortality in the first year after implantation is very encouraging and the trial inclusion criteria seem to provide a reliable guideline for future patient selection.

Device related thrombus formation remains one of the greatest challenges for LAAO since it has been shown to be a predictor for an increased stroke risk.[8,9] Despite a larger foreign body surface of the disc as compared to the plug device, the device related thrombus rate in the AMULET groups was numerically lower. If this refers to a different post-implant antithrombotic drug regimen or to device and patient specific criteria will be re-analyzed.

In conclusion, it is well appreciated that now the AMULET adds to our armamentarium for interventional stroke prophylaxis and it may help to decrease the number of failed LAAO implants. The study also consolidates the body of evidence for LAAO as a prophylactic therapy itself and the world of Interventional Cardiology is eagerly awaiting the results of ongoing randomized trials comparing AMULET to NOAC therapy.

It is well appreciated that now the AMULET adds to our armamentarium for interventional stroke prophylaxis and it may help to decrease the number of failed LAAO implants

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Left Atrial Appendage Occlusion Versus Direct Oral Anticoagulation

Propensity score matched analysis: Left atrial appendage occlusion has similar effectiveness in stroke prevention than direct oral anticoagulants with reduced risk of major bleeding and mortality.

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There is obviously a need for more randomised studies comparing LAAO with DOAC and such studies are ongoing

Introduction

The combined analysis of the randomised PROTECT-AF and PREVAIL trial demonstrated that left atrial appendage occlusion (LAAO) in atrial fibrillation (AF) had comparable stroke prevention efficacy compared with warfarin but with reductions in major bleeding and mortality[1]. However, direct oral anticoagulants (DOACs) have now largely replaced warfarin as the preferred medical stroke prophylaxis in AF. DOACs have about the same efficacy against thromboembolism in AF as warfarin, but the risk of intracerebral bleeding has been reduced with this type of anticoagulants[2]. Major bleeds from other internal organs, such as the gastrointestinal tract, remain a significant clinical problem with DOACs[3]. Due to the improvement in medical stroke prevention, studies comparing LAAO with DOAC are warranted.

PRAGUE-17 Study

The randomised PRAGUE-17 study compared LAAO with DOACs in 402 patients with a high risk of stroke and bleeding[4]. Mean CHA2DS2VASc score was 4.7 and HAS-BLED score 3.1. A total of 201 patients had LAAO (61.3% with the Amulet and 35.9% with the Watchman device) and 201 patients were treated by DOAC (Apixaban 95.5%). Patients were followed for a mean of 20.8 months. The primary study outcome was a combination of stroke or TIA, systemic embolism, clinically significant bleeding, cardiovascular death or significant peri-procedural complications. The trial demonstrated significant non-inferiority of LAAO versus DOAC on the primary combined outcome. The hazard ratio for clinically significant bleeding (HR=0.81) and non-procedural clinically significant bleeding (HR=0.53) was in favour of LAAO, but did not reach statistical significance. The conclusion from this trial is limited by the relatively low number of patients.

Propensity Score Matched Analysis

The Amulet Observational Study was a global prospective registry of AF patients having LAAO with the Amulet device[5,6]. A total of 1088 patients were enrolled and 1078 had successful Amulet implants. This was a high-risk population for stroke and bleeding with CHA2DS2VASc score of 4.2 and HAS-BLED score of 3.3. In a propensity score matched study, we compared this cohort of LAAO patients with a control group of AF patients treated by DOAC sampled from the Danish National Patient Registry and the Danish National Prescription Registry[7]. In the period from 2013-2015 we identified 18750 patients with a first-time diagnosis of AF who were initiated on stroke prevention treatment with DOAC. We used propensity score matching (1:2; greedy 5:1 digit matching with replacement) including each covariate of the CHA2DS2VASc and HAS-BLED score for matching (congestive heart failure, hypertension, age, diabetes, prior stroke/TIA, vascular disease, sex, renal/liver disease, prior major bleeding and drugs predisposing to bleeding) thereby creating a LAAO cohort (n=1071) and a DOAC cohort (n=1184) with similar risk of stroke and bleeding. The primary outcome was ischemic stroke, major bleeding or all-cause mortality. Events were counted for a period of two years.

The primary outcome occurred much less frequently with LAAO (256) than DOAC (461). The hazard ratio (95% CI) of 0.57 (0.49-0.67) was significantly in favour of LAAO over DOAC. Looking at each component of the combined clinical outcome, the ischemic stroke rate was comparable between the two groups (HR 1.11; 071-1.75), whereas major bleeding (HR 0.62; 0.49-0.79) and mortality (HR 0.53; 0.43-0.64) occurred significantly less frequent in the LAAO cohort.

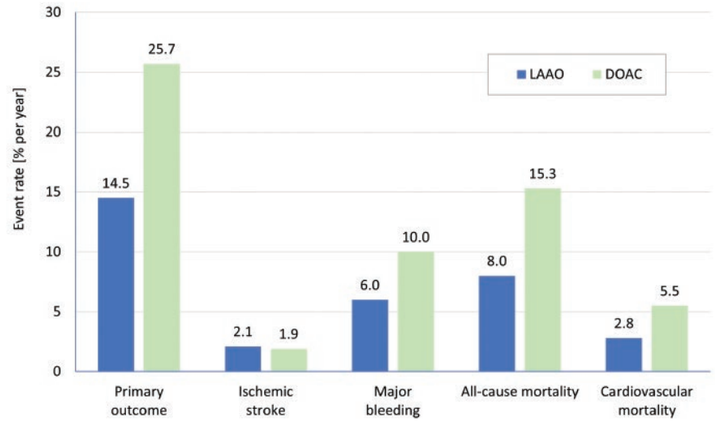

Figure 1: Outcomes from propensity score-matched patients treated by LAAO versus DOAC.

In order to strengthen the validity of this finding, we did two additional propensity score matched analyses based on the Amulet Observational Study cohort. In the first of those sensitivity analyses, we required patients in the DOAC cohort to have fulfilled their DOAC prescriptions over a period of at least two months and to be without any registered bleeding episode in this period. This would filter away AF patients being particularly prone to bleeding on DOAC. For the second sensitivity analysis, we required all patients in both cohorts to be without any history of cancer, thereby excluding patients having bleeds on DOAC due to underlying cancer disease (e.g., gastrointestinal cancer). The propensity score matched analyses were carried out as for the main analysis with matching to each covariate in the CHA2DS2VASc and HAS-BLED score. Also for these two additional analyses, the results significantly favoured LAAO over DOAC in the combined clinical outcome of ischemic stroke, major bleeding and mortality.

Discussion

Although these data seem very promising, there are still important limitations to this study. This was not a randomised study and there is a risk of selection bias. Patients having LAAO could be clinically selected as a group of less sick patients judged by referring physicians to tolerate an interventional procedure. On the other hand, those patients selected for LAAO could be a sicker group of patients selected for LAAO due to multiple bleeding problems on different drug regimens and with underlying multiple comorbidities. The Amulet Observational Study was carried out in 17 different countries, but the control group was sampled from a single country (Denmark). The time period for the Amulet Observational Study was 2015-2016, whereas the control group was sampled from 2013-2015. In the Amulet Observational Study all events were adjudicated by a clinical event committee, whereas events in the control group were based on ICD-10 diagnoses in the Danish National Patient Registry.

There is obviously a need for more randomised studies comparing LAAO with DOAC and such studies are ongoing. In the OCCLUSION-AF trial (NCT03642509), AF patients (n=750) with an ischemic stroke within 6 months are randomised to either LAAO or DOAC. This is secondary stroke prophylaxis in a group of AF patients with a high risk of recurrent stroke and bleeding. The OPTION-trial (NCT03795298) looks at LAAO versus DOAC in AF patients with CHA2DS2VASc score 2-3 that undergo ablation for AF (n=1600). Enrolment in this trial has ended. The CATALYST trial (NCT04226547) and CHAMPION-AF trial (NCT04394546) are large trials (n>2500) designed to test LAAO versus DOAC in a broader population of AF patients (CHA2DS2VASc score 2-3).

While the available data on LAAO versus DOAC published so far are very promising, we will have to wait for results from the ongoing randomised clinical trials to clarify if LAAO is going to be the preferred way of stroke prevention for a broad population of AF patients in the future. The concept of a non-pharmacological mechanical stroke prevention carried out as a one-time percutaneous procedure in local anaesthesia within less than one hour resulting in continuous prophylaxis avoiding long-term anticoagulation and its associated bleeding risk seem very appealing.

While the available data on LAAO versus DOAC published so far are very promising, we will have to wait for results from the ongoing randomised clinical trials to clarify if LAAO is going to be the preferred way of stroke prevention for a broad population of AF patients in the future

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The Novel Amplatzer Steerable Delivery Sheath for Left Atrial Appendage Occlusion

Steerable feature facilitates optimal device alignment effective occlusion of the left atrial appendage

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Conflict of interests:
I. Cruz Gonzalez, MD, PhD is proctor and consultant of Abbott

The Amplatzer Steerable Delivery Sheath is a new system that facilitates the delivery of the Amplatzer LAAO device

LEFT ATRIAL appendage occlusion (LAAO) has emerged as an excellent alternative to long-term oral anticoagulation in patients with non-valvular atrial fibrillation (AF). When anticoagulation treatment is contraindicated, this procedure has shown to be a safe and a successful option in the prevention of thromboembolic events. A growing body of evidence confirms a high success rate with a low complication rate. Therefore, this intervention is getting more and more frequent in daily practice. Due to the expansion of the technique interventional cardiologists are currently facing more challenging anatomies and clinical scenarios that could potentially add complexity to the procedure.

Critical success factors for safe and effective LAAO include a good transseptal puncture, coaxial alignment of the occluder with the left atrial appendage (LAA), and appropriate positioning of the occluder in the LAA ostium for optimal sealing. From the technical point of view, one of the key points of the procedure is to achieve a correct alignment of the delivery sheath with the neck of the appendage. This depends mainly on the location of the transeptal puncture. It is recommended to guide the puncture with transesophageal echocardiography to avoid possible complications and to look for the best location of the puncture in the atrial septum. The LAA is located anterior and superior to the interatrial septum, so the posterior and inferior transeptal quadrant is often the location selected for transseptal puncture. This strategy helps to achieve the best angle between the delivery system and the neck of the LAA. Accomplishing a coaxial approach is mandatory in order to achieve a correct position of the occlusion device. This position will simplify the intervention to obtain a good compression of the device and a complete isolation of the appendage, without complications such as leaks or device embolizations.

However, some cases could be challenging due to an unfavorable anatomy. Both left and right atriums in patients with AF are frequently dilated, modifying the usual anatomy and their relation with the other structures. Furthermore, left atrial appendages with an angled neck, such as those with an upper or forward direction (so-called chicken wing or reversed chicken wing anatomy),

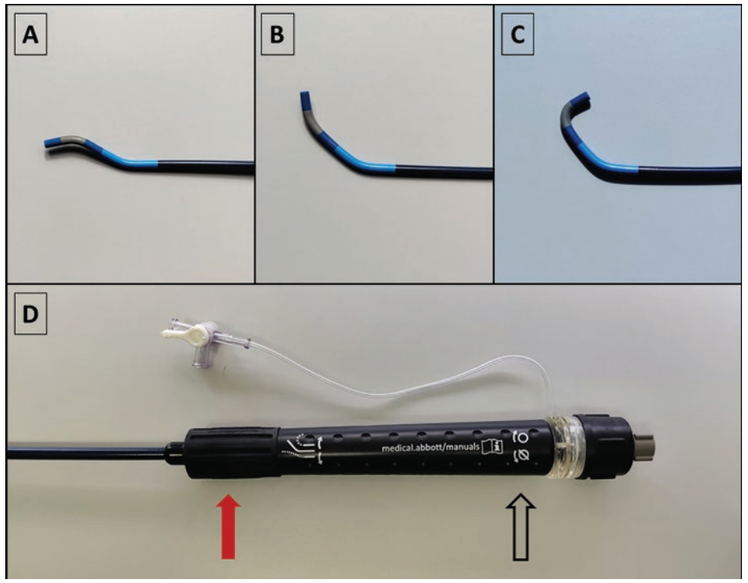

Figure 1. Deflection of the distal end of the sheath, at 0º (A), 45º (B) and 120º (C); D: sheath handle.

The steerable sheath offers the possibility of releasing the device in perpendicular direction with the appendage orifice even in difficult anatomies

could complicate coaxial alignment of the sheath and thereby a safe and effective deployment of the device. In these cases, a steerable sheath could make the procedure much easier.

The Amplatzer Steerable Delivery Sheath is a new system that facilitates the delivery of the Amplatzer LAAO device. It is an inner 14F system compatible with a 19F introducer and includes an integrated passive valve for hemostasis. This novel sheath has a primary curve with a fixed angle of 45 degrees (same as the fixed curve sheath). A special feature of this system is the ability to deflect the distal end in a wide range angle from 0 (Figure 1A), to 45 (Figure 1B), and to 120 degrees (Figure 1C). Moreover, this new design achieves a 1:1 torque. Thereby it facilitates the device deployment in general, and more specifically in LAA anatomies with a sharp angulation between the direction from the interatrial septum and the LAA neck.

So far, the available experience with the Amplatzer Steerable Delivery Sheath is limited as it has just recently been launched. In our experience the delivery sheath is useful in all cases due to the improved torque capacity, the hemostatic valve and the ability to deflect the distal tip as needed

Pre-procedure planning may show in advance in which cases this novel delivery system could be specifically useful. Not only conventional computerized tomography images, but also digital software applications are useful when planning the intervention. This new technology simulates the patient´s anatomy and its interaction with any device, and may help the operators to predict any complexity characteristic that would not allow an accurate delivery. In these simulations, when a coaxial alignment is not possible between the sheath (from any point of the interatrial septum) and the appendage neck, the steerable feature of the Amplatzer Steerable Delivery Sheath is expected to improve the success rate, minimizing future complications.

The steerable sheath offers the possibility of releasing the device in perpendicular direction with the appendage orifice even in difficult anatomies. After transeptal puncture, with the sheath in the left atrium and using a pig-tail catheter, clockwise and counterclockwise rotation of the whole system (black arrow, Figure 1D) helps advancement into the appendage. However, this could be insufficient to achieve a coaxial alignment with the neck of the appendage (Figure 2A). In such a situation, the new delivery sheath facilitates alignment by deflection of the distal tip in an angle ranging from 0 to 120 degrees. Turning the knob clockwise (red arrow, Figure 1D) provokes a deflection to 120º of the distal end into an inferior and anterior position. On the other hand, counterclockwise rotation of the knob deflects the distal part of the sheath to 0º, to a superior position (Figure 2 B-C). All these movements should be guided by echocardiography to prevent an extreme movement that could perforate the appendage. Assessing the coaxial direction before delivering is also important, not only with fluoroscopy, but also with ultrasound imaging. When the sheath is totally coaxial to the appendage neck, the device

deployment should start. In case it is not feasible to release the device in an optimal position, it can be recaptured as with the conventional sheath, and a new deployment attempt can be done. Finally, when the position and alignment of the occluder is appropriate it can be released as usual, and the sheath can be removed (Figure 2D).

In conclusion, LAAO is a good alternative in patients with non-valvular AF and contraindication to oral anticoagulation. The novel Amplatzer Steerable Delivery Sheath facilitates the procedure in all cases but especially in complex anatomies, with an angled direction of the appendage. It has the ability of deflecting the distal end from 0 to 120 degrees, which helps to achieve a coaxial alignment between the distal end of the sheath and the neck for optimal placement of the occluder. Thanks to all these features, a better position of the device can be achieved, with could potentially translate into a higher success rate and a lower rate of complications.

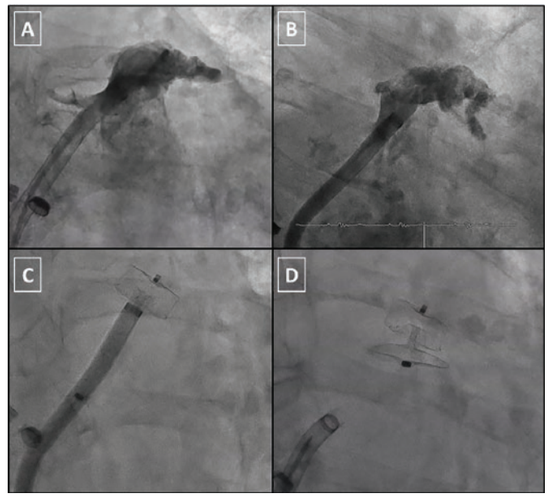

Figure 2. A: Absence of a coaxial angle between sheath and delivery sheath; B: counterclockwise deflection of the distal end to an upper direction; C: coaxial approach and device delivery; D: Final result.

In conclusion, LAAO is a good alternative in patients with non-valvular AF and contraindication to oral anticoagulation

How to Visualize Anatomical Landmarks and Understand Device-host Interaction for Percutaneous Left Atrial Appendage Occlusion: Pre-procedural Planning with FEops HEARTguide™

Cardiac computed tomography with or without computational modelling is expected to increasingly replace transoesophageal echocardiography as an imaging tool for pre-procedural planning of percutaneous left atrial appendage occlusion.

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It is expected that CCT will increasingly replace transoesophageal echocardiography as the preferred imaging tool to prepare the LAAO procedure

Summary

Considering the versatility and accuracy of cardiac computed tomography (CCT) in the pre-procedural planning of percutaneous left atrial appendage occlusion (LAAO), it is expected that CCT will increasingly replace transoesophageal echocardiography as the preferred imaging tool to prepare this procedure. Besides routine visualization of anatomical landmarks – such as left atrial appendage (LAA) ostium and landing zone – CCT also allows for computational modelling, integrating the delivery sheath and occlusion device into the pre-procedural imaging. This article aims to discuss how to assess CCT-based measurements of LAA landmarks and how to use computational modelling in order to optimize the pre-procedural planning of percutaneous LAAO.

Introduction

Percutaneous LAAO is being increasingly used as a treatment strategy to prevent stroke in patients with non-valvular atrial fibrillation (NVAF) and contra-indication(s) to oral anticoagulant therapy. In order to obtain a successful LAAO, correct LAAO device size selection as well as optimal implantation should be pursued.[1,2]

Various cardiac imaging techniques are currently used to assess the anatomy and size of the LAA, ranging from two-dimensional (2D) transoesophageal echocardiographic (TEE) to cardiac computed tomography (CCT).[3] As the LAA anatomy is highly variable and complex, accurate assessment of this structure is essential for a safe and successful procedure. Traditionally, imaging and sizing of the LAA has relied on TEE[1,2] (Figure 1A). However, in parallel with the acceptance of CCT as the 'gold standard' imaging tool to prepare for transcatheter aortic valve replacement (TAVR), CCT is nowadays also increasingly recognized as a valuable pre-procedural imaging modality to prepare for percutaneous LAAO.[3,4] In Figure 1, some advantages and disadvantages of using CCT over TEE in the preparation of a percutaneous LAAO procedure are listed.

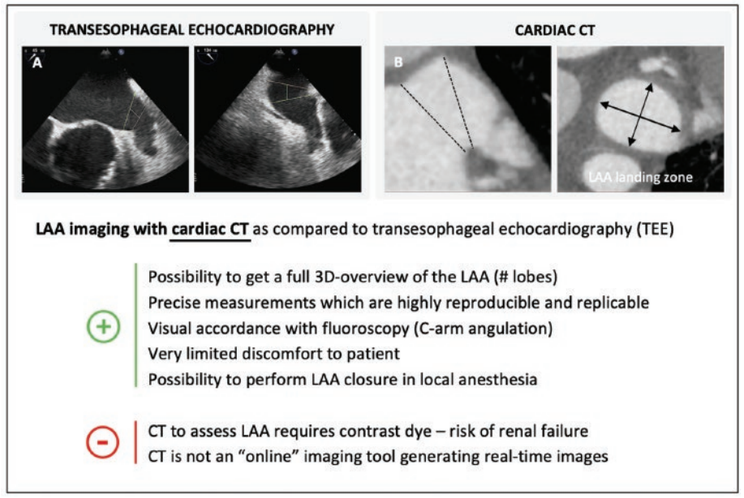

Figure 1. (Dis)advantages of LAA-imaging with cardiac CT.

Besides routine visualization and assessment of anatomical landmarks – such as the LAA ostium and LAA landing zone – CCT also allows for computational modelling, integrating the delivery sheath and LAAO device into the pre-procedural imaging.[5] Currently, the only reliable and validated CCT analysis software offering patient- and device-specific computational modelling is FEOPS HEARTguideTM developed by FEops NV (Ghent, Belgium). This article aims to discuss how to assess and interpret CCT-based measurements of LAA landmarks and how to use computational modelling in order to optimize pre-procedural planning of a percutaneous LAAO procedure.

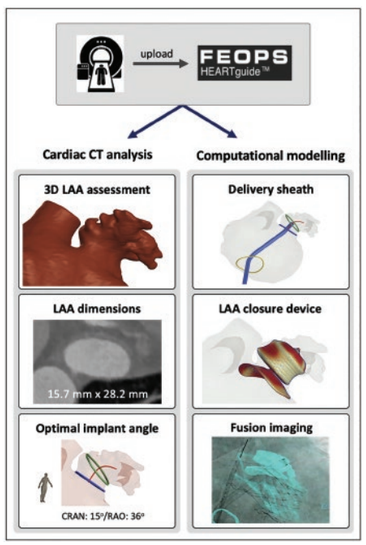

Figure 2. FEops HEARTguide™-generated data and modelling.

An overview on which information is routinely provided by FEops' pre-procedural CCT analysis and computational modelling is shown in Figure 2 – these items are discussed in more detail below.

Three-dimensional (3D) LAA assessment – As the LAA is a complex 3D structure with often multiple lobes in different planes, a thorough and accurate 3D assessment of this cardiac structure helps in obtaining a solid pre-procedural plan. Not only the number of LAA lobes but also the orientation of these lobe(s) may have an impact on the preferred LAAO device, device positioning and even on the preferred site of transseptal puncture. 3D volume-rendered images as shown in Figure 2-3 can be easily generated using CCT data.[3-7] In contrast, this information is more difficult to capture with and interpret on TEE imaging. An additional advantage for the operator performing the LAAO is that 3D volume-rendered CCT images are much easier to compare and link to the fluoroscopic images and angulations obtained during the intervention; this same advantage is also applicable to other transcatheter structural heart interventions.

Accurate measurement of LAA dimensions – Although official instructions for use and sizing charts for LAAO devices are (still) based on 2D-TEE imaging, this methodology has its shortcomings. As the LAA is most often an elliptical structure, accurate measurements of the maximum and perimeter-derived mean diameter of the LAA ostium and LAA landing zone should be made on 3D double-oblique images, which can be easily obtained by CCT-based 3D multiplanar reconstructions (Figure 1B, Figure 3).3 This may not be possible on 2D images.[8] The use of 3D-TEE imaging could theoretically

As the LAA is a complex 3D structure with often multiple lobes in different planes, a thorough and accurate 3D assessment of this cardiac structure helps in obtaining a solid pre-procedural plan

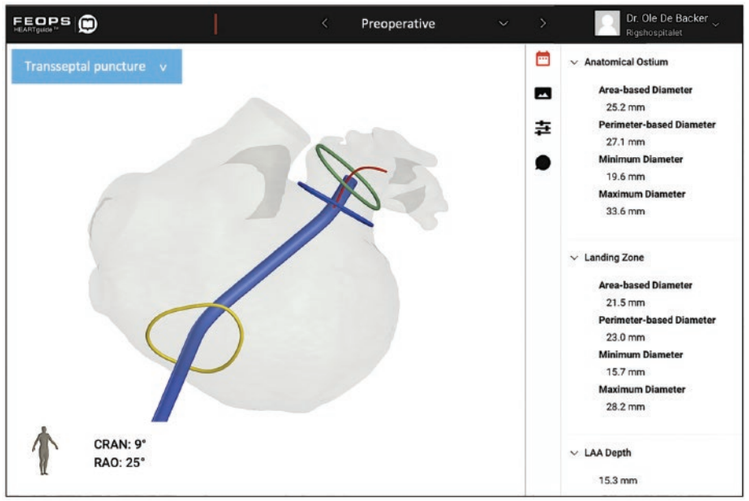

Figure 3. Cardiac CT-analysis with delivery sheath simulation.

With the recent introduction of the Steerable Amplatzer™ delivery sheath for the Amulet™ LAAO device, one can expect that this aspect of the procedure may become easier to adjust during the procedure, regardless of the exact transseptal puncture site

overcome this limitation; however, determining and measuring the LAA landing zone by 3D-TEE may not always be easy or feasible. Also, the measurement of LAA depth (even in different lobes) and assessment of LAA trabecularization and thrombus is possible and accurate on CCT imaging.

Optimal implant angle – Besides accurately sizing the LAA ostium and landing zone, CCT-analysis also allows to predict the optimal C-arm angulation for LAAO device implantation. Typically, the most optimal implant angle (RAO/LAO, caudal/cranial) should generate a fluoroscopic view in which (1) the LAA ostium and landing zone are (near)-aligned, (2) there is as little as possible foreshortening of the LAA, and (3) there is a minimum of overlap between the LAA, left atrium and left upper pulmonary vein (Figure 3). This C-arm angulation is not only the best projection to assess device compression but is also helpful in verifying co-axial alignment of the LAAO device with the LAA structure. This is of importance, as off-axis LAAO device implantation has been reported to be associated with a higher risk of peri-device leak.[9] Furthermore, as this CCT-analysis to determine the most optimal C-arm implant angle can be made 'off-line', before starting the actual procedure, this methodology also helps to keep the use of radiation and contrast dye to a minimum.

Optimal transseptal puncture/delivery sheath – The choice of the transseptal puncture site largely impacts the possibility to obtain co-axial alignment between the delivery sheath and the LAA central axis. As mentioned earlier, obtaining co-axial alignment does not only help avoiding off-axis device implantation, which is associated with a higher risk of peri-device leak,[9] but also makes the procedure less complex and potentially safer. Determining an optimal transseptal puncture site on CCT is possible and dependent on the fossa ovalis/LAA position and orientation of the LAA lobe(s). Typically, a standard inferoposterior transseptal puncture has been recommended.[10] However, a more central-anterior transseptal puncture should sometimes be considered in case of a more posteriorly oriented LAA lobe (e.g., reverse chicken wing);[11] this can easily be detected on pre-procedural CCT. The current version of FEops HEARTguide allows both judging the degree of co-axial alignment when crossing the interatrial septum at different sites (posterior vs. anterior, inferior vs. superior) as well as simulating the Amplatzer™ TorqVue™ delivery sheath into the CCT-rendered images (Figure 3).

With the recent introduction of the Steerable Amplatzer™ delivery sheath for the Amulet™ LAAO device, one can expect that this aspect of the procedure may become easier to adjust during the procedure, regardless of the exact transseptal puncture site. Still, assessment of and reflection on the transseptal puncture site and/or choice of the delivery sheath pre-procedurally can only lead to further optimization of the LAAO procedure and outcomes.

Computational modelling of LAAO device – Although standard CCT analysis allows better understanding and sizing of the patient's LAA anatomy,[3] predicting the actual 'landing zone' of the LAAO device still remains difficult and an important source of sizing error. The use of printed 3D-LAA models has been reported as a method to improve the pre-procedural planning;[12]

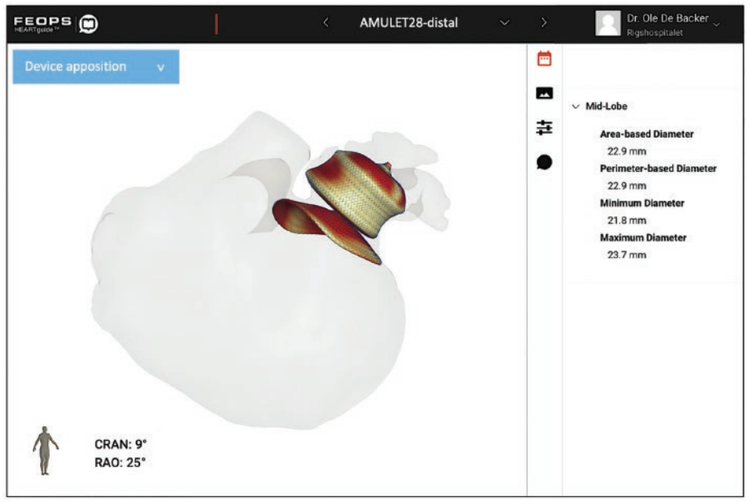

Figure 4. Patient-specific computational model with device simulation.

however, this approach cannot be implemented on a large scale due to logistical requirements. In accordance with 3D-model testing, computational modelling can complement standard CCT analysis and provide additional insights into the patient-specific LAA anatomy and its interaction with the implanted device.

The FEops HEARTguideTM simulation technology has been developed and is capable of simulating the mechanical interaction between the implanted device and the patient's anatomy (Figure 4) and has been validated for percutaneous LAAO[13] and other structural heart interventions.[14] Different sizes of the LAAO device can be simulated at different implant depths within a patient-specific LAA anatomy. The computational models generate information on device compression (%) and wall apposition (Figure 5), the latter being predictive for the risk of peri-device leak.[13] Although the importance of complete LAAO is still a topic of debate, it seems obvious that complete LAAO should be the goal when performing this procedure. Ultimately, these patient-specific computational models simulating different LAAO device sizes and positions should allow the operator to take the best possible decision and this before starting the actual procedure.

Possibility for CCT-fluoroscopy fusion imaging – The use of fusion imaging in complex structural heart interventions has

The use of fusion imaging in complex structural heart interventions has gained interest over the past few years

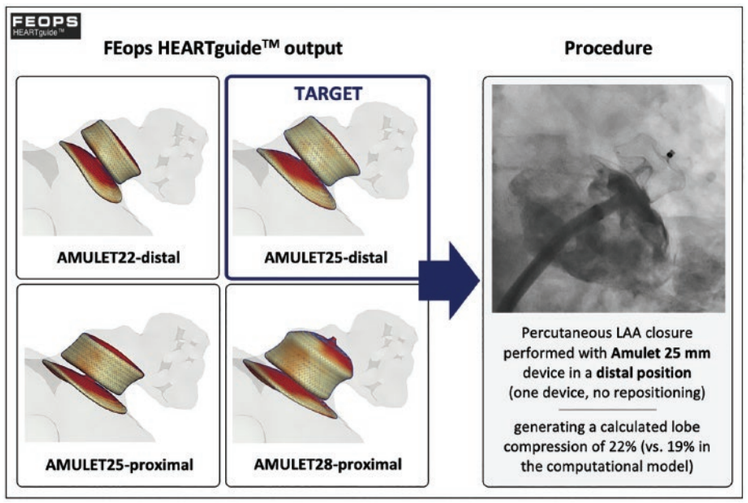

Figure 5. Case example of HEARTguide™-simulations and procedure.

gained interest over the past few years. Currently, only the combination of TEE with fluoroscopy allows real-time fusion imaging. The shortcoming of CCT and fluoroscopy overlay is the inability of live fusion. Still, CCT-fluoroscopy fusion imaging has shown its value by providing visual anatomical markers during ablation procedures.[15] The use of markers can also be helpful to localize the otherwise invisible LAA on fluoroscopy and can potentially increase procedural success while reducing radiation, procedure time, and the use of contrast dye. Markers can be placed at the LAA ostium, LAA landing zone, or the tip of the LAA. In addition, overlay imaging of a simulated LAAO device may help to ensure correct device positioning. However, to date there is only limited evidence that fusion imaging improves safety and outcomes of structural heart interventions.

Discussion

Considering the above items, it is hard to deny the added value of using CCT in the pre-procedural work-up of a percutaneous LAAO procedure. As CCT allows a comprehensive and accurate pre-procedural planning at such a high level, several centres are nowadays performing percutaneous LAAO in local anaesthesia without TEE. In order to guide the critical steps of LAAO and evaluate the implant result intra-procedurally, most operators have been using intracardiac echocardiography (ICE), which can be introduced by the femoral vein and into the left atrium.[16] Other operators are more familiar with micro- or mini-TEE to guide the percutaneous LAAO procedure. However, as both ICE and micro-TEE have their limitations, especially with regards to accuracy in LAA sizing, it is important that such approach is only chosen when high-quality CCT imaging is available pre-procedurally. As general anaesthesia is no longer an absolute need for performing LAAO, this approach may also facilitate the entire logistical process in some hospitals.

As CCT allows a comprehensive and accurate pre-procedural planning at such a high level, several centres are nowadays performing percutaneous LAAO in local anaesthesia without TEE

The PREDICT-LAA clinical trial (ClinicalTrials.gov: NCT04180605) will be the first randomized clinical trial studying the efficacy of the pre-procedural planning for percutaneous LAAO, comparing a standard approach relying on CCT analysis only vs. a pre-procedural planning that integrates patient-specific computational simulations. The PREDICT-LAA trial investigates the hypothesis that a better pre-procedural planning using FEops HEARTguide™ may ultimately result in higher rates of complete LAAO and lower rates of device-related thrombus, as assessed on post-procedural CCT imaging.[5] Additional parameters evaluated in the trial are indicators of procedural safety and efficiency, such as procedural time, radiation exposure, number of devices used, device repositioning, etc. The enrolment of 200 patients in this trial is expected to be completed in December 2021 and one-year follow-up results can be expected at the end of 2022.

Conclusions

Considering the versatility and accuracy of CCT in the pre-procedural planning of percutaneous LAAO, it is expected that CCT will increasingly replace TEE as the preferred imaging tool to prepare this procedure. Also, the field of computational modelling is continuously evolving and making further improvements, adding to a continuous improvement in this pre-procedural planning. More data supporting the usage and advantages of CCT and computational modelling are needed and CCT-based recommendations from the LAAO device vendors have to follow in order to establish CCT as the new 'gold standard' imaging tool to prepare for percutaneous LAAO.

OPTIMISING LEFT ATRIAL APPENDAGE OCCLUSION (LAAO) PROCEDURES FOR PATIENTS AT RISK OF STROKE

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Intracardiac Echocardiography to Guide Left Atrial Appendage Occlusion

Intracardiac echocardiography provides an alternative to transoesophageal echocardiography for guidance of left atrial appendage occlusion.

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Intracardiac echocardiography (ICE) can be used instead of TEE to guide LAAO

Introduction

Transoesophageal echocardiography (TEE) is the most widely used imaging modality to guide left atrial appendage occlusion (LAAO). It gives high-quality images of the left atrial appendage (LAA) in most patients and has the advantage of multiplane imaging and a 3-dimensional imaging option with advanced probes. However, the drawback of this technique is the requirement of a separate TEE operator and an anaesthesiology team. In some centres, TEE-guided LAAO is performed using conscious sedation either with a conventional TEE probe or with a mini-TEE or micro TEE-probe. However, use of miniaturized TEE probes is associated with loss of image quality. TEE carries a risk of injury to the mucosa of the oesophagus[1] and it cannot be used in some patients with gastroesophageal or hepatic disorders. A TEE-guided approach for LAAO is often limited by the accessibility of personnel for anaesthesia and TEE and it is associated with long turn-over times in the interventional suite. Moreover, TEE is an aerosol generating procedure with near contact between patient and operator creating an environment that can facilitate virus transmission.

Intracardiac echocardiography (ICE) can be used instead of TEE to guide LAAO. This allows the procedure to be carried out in local anaesthesia with the patient being awake, cooperating and capable of reporting any unexpected symptoms that might occur during the procedure. Patients can be allowed to drink freely up to the procedure and cardiac filling pressures will not be influenced by fasting or anaesthesia. The ICE catheter can be operated by the LAA implanter without the need for an additional cardiologist to do the imaging and planning, logistics and turn-over times in the catheterization laboratory will be improved. Pre-planning LAAO by cardiac CT is highly recommended irrespective of the use of ICE or TEE for guiding the procedure (Figure 1).

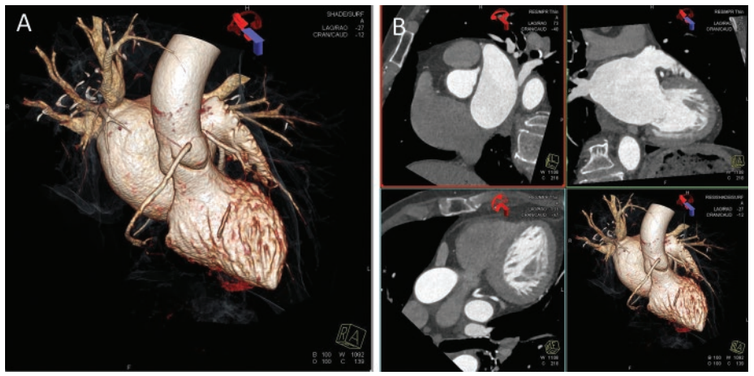

Figure 1: Pre-planning LAAO by cardiac CT. A: 3-dimensional reconstruction of the left heart showing a chicken-wing LAA. B: Multiplanar reconstruction (MPR) views showing the LAA with an optimal C-arm position for implantation (upper right; RAO30/CAU10) and a cross-sectional view of the LAA orifice (lower left).

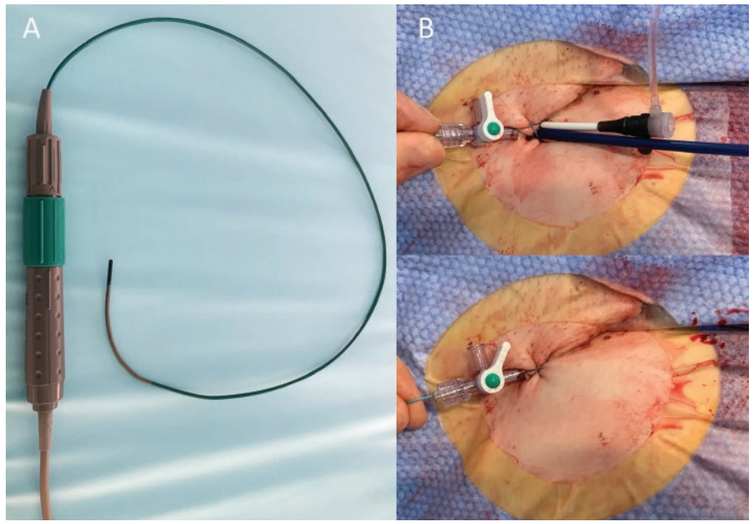

Figure 2: A: The Abbott ViewFLEX ICE catheter with a steerable tip, anterior/posterior (grey wheel) and left/right (green wheel). B: Two sheaths inserted into the right femoral vein through separate punctures. Towards the midline a 9F 20 cm long Terumo sheath for the ICE catheter and more lateral and a little higher the venous access for initially the transseptal sheath and then the delivery sheath. At the end of the procedure haemostasis is obtained by a figure of eight suture tightened with a 3-way stopcock.

The most widely used ICE catheters are the Abbott ViewFlex (9F) and the AcuNav (8F or 10F). The ViewFlex (Figure 2) runs on the Abbott ViewMate/Zonare platform or on certain Philips echomachines through an interface. The AcuNav can be used on Siemens or GE echomachines using relevant interface connectors. The ultrasound frequency range is 3-10 MHz and the field of depth up to 16-18 cm. Both catheters gives only monoplane imaging and imaging should therefore be controlled by steering the tip of the ICE catheter (posterior/anterior, right/left and rotation of the shaft). Novel ICE catheters offer 3D imaging. The AcuNav volume catheter provides 3D imaging in a limited sector, but there is loss of resolution when the volume catheter is used for 2D imaging compared with the 2D AcuNav catheter. The VeriSight Pro catheter from Philips received FDA approval very recently and offers 3D as well as multiplane imaging in a similar way as known from TEE probes. The cost of the catheters is a frequently raised argument against an ICE-guided approach, but analyses indicate that costs are neutral due to savings in personnel and improved logistics and procedural capacity in the catheterization laboratory[2]. Moreover, the catheters can be resterilised without technical problems.

The LAA can be viewed from several right-sided positions within the heart (right atrium, coronary sinus, right ventricular outflow tract, pulmonary artery), but most operators using ICE for LAAO are now imaging the LAA directly from the left atrium (LA)[3]. This position of the ICE catheter gives high-resolution images of the LAA and of all the anatomical markers necessary for an optimal device implantation. The efficacy and safety of using ICE compared with TEE for implantation of the Amulet device have been documented in both single-centre[4] and multi-centre studies[5] and in a sub-study of the Amulet Observational Registry[6]. ICE is very suitable for guiding transseptal puncture and optimal LAA device implantation, but less suitable for accurate device sizing. Cardiac computed tomography (CT) for preplanning of LAAO is recommended for optimal understanding of the LAA anatomy, setting of optimal C-arm positions and accurate device sizing[7].

This position of the ICE catheter gives high-resolution images of the LAA and of all the anatomical markers necessary for an optimal device implantation

How to Perform ICE For LAAO

Two separate vein punctures in the right femoral vein are used for an ICE-guided approach (Figure 2). One lower puncture towards the midline is used for insertion of a 20 cm long 9F Terumo sheath and the ICE catheter. The shaft of the ICE catheter can be positioned between the legs of the patient. Another puncture is done a little higher and a bit more lateral for the transseptal sheath first and then the delivery sheath for the LAA device. The transseptal sheath with dilator and needle is initially advanced to the superior vena cava (SVC). The ICE probe is then positioned in the mid-portion of the right atrium and the “home-view” with the tricuspid valve and right ventricular outlet tract is obtained by clockwise rotation without any steering of the

There is obviously a learning curve for ICE to guide LAAO. It is an advantage if the implanter first achieves experience with LAAO from a TEE-guided approach where focus can be completely on the device implantation itself

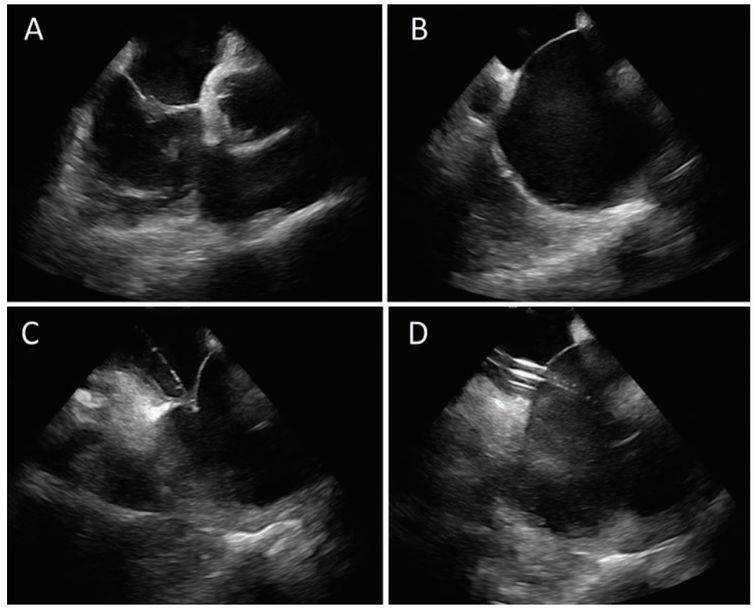

Figure 3: ICE images obtained from the right atrium (RA) to guide the transseptal puncture. A: The "home-view" showing the tricuspid valve, right ventricular outflow tract and the aorta and pulmonary artery. The tip of the ICE probe is mid-RA and in the neutral position (no steering). B: The septal view is obtained simply by rotating the shaft of the ICE catheter clockwise from the home-view. It shows the superior-inferior aspect of the interatrial septum. C: The transseptal needle is tenting in the inferior part of the interatrial septum. Rotating the shaft of the ICE catheter clockwise will show the posterior part of the septum and a counter clockwise rotation will show the anterior part. D: The transseptal sheath is across the inferior part of the interatrial septum.

tip of the catheter (Figure 3). Further clockwise rotation of the catheter will image the interatrial septum and a little posterior steering of the tip will display the SVC and the interatrial septum (superior and inferior septum). The transseptal system is now taken slowly down from the SVC. It can easily be seen when it drops into the oval fossa. It is taken further down until the needle is tenting in the inferior part of the septum. If the ICE catheter is rotated clockwise, the posterior part of the septum will be displayed and by counter clockwise rotation the anterior part of the septum is seen. In this way, the transseptal puncture can be done in the inferior-posterior part of the septum that in most cases gives the best access and coaxial alignment to the LAA. Once in the LA with the transseptal sheath, a stiff wire is advanced to the left upper pulmonary vein (LUPV). The delivery sheath is then advanced over the wire into the LA which will increase the diameter of the transseptal puncture hole. It is taken back again to the inferior vena cava (IVC) and the ICE catheter is now advanced along the wire into the LA. This movement of the ICE catheter into the LA is best controlled under fluoroscopy using the AP projection with a few sweeps to a LAO or lateral projection. In this way the ICE catheter can be advanced strictly parallel along the wire from the RA into the LA (Figure 4). There should be absolutely no resistance when advancing the ICE probe into the LA. The catheter is now positioned just in front of the LUPV ostium or slightly into the LUPV which gives a nice long-axis image of the LAA, LUPV ridge, mitral valve and the circumflex artery (LUPV view; Figure 4). While fixing the ICE catheter, the delivery sheath can now be moved over the septum and into the LUPV. A pigtail catheter is now advanced in the delivery sheath with the tail protruding from the tip of the sheath. The delivery sheath and pigtail catheter together are then taken back towards the LA. It can nicely be seen by ICE when the delivery sheath with the pigtail comes free of the PV ridge and drops down just in front of the LAA. The pigtail is then advanced into the LAA followed by the delivery sheath. Implantation of the device in the neck of the LAA can now be viewed from the LUPV position and also from the mid-LA position with a little posterior steering of the tip of the ICE catheter. With further posterior tilting of the tip and clockwise rotation, the ICE catheter can be positioned just above the mitral valve and beneath the LAA to give the supramitral view of the LAA that resemble the 120o TEE view. The three ICE catheter positions inside the LA (LUPV, mid-LA and supra-mitral) are sufficient to evaluate device position, sealing (colour Doppler) and potential interaction with the mitral valve or

LUPV (Figure 4). After device release, it is good practice to look for possible pericardial effusion. The tip of the ICE catheter (still in the LA) is then steered anteriorly to look down on the mitral valve and LV including the pericardial cavity.

There is obviously a learning curve for ICE to guide LAAO. It is an advantage if the implanter first achieves experience with LAAO from a TEE-guided approach where focus can be completely on the device implantation itself. Implanters that have gained experience with ICE from transseptal punctures and/or closures of patent foramen ovale or atrial septal defects will have a faster learning. Simulators for ICE and ICE-guided LAAO are becoming available and will be a way to facilitate learning of the technique. Ideally, training in ICE-guided LAAO should go along with training in preplanning LAAO by cardiac CT.

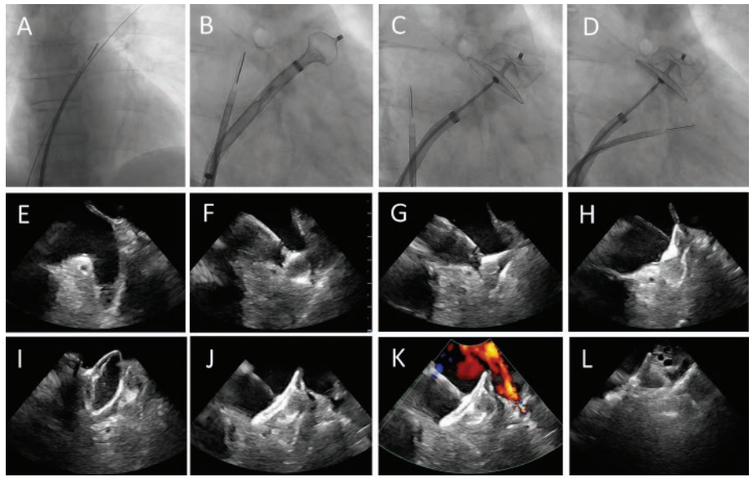

Figure 4: A: An extra-stiff guidewire is across the septum and in the left upper pulmonary vein (LUPV). The ICE catheter has been advanced from the RA into the LA along the guidewire. B: The ICE catheter is in a position to show the LUPV view, C: the mid-LA view and D: the supra-mitral view. E: ICE image of the LAA in the LUPV view. F: The Amulet lobe is in the ball configuration, G: Lobe is in the triangular shape, H: Lobe is fully deployed, I: The Amulet disc is in the American football configuration, J: The disc is fully deployed, K: Colour Doppler to evaluate sealing, L: The Amulet seen in the supra-mitral view.

Simulators for ICE and ICE-guided LAAO are becoming available and will be a way to facilitate learning of the technique

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