Amplatzer™ Amulet™ Occluder

Left Atrial Appendage Occluder

CLOSURE. ONCE AND FOR ALL.

THE AMULET OCCLUDER REFERENCE GUIDE

A European Compendium of Excellence in LAAO with the Amplatzer™ Amulet™ Left Atrial Appendage Occluder

Abbott

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CLOSURE. ONCE AND FOR ALL.

A EUROPEAN COMPENDIUM OF EXCELLENCE IN LAAO WITH THE AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER

1. DUAL-SEALING TECHNOLOGY FOR SUPERIOR CLOSURE

DUAL-SEALING AND CLINICAL ADVANTAGES OF THE DISC WITH X. FREIXA

DUAL SEALING, OCCLUDER COAXIALITY

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INTRODUCTION

The number of patients undergoing left atrial appendage (LAA) occlusion (LAAO) is rapidly growing in developed countries[1]. Currently, LAAO represents a very valid alternative to oral anticoagulation (OAC) with increasing evidence supporting its efficacy and safety[1]. Procedural major adverse events are progressively being reduced with device developments [2] and increasing experience of operators. In fact, pericardial effusion and device embolization used to be the main concerns of operators within the initial years of the therapy. Nonetheless, the low incidence of the aforementioned complications and the growing evidence on long-term outcomes after LAAO has somehow change the focus of the intervention.

With this regard, LAAO is associated with a non-negligible rate of thrombotic and hemorrhagic events within the first year of the therapy. Device related thrombosis (DRT) incidence ranges between 3% and 10% and is associated with a higher rate of stroke[3,4]. Intensive antithrombotic therapy after LAAO seems to be effective to reduce the incidence of DRT but might translate into a higher risk of bleeding in a population that generally is at high-risk of hemorrhagic events. In fact, the rate of major bleeding after LAAO has been reported to reach up to 10% within the first year [5].

Additionally, the presence of a significant (>3mm) peri-device leak (PDL) seems to also play a relevant role in increasing the incidence of thrombotic events after LAAO[6]. All in one, the optimal situation would consist of having the lowest DRT risk which might therefore allow a less intensive antithrombotic therapy and subsequently a lower hemorrhagic risk. Unfortunately, most of the DRT predisposing factors are non-modifiable and linked to patient´s baseline characteristics (diabetes, prior stroke, permanent AF, age or hypercoagulable states)[7,8].

Identification of modifiable factors is crucial to impact on the reduction of DRTs. Among others, optimal device positioning with complete LAA sealing seems to be the most accepted factor impacting on a significant reduction of DRT occurrence[9,10]. This is probably the reason why most experienced operators are currently focused on performing not only a complication-free procedure, but also to provide optimal LAA sealing. In this sense, proximal device implantation and complete coverage of the pulmonary ridge seem to be associated with a lower incidence of DRT[8-10].

DUAL SEALING & COAXIALITY

Proximal device implantation with large devices and complete coverage of the pulmonary ridge is currently one of the main objectives of the intervention. Pre-planning with CT or 3D- TEE or even with dedicated software (FEOPS, VIDAA, 3Mensio...) may be helpful to achieve these objectives. Nonetheless, among all other factors, device design, procedural tools and operator´s experience are pivotal factors to ensure an optimal LAA sealing. The Amplatzer™ Amulet™ (Abbott Medical), a disc and lobe device, has been associated with a higher sealing performance compared to single-lobe devices[11]. **The presence of an external disc allows additional closure performance while keeping a lobe with a highly sealing capacity. Full LAA coverage with no uncovered proximal areas has been associated with higher blood velocities over the device, less turbulences and thus, less thrombogenic risk[12].**

Complete ostium coverage might be more or less challenging depending on LAA anatomy. **Proximal implantation and specially device co-axiality are pivotal factors to achieve optimal implanting results.** In the following example, the use of a same size device with suboptimal **(figure 1A)** or optimal **(figure 1B)** axial alignment provided incomplete **(figure 1C)** or complete

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(figure 1D) pulmonary ridge coverage. Gentle counter-clock wise rotations of the delivery catheter are generally needed to improve device alignment. Nonetheless, catheter manipulation might be challenging in certain scenarios such us stiff interatrial septum or suboptimal transeptal access (generally high punctures).

In this regard, novel procedural tools such as the Amulet™ Steerable Sheath represent a relevant step forward to ensure catheter rotation and alignment without kinking risk. As shown in **video 1**, the use of the Amulet™ Steerable Sheath allowed a perfect coaxial device alignment by translating the desired torque just at the tip of the catheter with no catheter rotation and therefore no additional manipulation. In other words, the steerable catheter converted a less-predictable movement with a complete rotation of the guiding catheter in a highly controlled and safe movement of the tip of the catheter.

Availability of novel tools specifically designed to optimize device position is definitely the right way to offer all operators not only the capacity to implant an occluder device without procedural complications but also to offer a perfect implant from a technical perspective and thus better long-term outcomes for the patient.

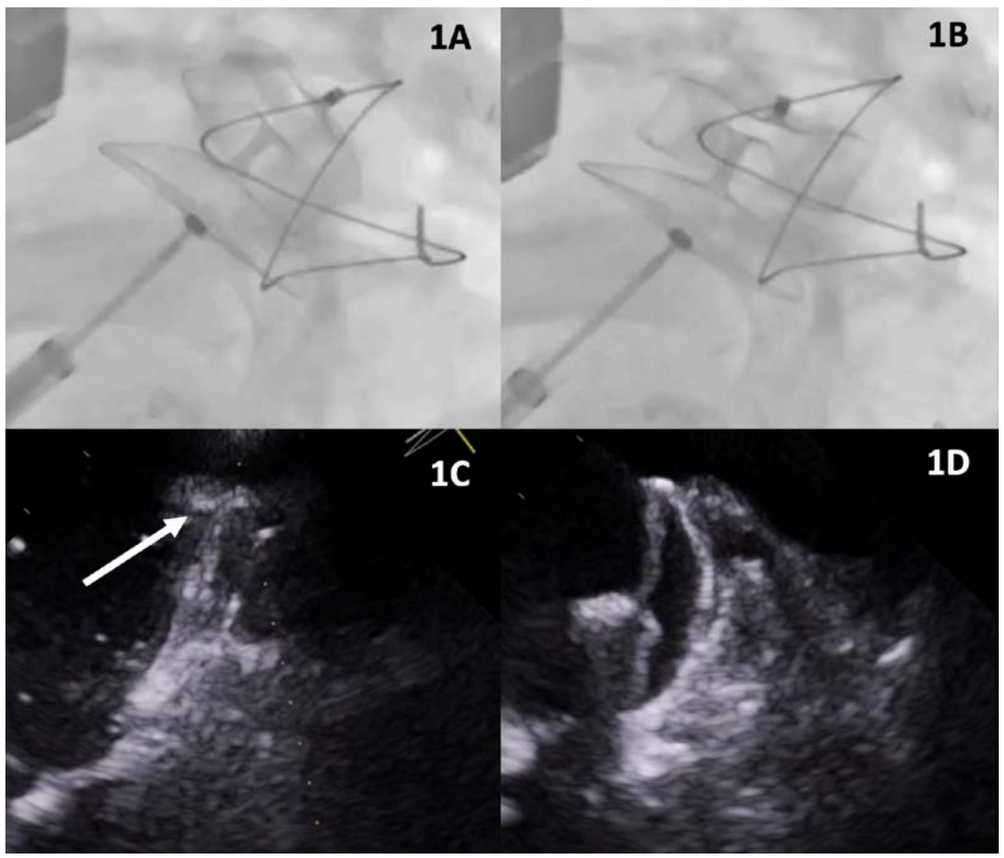

Figure 1: Changes in device axial alignment and pulmonary ridge coverage.

CONCLUSION

The Amulet Occluder, a disc and lobe device, has been associated with a higher sealing performance compared to single-lobe devices **(ref 11)**.
Full LAA coverage with no uncovered proximal areas has been associated with higher blood velocities over the device, less turbulences and thus, less thrombogenic risk.

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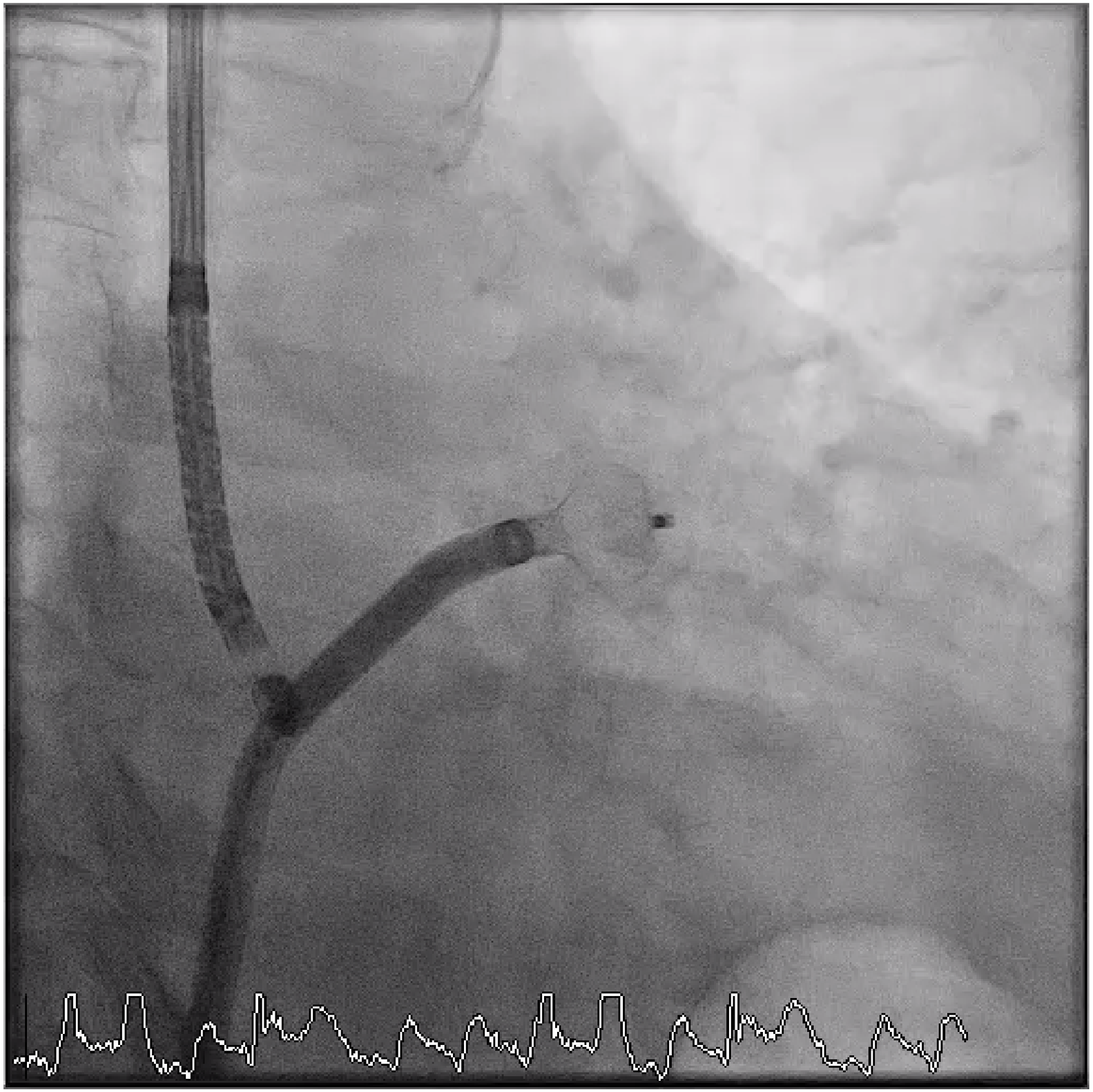

Video 1: Axial alignment of the tip of the catheter using the torque provided by the Amplatzer™ Steerable Sheath. The movement reaches perfect axial alignment by recreating a counter-clock wise rotation of the TorqVue catheter just using the deflection feature of the Amplatzer™ Steerable Sheath without rotating the catheter.

SPAIN: DUAL SEALING, OCCLUDER COAXIALITY

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2. THE ADVANTAGES OF PRE-PROCEDURAL PLANNING

IMAGING MODALITIES AND PLANNING FOR PRECISION WITH O. DE BACKER

PRE-PROCEDURAL IMAGING AND PLANNING FOR PRECISION OF LEFT ATRIAL APPENDAGE CLOSURE PROCEDURES

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SUMMARY

Cardiac-computed tomography (CCT) is a versatile and accurate imaging modality that is expected to increasingly replace transesophageal echocardiography (TEE) as the preferred imaging tool for left atrial appendage occlusion (LAAO).

Besides routine visualisation of anatomical landmarks - such as the left atrial appendage ostium and landing zone - CCT also allows determination of the most optimal fluoroscopic implant angle and transseptal puncture site.

Furthermore, use of CCT opens up the possibility to obtain computational models of the LAAO procedure and integrate some of this information intra-procedurally by means of fusion imaging.

Here we discuss how to use pre-procedural CCT analysis and computational modelling in order to optimise procedural outcomes of LAAO.

CASE PRESENTATION

In order to obtain a successful LAAO is dependent on correct device size selection as well as optimal implantation.[1,2]

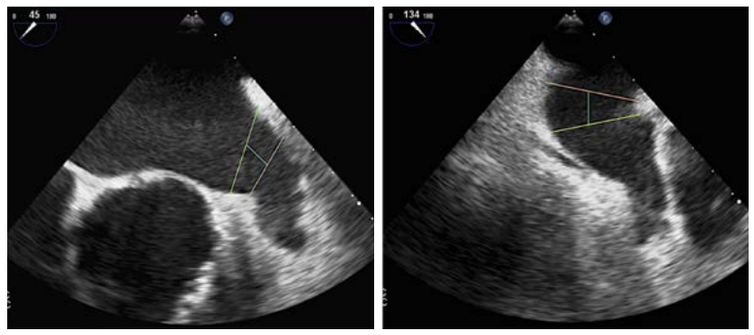
Various cardiac imaging modalities are currently used to assess the anatomy and size of the LAA, ranging from two-dimensional TEE to CCT.[3] As the LAA anatomy is highly variable and complex, accurate assessment of this structure is essential for a safe and successful procedure.

Traditionally, imaging and sizing of the LAA has relied on TEE.[1,2] Unfortunately, TEE imaging of the entire LAA anatomy is not always possible and the measurement of LAA dimensions by means of TEE often comes with a large variation and underestimation of the true actual LAA dimensions. Use of three-dimensional (3D)-TEE can overcome some of these limitations; however, still struggles with the same issues and its reliability is very much imager/operator-dependent.

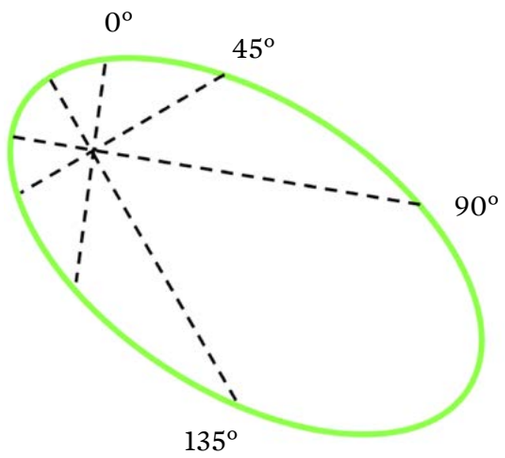
CCT is nowadays increasingly recognised as **the most optimal pre-procedural imaging modality** to prepare for LAAO.

In **Figure 1**, some advantages and disadvantages of using CCT vs. TEE to prepare for LAA closure procedures are listed.

TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)



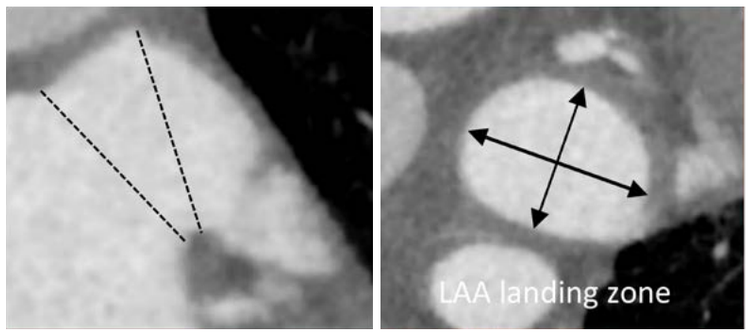
2D-TEE-BASES SIZING



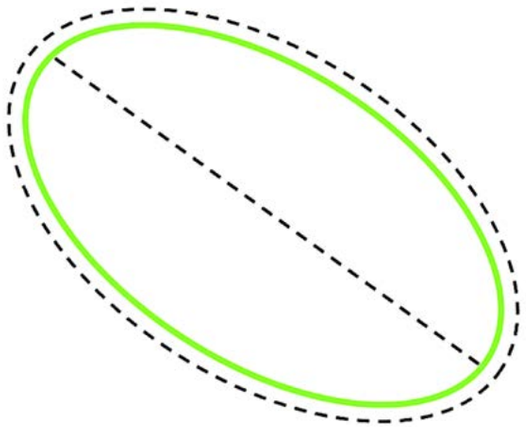
Measured maximal LAA diameter

- Actual maximal LAA diameter

CARDIAC CT (CCT)



CCT-BASED SIZING



Accurate measurement of:

- Perimeter-derived mean diameter
- Maximal diameter

LAA IMAGING WITH CARDIAC CT

AS COMPARED TO TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)

+ Possibility to get a full 3D-overview of the LAA (# lobes)
+ Precise measurements which are highly reproducible and replicable
+ Visual accordance with fluoroscopy (C-arm angulation)
+ Very limited discomfort to patient
+ Possibility to perform LAA closure in local anesthesia

- CCT to assess LAA requires contrast dye – risk of renal failure
- CCT is not an “online” imaging tool generating real-time images

Figure 1: Imaging of the LAA with different imaging modalities. Pros and cons. CCT, cardiac computed tomography; LAA, left atrial appendage; TEE, transesophageal echocardiography.

Besides routine visualization and assessment of anatomical landmarks such as the LAA ostium and LAA landing zone, the use of CCT in the pre-procedural planning also allows to determine the most optimal fluoroscopic implant angle and transseptal puncture site. Furthermore, it opens up for the possibility to obtain computational models/ simulations of the LAA closure procedure and even integrate some of this pre-procedural CT-information intra-procedurally by means of fusion imaging.[4]

Figure 2 gives an overview of the possible advantages of using CCT in the pre-procedural planning of LAA closure.

3D assessment – As the LAA is a complex structure, often with multiple lobes in different planes, a thorough 3D assessment.

Not only the number of LAA lobes but also the orientation of these lobe(s) may have an impact on the preferred LAA closure device, device positioning and even transseptal puncture site.

3D volume-rendered images as shown in **Figure 2** 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 LAA closure is that 3D CCT images are much easier to compare and link to the fluoroscopic images and angulations obtained during the intervention.

Accurate measurement of LAA dimensions – Although official instructions for use and sizing charts for LAA closure 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 landing zone should be made on 3D double-oblique images, which can be easily obtained by CCT-based 3D multiplanar reconstructions **(Figure 1-2)**.[3]

This may not be possible by 2D TEE imaging.[8] The use of 3D-TEE imaging could theoretically overcome this limitation; however, determining and measuring the LAA landing zone by 3D-TEE may not always be feasible or easy. Also, the measurement of LAA depth (even in different lobes) and assessment of LAA trabecularization and thrombus is possible and accurate on CCT imaging.

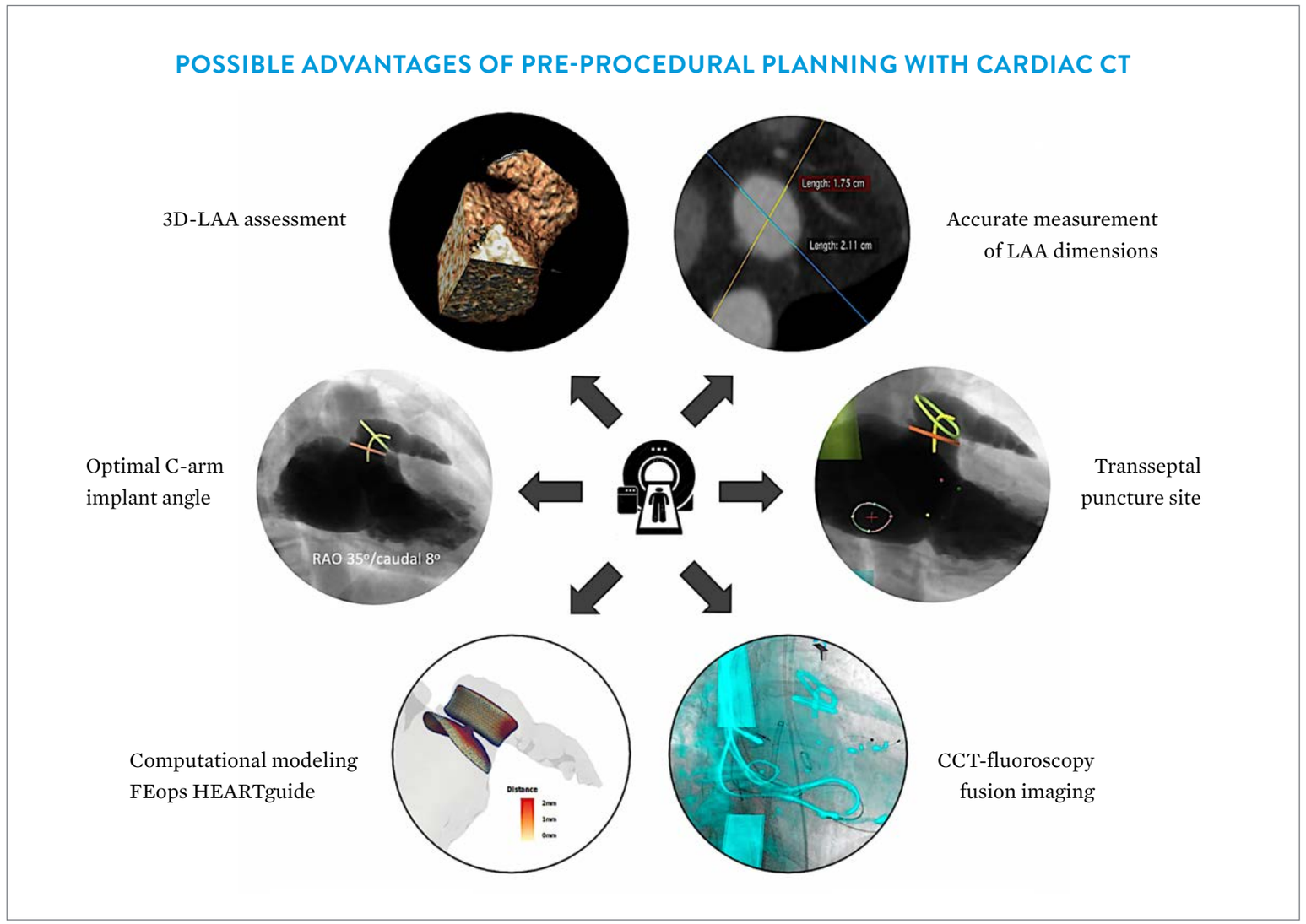


Figure 2: Possible advantages of pre-procedural planning with cardiac CT. CT, computed tomography; LAA, left atrial appendage.

Optimal implant angle – The use of CCT in the pre-procedural planning for LAA closure also allows to predict the optimal C-arm angulation to cannulate the LAA and implant the closure device. The most optimal implant angle 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 left atrium and LAA **(Figure 3)**. Typically, this is obtained in a RAO 20-40° and caudal/cranial 0-30° fluoroscopic view.

C-arm angulation is most optimal for:

- Identifying a good fluoroscopic projection to assess device compression
- Verifying coaxial alignment of the delivery system and closure device with the LAA central axis. Coaxial align-ment is associated with a lower risk of peri-device leak
- Minimizing use of radiation and contrast dye during the procedure

CARDIAC CT ANALYSIS TO DETERMINE THE OPTIMAL IMPLANT ANGLE FOR LAA CLOSURE

Optimal implantation view

- Aligned LAA ostium/landing zone
- Minimal LAA foreshortening
- Minimal overlap between LAA–LA

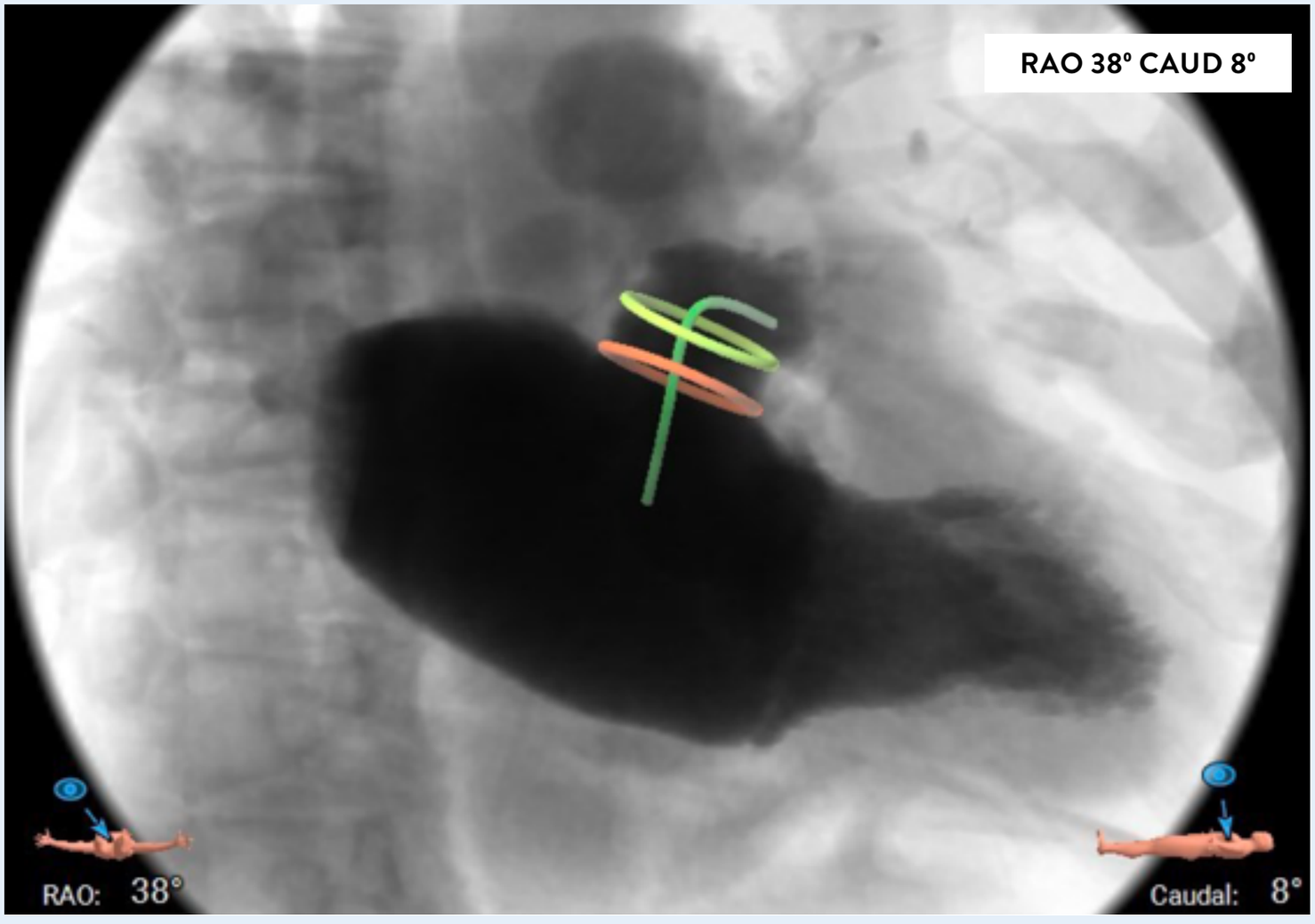


Figure 3: Cardiac CT analysis to determine the optimal implant angle for LAA closure. CT, computed tomography; LA, left atrium; LAA, left atrial appendage.

Optimal transseptal puncture site – The choice of the transseptal puncture site largely impacts the possibility to obtain coaxial alignment of the delivery sheath with the LAA central axis.

As mentioned, obtaining coaxial alignment does not only help avoiding off-axis device implantation, 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 latest version of FEops HEARTguide allows both judging the degree of coaxial 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.

Amplatzer™ Steerable Delivery Sheath – With the recent introduction of a steerable delivery sheath for the Amplatzer™ Amulet™ LAA closure device, two advantages have come forward: (1) nowadays, complex LAAs can also be closed in a straightforward fashion.

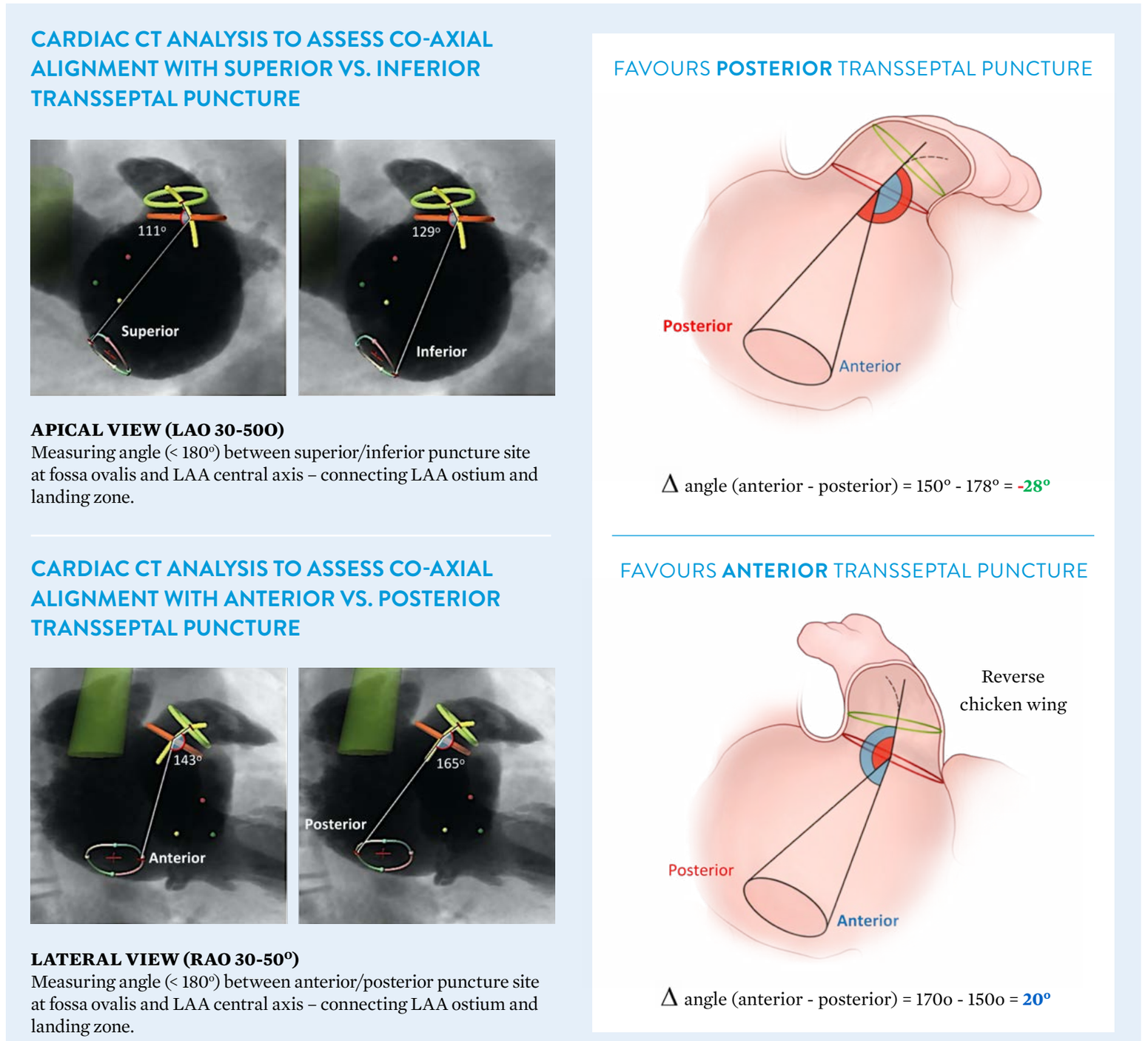


Figure 4: Cardiac CT-analysis to determine the optimal transseptal puncture site. CT, computed tomography; LAA, left atrial appendage; LAO; left anterior oblique; RAO, right anterior oblique.

Figure 5 shows a typical example of a reverse chicken wing LAA which is challenging to close with the standard materials/techniques due to the extreme anterior bending of the LAA central axis – this can be turned into a straightforward LAA closure procedure using the flex/extension option of the Amplatzer™ Steerable Delivery Sheath, and (2) theoretically, it should be easier to obtain coaxial alignment between the LAA central axis and the LAA closure device, promoting complete LAA closure in nearly all cases. It is not recommended to use the steerable sheath as a tool to compensate or correct for a sub-optimal transseptal puncture. Also, it is important to realize that the steerable tip of this new delivery sheath does not replace the (overall) need for anterior torque of the delivery sheath during LAA closure.

Computational modelling and LAAO – Although standard CCT analysis allows better understanding and sizing of the patient's LAA anatomy,[3] predicting the actual 'landing zone' of the LAA closure device still remains difficult and an important source of sizing error. 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 HEARTguide™ simulation technology is capable of simulating the mechanical interaction between the implanted device and the patient's anatomy and has been validated for percutaneous LAA closure.[13]

Different sizes of the LAA closure 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, the latter being predictive for the risk of peri-device leak.[13]

Although the importance of complete LAA closure is still a topic of debate, it seems obvious that complete LAA closure should be the goal when performing this procedure. Ultimately, these patient-specific computational models simulating different LAA closure device sizes and positions allow the operator to take the best possible decision and this before starting the actual procedure.

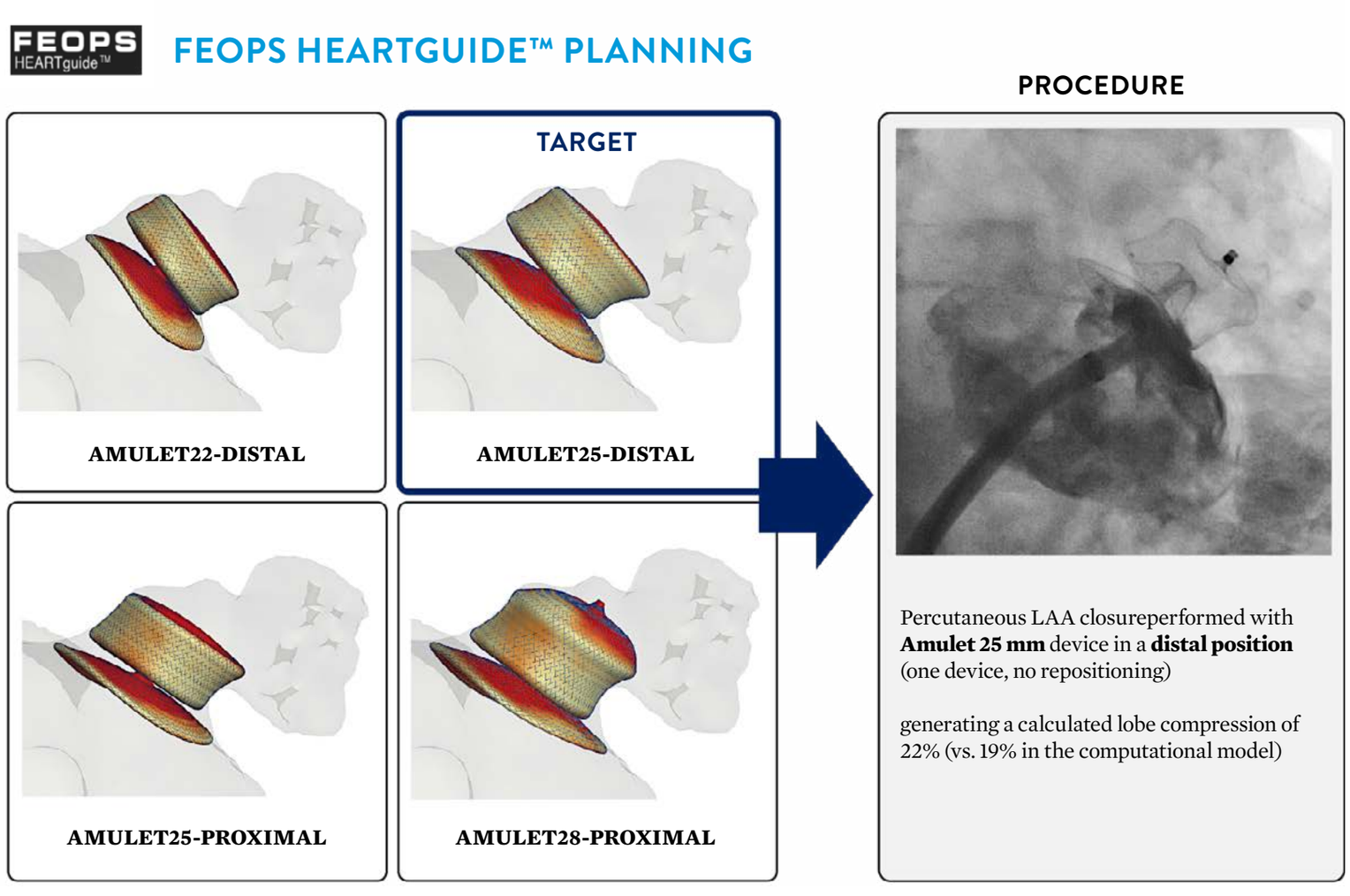


Figure 5: Case example of FEops HEARTguide™-simulations and the final procedure.

CASE DISCUSSION

Considering the above, it is hard to deny the added value of using CCT in the pre-procedural work-up of a percutaneous LAA closure procedure. As CCT allows for a comprehensive and accurate pre-procedural planning at such a high level, several centres are nowadays performing percutaneous LAA closure in local anaesthesia without TEE. In order to guide the critical steps of LAA closure and evaluate the intra-procedural result, an increasing number of operators are nowadays using intracardiac echocardiography (ICE), which can be introduced by the femoral vein and into the left atrium.[14]

Other operators are more familiar with micro- or mini-TEE to guide the percutaneous LAA closure procedure. However, as both ICE and micro-TEE have their limitations, especially with regards to accuracy in LAA sizing, it is important that such an approach is only chosen when high-quality CCT imaging is available pre-procedurally. As general anaesthesia is no longer an absolute need for performing LAA closure, this approach may also facilitate the entire logistical process in some hospitals.

Considering computational modelling, the PREDICT-LAA trial has been be the first randomized clinical trial studying the efficacy of the pre-procedural planning for LAA closure, comparing a standard approach relying on CCT analysis only vs. a pre-procedural planning that integrates patient-specific computational simulations.

In a study population of 200 patients, pre-procedural availability of CCT-based computational models proved to result in improved procedural efficiency with use of fewer Amulet™ devices, less device repositionings per procedure and a 25% reduction in the use of radiation and contrast medium. Furthermore, optimal implant results with complete LAA closure and without retraction of the Amulet Occluder into the LAA were more often achieved in cases prepared with FEops HEARTguide™ simulations.[15] Future studies should address whether integration of computational models intra-procedurally by means of fusion imaging can further improve procedural efficiency and outcomes.

CCT AS THE FUTURE

Considering the versatility and accuracy of CCT in the pre-procedural planning of percutaneous LAA closure, it is expected that CCT will increasingly replace TEE as the preferred imaging tool to prepare for this procedure.

Also, the field of computational modelling is still continuously evolving, adding to a continuous improvement in the pre-procedural planning of this procedure. More data supporting the use of CCT and computational modelling are needed and CCT-based recommendations from the LAA closure device vendors have to follow in order to establish CCT as the new 'gold standard' imaging tool to prepare for percutaneous LAA closure.

3. COMPLICATION MANAGEMENT

PROCEDURAL RISK MITIGATION AND MANAGEMENT WITH H. OMRAN

COMPLICATION MANAGEMENT
PROCEDURAL RISK MITIGATION AND MANAGEMENT

Professor Heyder Omran.
St Marien Hospital, Bonn, Germany.

AVOIDING COMPLICATIONS

The safety of left atrial appendage occlusion improved over the last decade due to technical developments regarding the device itself, optimized image guidance of the procedure and systematic training of the implanters. However, there are still a number of important and potentially clinically relevant complications.

> Most of the complications may be addressed without meaningful consequences to the patient and may be prevented by means of a careful implantation technique.

An important complication are **peri device leaks (PDLs)**. Clinically relevant peri device leaks are more common with the Watchman‡ than with the Amplatzer™ Amulet™ LAA Occluder. Peri device leaks are associated with thrombus formation or device embolization. Hence, leaks should not be accepted.

Formation of **device related thrombi (DRTs)** after left atrial appendage closure is potentially a serious complication resulting in increased mortality and stroke rates. Device related thrombi were reported in 3.7% in the EWOLUTION trial. Risk factors for device related thrombi are patient-, device- or procedure-related. In any case patients should be instructed to adhere to the proposed anticoagulatory therapy. In our experience, device related thrombi are more frequent with incomplete sealing of the left atrial appendage orifice or angulated implantation of the device.

In approximately 80% of patients with device related thrombus formation, adjustment of anticoagulation results in dissolvement of the thrombus. Therefore, we recommend serial echocardiographic or CT follow up studies in all patients with left atrial appendage occlusion.

Pericardial effusions occur in approximately 1.4% of cases. Therefore, it is important to monitor all patients and take all measures to prevent this complication. Most pericardial effusion may be treated conservatively. However, pericardial tamponade requiring immediate action is rare with 0.3 – 0.5% of cases. Early detection of pericardial effusions is key for appropriate treatment. Hence, it is recommended to perform echocardiography prior to, during and after the procedure. In some cases pericardial effusion may occur only hours or days after the procedure, therefore clinical and potentially echocardiographic monitoring of the patients is helpful to detect this complication.

The causes of pericardial effusion are manifold. It is useful to monitor the position of the wire, the sheath and the device either with echocardiographic imaging or fluoroscopy. Probably the safest approach to the left atrial appendage is the use of a pigtail catheter.
The tip of the delivery sheath should not touch the wall of the appendage.

The tip of the device is fairly stiff while it is ball-shaped. Once the device develops a triangular shape it may cause less pressure during deployment. As a consequence the device itself should not be pushed to the wall of the left atrial appendage as long as it is still ball-shaped. Imaging guidance to identify the distal position of the device may reduce iatrogenic perforation of the left atrial appendage.

Adequate anchoring of the device is assured by different means. Compression of the device and engagement of the hooks into the tissue are of the utmost importance. In addition, frequent recapture and redeployment of the device itself may cause minor perforations of the left atrial appendage wall leading to pericardial effusions. Therefore, adequate sizing of the device either prior to the procedure or at the beginning of the procedure is necessary.

In any case, forward pressure on a fully deployed device should be avoided to prevent perforation of the left atrial appendage.

Major bleeding during and after the procedure is a possible complication. Potential causes are laceration of the vessels, rigorous anticoagulation or antiplatelet therapy in patients with high bleeding risk, i.e. patients with Osler disease.

Mortality of the procedure is low, but may rise up to 0.2% and is often associated with complications, in particular with pericardial tamponade.

Device infections are rarely reported. However, to avoid infections it is recommended to provide either intravenous or oral antibiotic prophylaxis prior to the procedure.

Femoral vein puncture may cause iatrogenic bleeding complications and groin hematoma. To reduce this complication, ultrasound guided puncture may be performed. Femoral artery puncture for hemodynamic monitoring may be another cause of complications and hence should be avoided. Radial artery puncture is potentially safer than femoral puncture, if invasive hemodynamic monitoring is required.

To prevent relevant bleeding complications, early dual antiplatelet therapy prior to the procedure may be started after successful and uncomplicated procedure.

Embolization of the device itself is a rare complication and occurs in only approximately 0.1% of cases. If embolization occurs, interventional retrieval of the device is often feasible, in particular, if the device is embolized in the aorta. Embolization of the device is sometimes caused by an impaired connection of the device with the delivery cable. The device should not be disconnected before implantation and the connection itself should be ensured during the advancement through the delivery sheath. The most frequent cause for embolization of the device itself is improper sizing of the device and failure to follow the CLOSE criteria for implantation. Hence it is recommended to perform the implantation procedure with image guidance.

Periinterventional strokes are another rare complication and may be caused by air embolism or thrombus formation during the procedure. Therefore, meticulous care is required to prevent the artificial introduction of air into the system. The valve should not be opened while advancing the device and the delivery sheath should be continuously flushed with saline. Importantly, backflow through the sheath should be checked before the introduction of the device, because wall entrapment of the sheath may cause negative pressure in the delivery sheath and result in air suction through an incompletely closed valve. Thrombus formation on the sheath, delivery cable or the device itself occurs infrequently. Factors influencing thrombus formation are the duration of the procedure, inadequate anticoagulation, lack of control of anticoagulatory effect, repeated recapture and deployment attempts of the device and patient related risk factors as elevated thrombocytes or other prothrombotic states.

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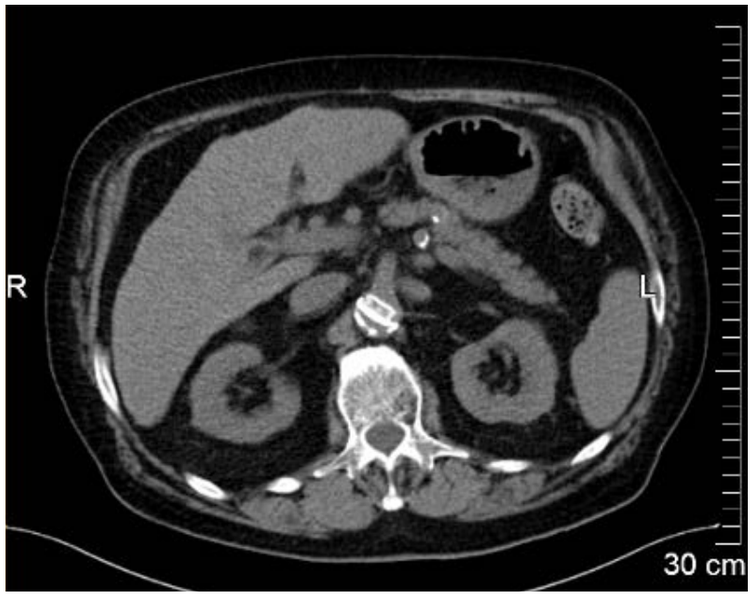

Figure 1: Embolized left atrial appendage occlusion device in the abdominal aorta

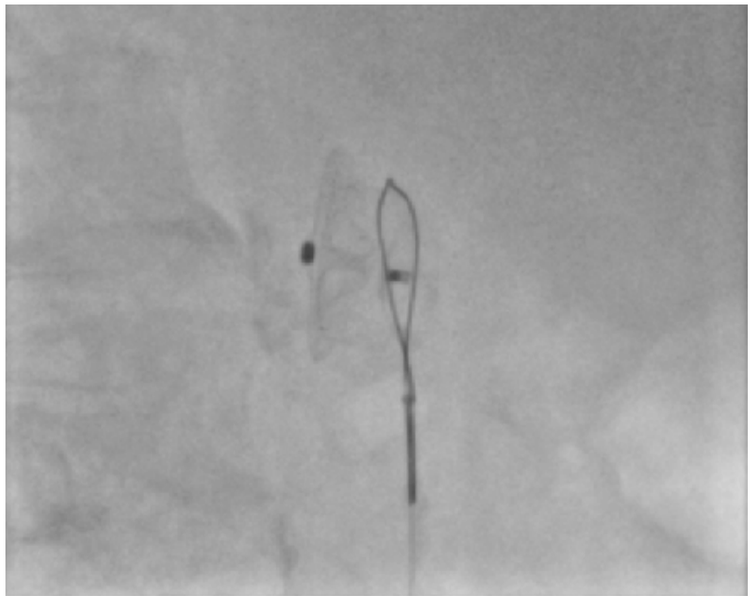

Figure 2: Retrieval of the device with a snare

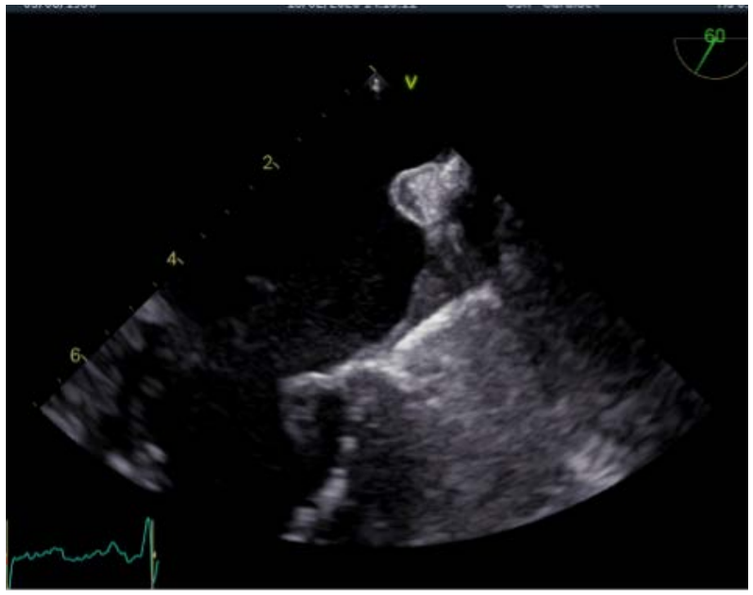

Figure 3: Thrombus on the surface of the occlusion device

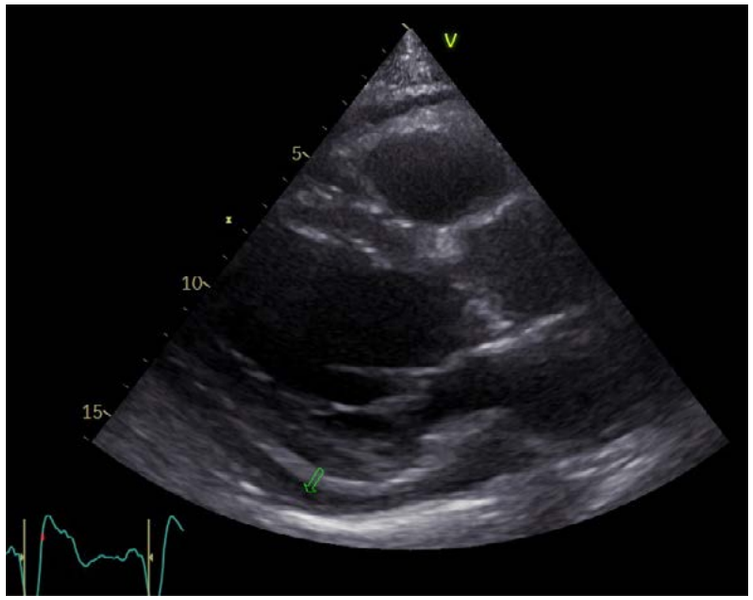

Figure 4: Small pericardial effusion (arrow)

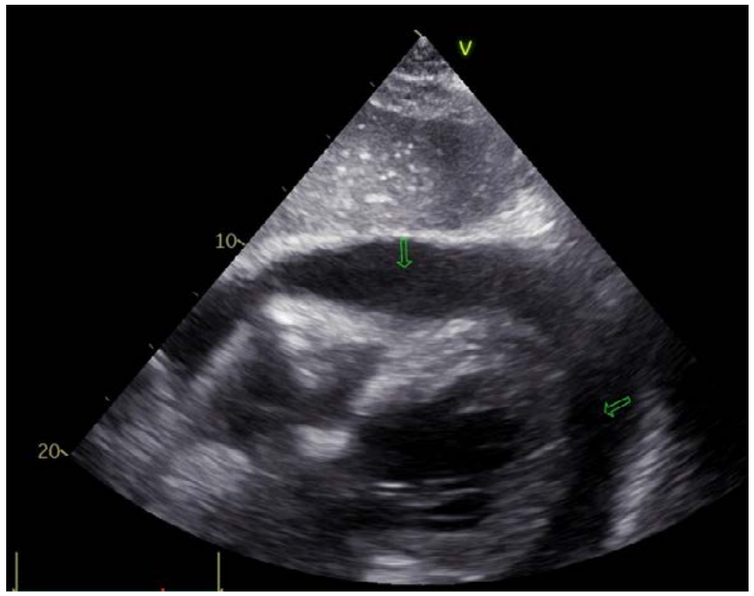

Figure 5: Large pericardial effusion (arrows)

4. ANATOMICAL SHOWCASE WITH THE AMULET OCCLUDER

CHICKEN WING AND SANDWICH TECHNIQUE WITH S. BERTI AND L. PASTORMELO

CLOSURE OF A LARGE AND CONICAL LEFT ATRIAL APPENDAGE WITH N. AMABILE

CLOSURE OF A MULTILOBULAR LAA ANATOMY WITH A. POLZIN

SUPERIOR VASCULAR ACCESS WITH R. GALEA AND L. RABER

LEFT ATRIAL APPENDAGE OCCLUSION PROCEDURE WITH ABBOTT AMULET DEVICE AND AMULET™ STEERABLE SHEATH **IN A RETROFLEX CHICKEN WING ANATOMY**

Dr. Luigi Emilio Pastormerlo, Dr. Sergio Berti
Fondazione Toscana Gabriele Monasterio, Massa, Italy

ABSTRACT

Left atrial appendage occlusion procedure may become challenging in some specific anatomic morphologies. Chicken wing is the most common anatomy. Sometimes chicken wing may be challenging depending on some variables as the neck length, wing orientation and angle. In similar cases the advantage of a steerable delivery system may be fully appreciated. The present case describes a successful LAAO procedure with Abbott Amulet device, using the Abbott Steerable Sheath in a retroflex chicken wing anatomy.

INTRODUCTION

Left atrial appendage occlusion (LAAO) procedure may become challenging in some specific anatomic morphologies. Chicken wing (CW) is the most common anatomy of LAA. CW morphology is defined by the presence of an obvious bend, with variable degree of angulation, at some distance from the left atrial appendage main body. This anatomy has a main lobe with, sometimes, secondary lobes. While the proximal neck is invariably directed in antero-superior direction, the wing of the left atrial appendage may have different direction. When the wing continues to be mainly directed in the antero-superior direction we define it as classical CW. Conversely when the wing is reflected toward a mainly posterior, superior or rightward direction, we define it as reverse CW.

Even if CW anatomy is associated with lower incidence of ischemic events, this specific anatomy may be associated with technical difficulties during LAAO procedures. In particular, CW anatomy may be challenging in about 15% of CW cases, when the neck is shorter than 15-20 mm as the space for the landing of the device lobe is limited and/or when the bend of the chicken wing has extreme angulation and is directed posteriorly as the orientation of the device.

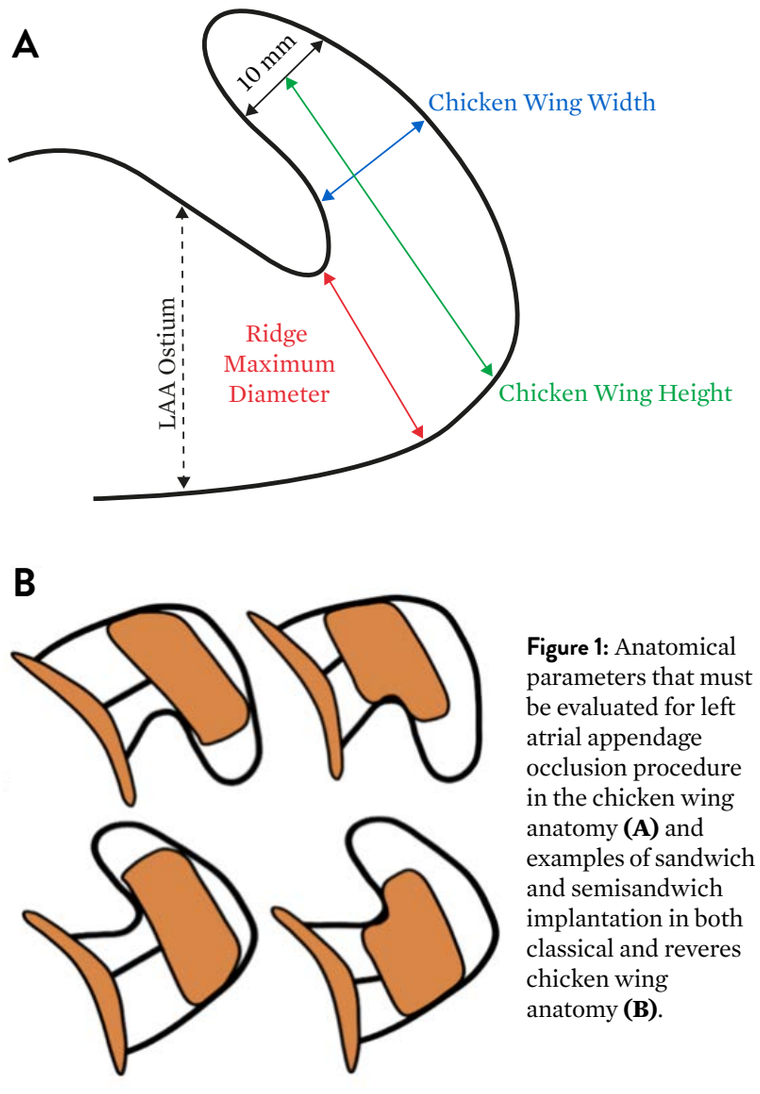

Figure 1: Anatomical parameters that must be evaluated for left atrial appendage occlusion procedure in the chicken wing anatomy **(A)** and examples of sandwich and semisandwich implantation in both classical and reveres chicken wing anatomy **(B)**.

CASE PRESENTATION

Accurate pre-procedural planning is mandatory in similar cases and use of computed tomography may be extremely advantageous. Beyond landing zone and neck length evaluation, some others anatomical parameters must be collected as wing height and width for better choice between classical implantation, semi sandwich or sandwich technique1 **(figure 1)**. The present case describes a successful LAAO procedure with Abbott Amulet device, using the Amulet™ Steerable Sheath in a retroflex chicken wing anatomy.

This was a 78 year old man with diagnosis of cerebral amyloid angiopathy that represents an absolute contraindication to oral anticoagulation.
The pre-procedural planning with computed tomography revealed a CW anatomy with a short neck and a superior and right ward orientation of the wing. In particular the neck was 12 mm and the bend had an extreme angulation. The CW ridge perimeter derived diameter measured 19 mm, the wing height was 23 mm and the width was 12 mm **(figure 2)**.

The late CT acquisition excluded thrombosis inside LAA. As for our common practice we used intracardiac echocardiography (ICE) for procedural guidance[2].

Given the LAA orientation we modified our transeptal puncture (TSP) site, with a less posterior than usual puncture. This may help for better orientation inside the LAA wing when as in the reverse CW wing, it does not have an anterior orientation.

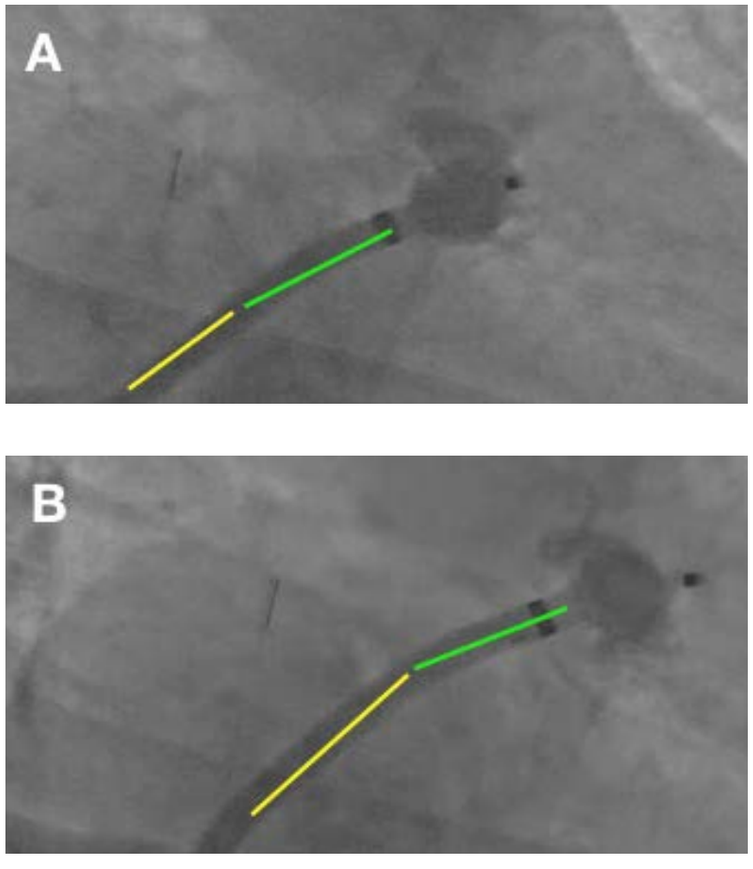

Figure 2: 3D volume rendering of left atrial appendage with its superior and rightward orientatation (A). Multiplanar reconstruction showing different anatomical parameters of the chicken wing anatomy, ridge perimeter (B), wing width (C) and wing height (D) respectively.

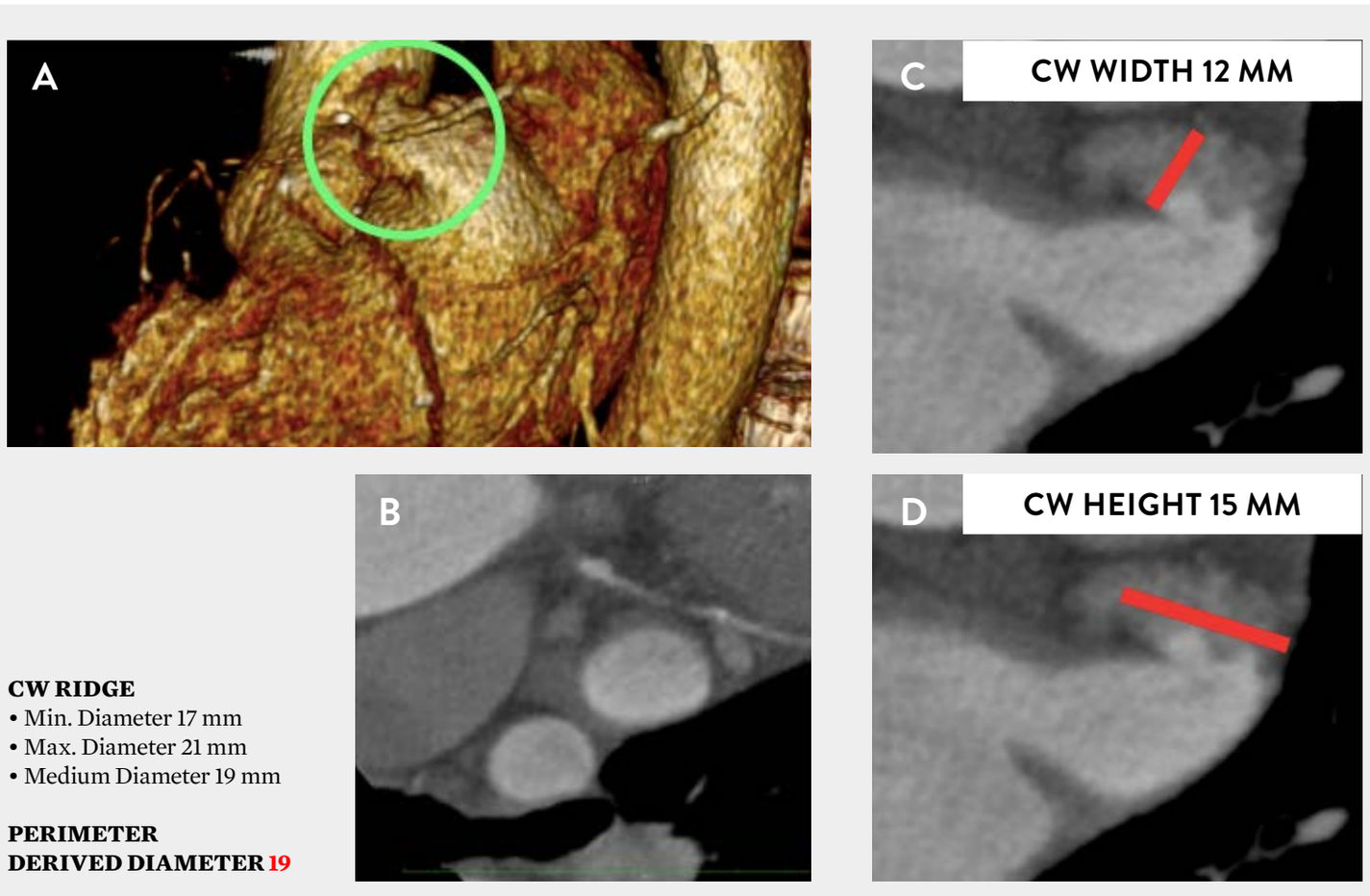

Figure 3: Angiographic evaluation of left atrial appendage, caudal (A) and cranial (B) RAO view respectively.

After successful TSP and ICE probe placement in left atrium, we used the Abbott Steerable Sheath in order to try to gain a best orientation. We used a 6Fr pig-tail catheter to guide the Steerable Sheet inside the LAA. RAO cranial view confirmed a very short LAA neck, with a diameter of 17 mm, while the RAO caudal view gave a landing zone (LZ) measure of 21 mm, showing a quite elliptical LAA main body and showing the extreme wing rotation **(figure 3)**. ICE LZ measure from mid atrial view was 18 mm. According to these measures and this specific anatomy we choose to implant a 25 mm using a semi-sandwich technique.
The use of Amulet™ Steerable Sheath enabled us to gain a better orientation to move inside the LAA, moving the device in ball shape almost beyond the CW ridge **(figure 4)**.

We released the lobe that found its space in overlap to the CW ridge in a semi sandwich configuration, well inside the LAA ostium as shown by ICE. Then we could release the disc. Both ICE and angiography revealed adequate sealing and compression, good device position and stability **(figure 5)**.

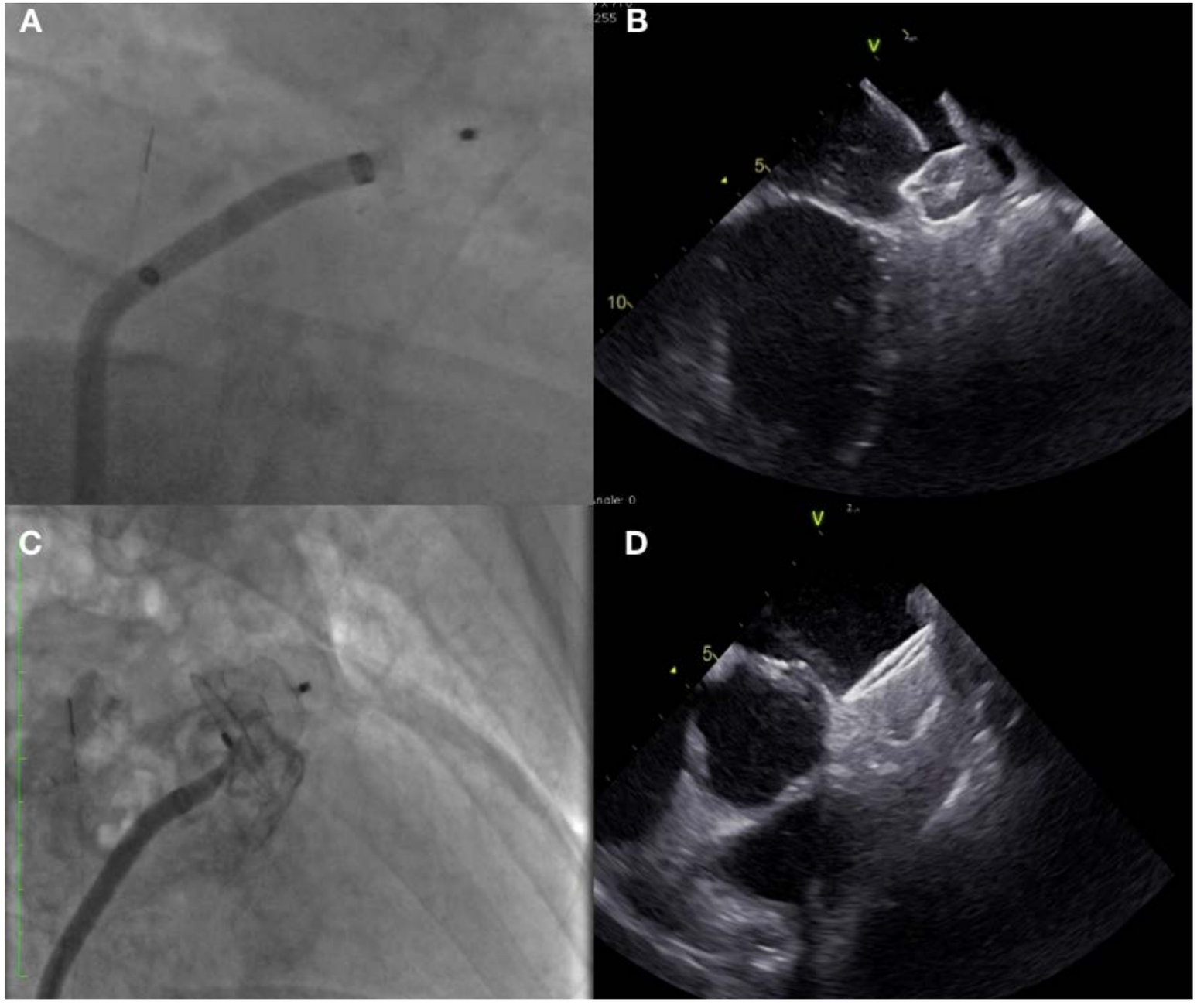

Figure 4: Different position of device ball inside LAA. In A a more proximal position of device ball. In B, after a slight flexion of the Steerable Sheet, achievement of a more distal position beyond LAA neck.

CASE DISCUSSION

The present manuscript suggests some technical consideration about LAAO in some challenging cases such as the CW anatomy, especially in case of reverse CW. The first advice we suggest is to consider an accurate pre- and intra- procedural imaging assessment. Full knowledge of the anatomy with all available imaging modality is a crucial factor for procedural success, especially in difficult anatomies.

Some procedural tips and tricks may be highlighted. Deep incanulation of the LAA is usually very important for the final device deployment as well as a good orientation with the selected implantation axis. When the orientation of the CW bend is not anterior, the classical inferior-posterior TSP site may need to be revised and a more anterior position on the fossa ovalis must be achieved. Steerable sheath may be extremely advantageous in a similar case as it may give us a "full optional" strategy of implant. The potential of gaining the best compromise between orientation and depth of implant may ensure the best choice between sandwich, semi sandwich and classical implant. Such a precise implant may give the best result in terms of sealing, position and device stability.

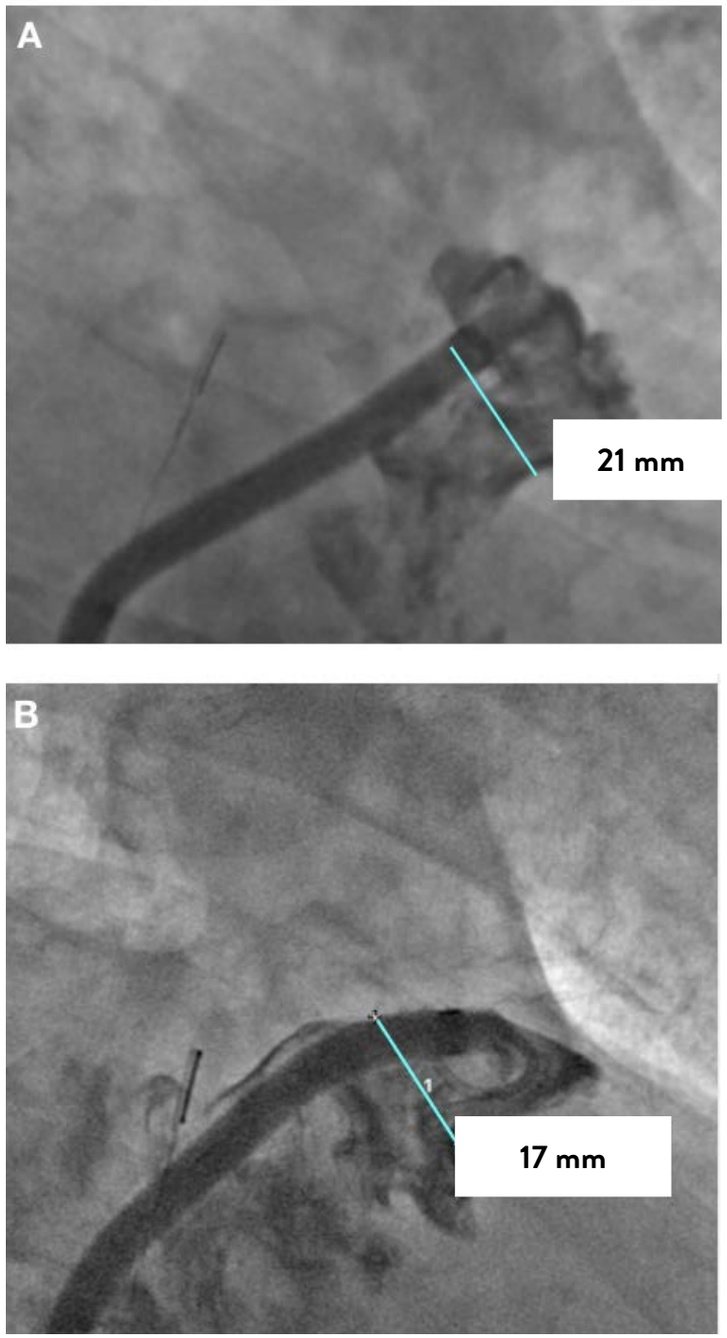

Figure 5: Lobe position inside beyond LAA neck in a semi-sandwich technique (A fluoroscopic view, B ICE view) and final device position after disc release (A fluoroscopic view, B ICE view).

CONCLUSION

LAA chicken wing anatomy, in particular in the reverse form, represents one of the most challenging anatomy for LAAO procedures.

Accurate imaging for pre and intraprocedural guidance is a main pre-requisite. Steerable sheath may be extremely useful in these specific anatomies as it enables a better orientation for precise device release.

ITALY: LEFT ATRIAL APPENDAGE OCCLUSION PROCEDURE WITH ABBOTT AMULET DEVICE AND ABBOTT STEERABLE SHEATH IN A RETROFLEX CHICKEN WING ANATOMY. All content provided by Dr. Luigi Emilio Pastormerlo, Dr Sergio Berti unless otherwise noted.

CLOSURE OF A LARGE AND CONICAL LEFT ATRIAL APPENDAGE

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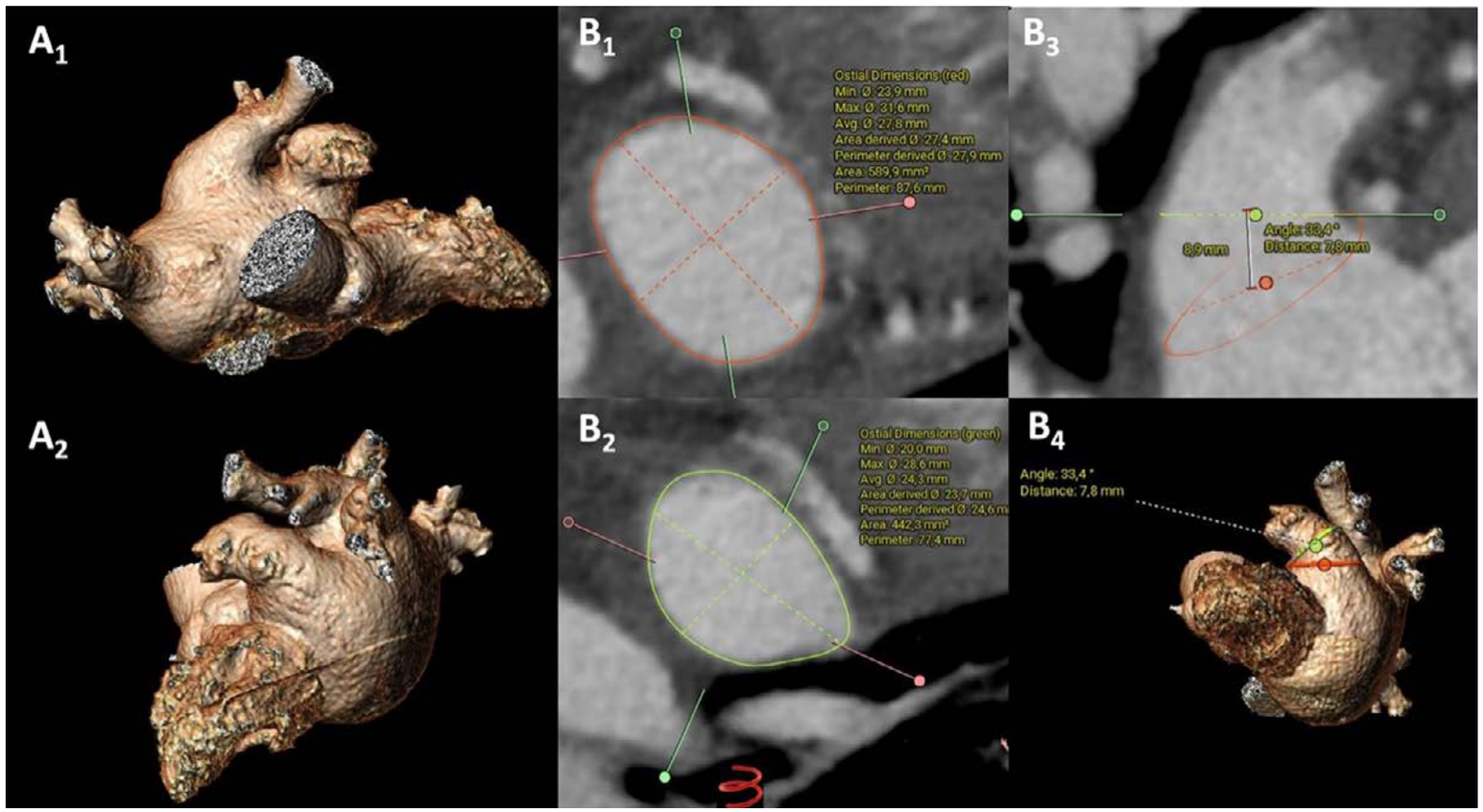
ABSTRACT

The presence of a large conical left atrial appendage represents a challenging situation in case of percutaneous closure procedure. This case illustrates the technical options undertaken to overcome the potential difficulties and improve the procedural success.

INTRODUCTION

Percutaneous left atrial appendage closure (LAAC) has emerged as a valid option for prevention of thromboembolic events in patients with non-valvular atrial fibrillation (AF) and contraindications for oral anticoagulation[1]. This technique is currently performed in daily practice and can be proposed for a vast range of anatomies[1]. However, several situations challenge the operator and might require dedicated strategies and adapted tools, such as steerable delivery sheath, to achieve optimal results and adequate LAA occlusion without residual leak.



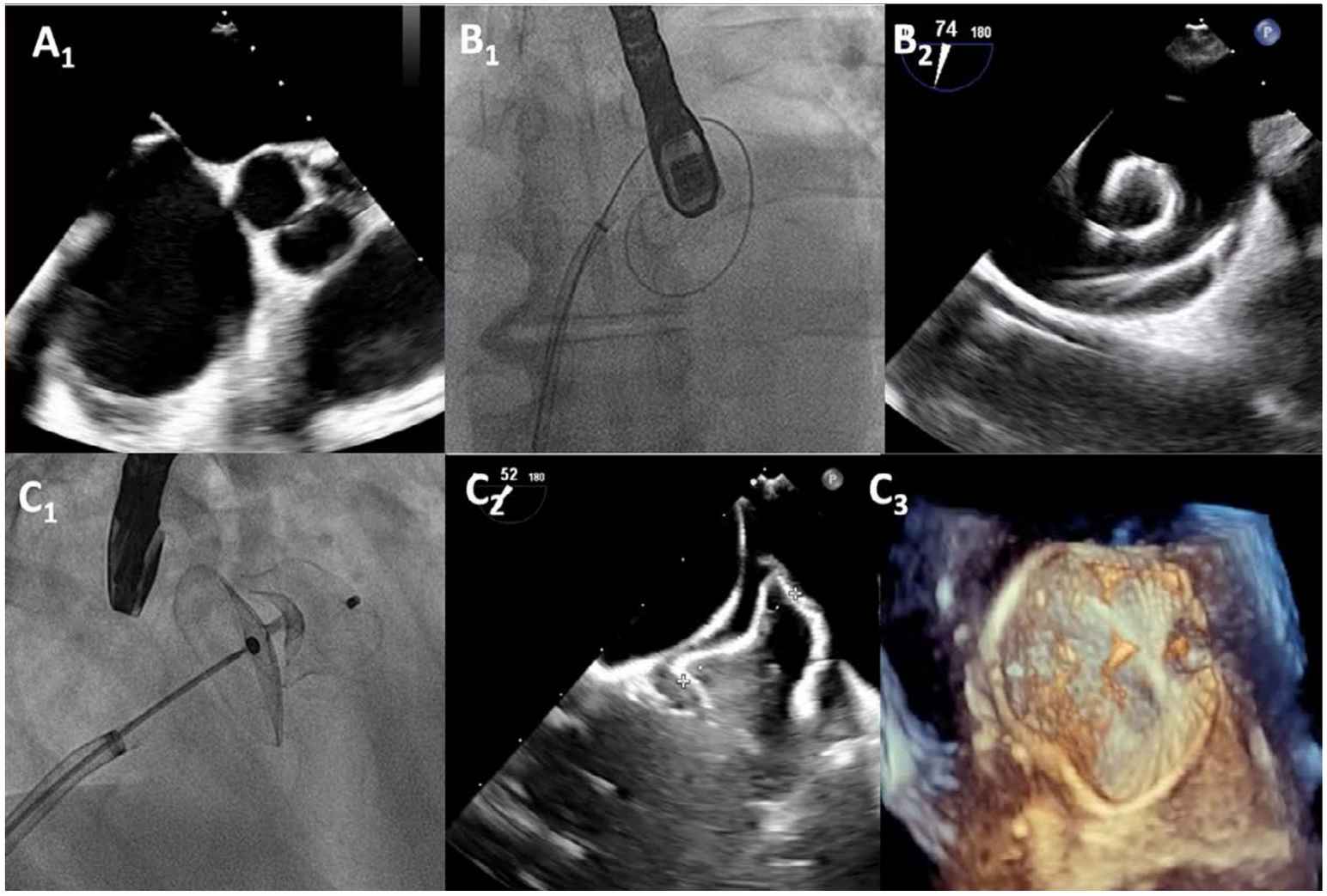
CASE PRESENTATION

A 61 y-o woman was referred to our center for a percutaneous left atrial appendage occlusion procedure. The patient had an history of hypertension, previous alcohol abuse and diffuse cerebral amyloid angiopathy (CAA) with definitive contra-indication to oral anticoagulation. She also suffered from a severe isolated tricuspid regurgitation with severe bi-atrial enlargement. Three months before she was diagnosed persistent atrial fibrillation during a first episode of acute heart failure. Her $CHAD_2SVASC$ score was calculated to 3.

The Heart Team decision was to propose LAAC and further evaluate the options for TR management in case of inadequate control with optimal medical therapy.

Pre intervention transthoracic echocardiography confirmed severe TR, mild mitral regurgitation, left and right atria severe dilation, normal LVEF and absence of pulmonary hypertension. CT scan **(figure 1)** identified a large cauliflower LAA with conical neck **(Figure 1/ A1-A2)** and moderate blood stasis. The LAA ostium and potential landing zone dimensions were measured respectively to 32x 24 and 28x20 mm **(Figure 1/ B1-B4)**. The LA volume was measured to 100 ml/m2 body surface area. The distance between the potential LZ and the circumflex artery was >3 mm **(Figure 1/ B2)**

In order to anticipate and avoid the technical difficulties (see below) and obtain the best results, our strategy slightly differed from the conventional LAAC strategy according to the anatomy. We decided to implant an Abbott 34 mm Amulet device in shallow position using a 14 Fr steerable delivery sheath. The procedure was performed under general anesthesia with 3D TEE guidance and TEE/angio fusion imaging support **(Figure 2**).



The interatrial septum was punctured in antero-inferior **(Figure 2/A1)** position using a manually "customized" BRK needle with a large J shape (in order to overcome the issues related to the right atrium enlargement).
A pig-tail shaped 0,35" exchange wire (Boston Scientific Safari TM Small) was then inserted in the left atrium **(Figure 2/B1-B2)** and the delivery sheath was advanced towards its destination, in front of the LAA ostium.
The Amulet was deployed in ball position and advanced within the LAA with a gentle flex from the sheath associated to moderate clockwise rotation.

The Amulet was very progressively deployed in shallow position (with the LZ crossing the plane of the circumflex artery) while the device axis was corrected with progressive deflection in order to maintain the Disc-lobe alignment **(Figure 2/C1-C2)**. The final device compression was 20% (**(Figure 2/C3)**. The disc was mildly protruding towards the mitral valve without any significant conflict. There was no residual leak on color flow analysis nor on control angiography: prosthesis was finally released after a total procedural time of 35 mins.

CASE DISCUSSION

The patient was discharged under single antiplatelet therapy (aspirin 75 mg/d) and the subsequent evolution was uneventful. The 8-weeks follow up control CT scan revealed the device was in shallow adequate position, tire-shaped, correctly aligned with the appendage axis **(Figure 3)**. The LAA was completely occluded without any peridevice leak. No device related thrombus was identified.

This case illustrates the different procedural options that could be considered in this challenging situation combining large conical LAA and enlarged left atrium. The risks carried out by this combination include off-axis device position, poor disc/lobe alignment (which favors incomplete closure[2]), incomplete ostial sealing (in case of deep implantation) and prosthesis instability (in case of under sizing).

We decided to perform TSP in anterior TSP rather than the classical posterior site, since this strategy reduces the distance between IAS and LAA ostium and improves the coaxialty of the delivery sheath with the appendage axis **(Figure 4)**[3]. In addition, the use of the steerable sheath allows a more precise device position correction during the lobe and disc deployment in order to prevent misalignment[4].

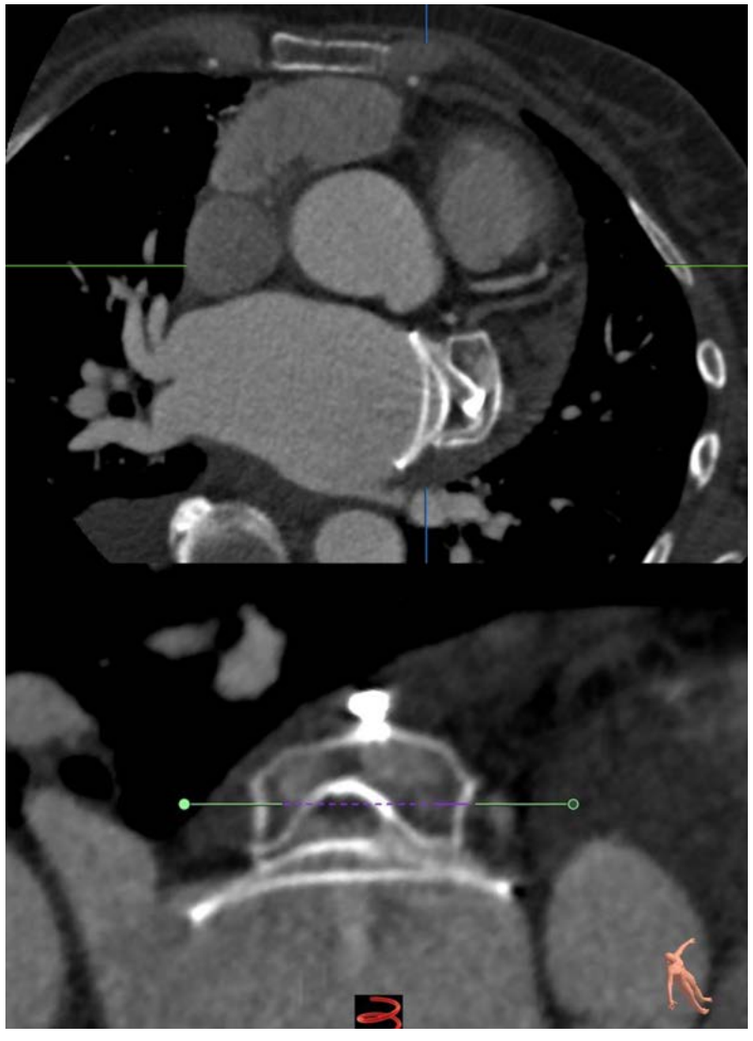


Figure 3

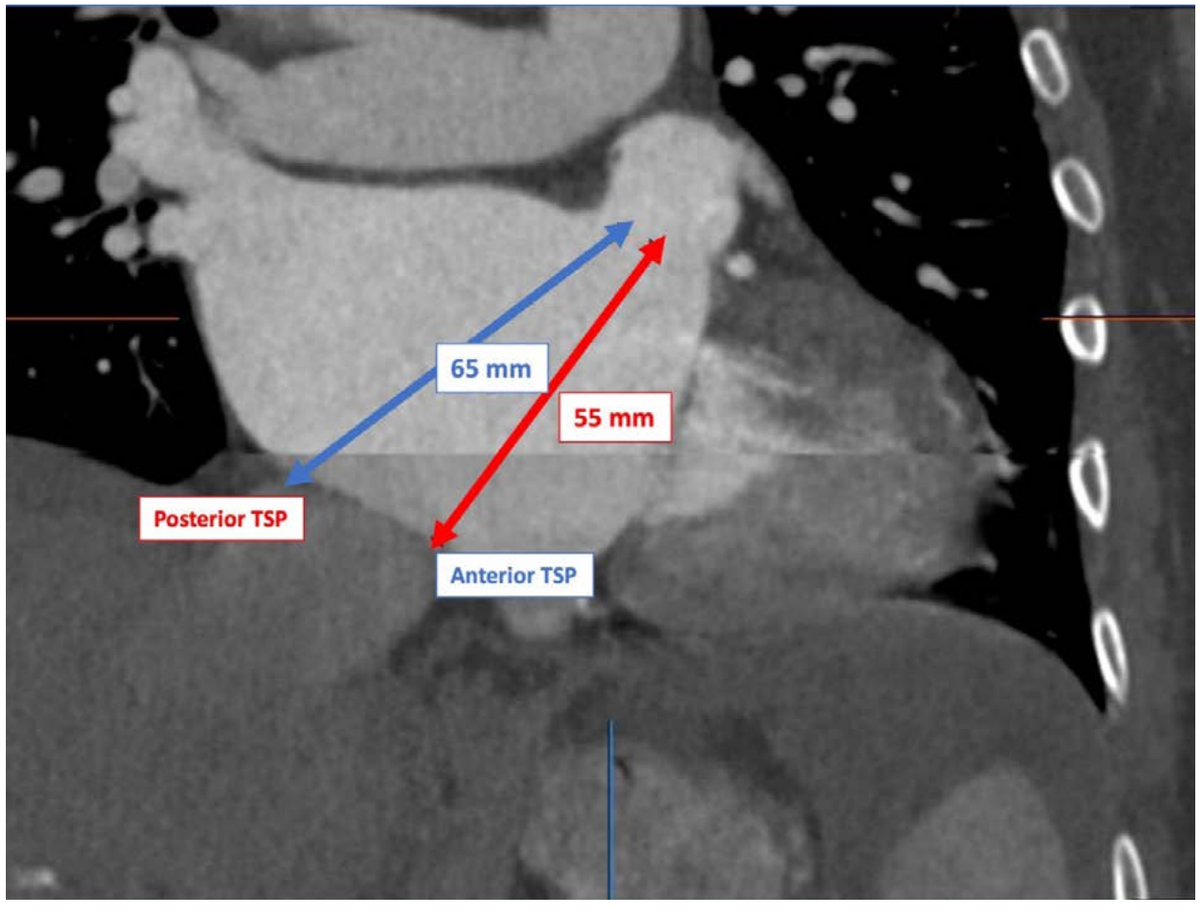


Figure 4

The wide conical LAA neck that was present in our case implies the implantation of a large disc to be able to completely cover the ostium and obtain full sealing and a large oversized lobe to get a correctly compressed and stable device. This involves the implantation of the device in “shallow” (i.e. not distal to circumflex) position.

The target landing zone was elliptical and measured to 28 x 20 mm with CT scan and 30x 20 mm with 3D TEE (these discrepancies could be explained by potential differences in LZ identification according to the technique). Hence, this LAA could have been closed with a 31 mm (standard) or a 34 mm (oversized) Amulet[5].

We chose the largest device in order to 1) get the best compression and stability 2) get the largest disc (41 mm diameter). In case the oversized device strategy is applied, the operator needs to carefully check the absence of any external circumflex artery compression by the lobe (which can be prevented by the CT scan analysis of the distance between Cx and LZ) and the absence of major conflict between disc and mitral valve leaflet. These points are mandatory before releasing the device.

CONCLUSION

This case illustrates the challenges associated with percutaneous closure of a conical appendage and underlying enlarged left atrium. The use of a tailored strategy based on precise pre-intervention CT scan and combining modified transseptal puncture site and steerable delivery sheath, allowed a precise and more effective implantation of the Amulet device.

All content provided by Dr Nicolas Amabile unless otherwise noted.

CLOSURE OF A MULTILOBULAR LAA ANATOMY USING THE AMULET OCCLUDER

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ABSTRACT

Percutaneous left atrial appendage occlusion (LAAO) is a safe and effective alternative to anticoagulation in patients with atrial fibrillation. Substantial inter-individual variability in LAA anatomy can make LAAO technically challenging. Especially in multilobular LAA anatomy, optimal sealing is hard to achieve. We here report a case of successful LAAO using the Amplatzer™ Amulet™ occluder (Abbott Medical) in multilobular LAA anatomy.

INTRODUCTION

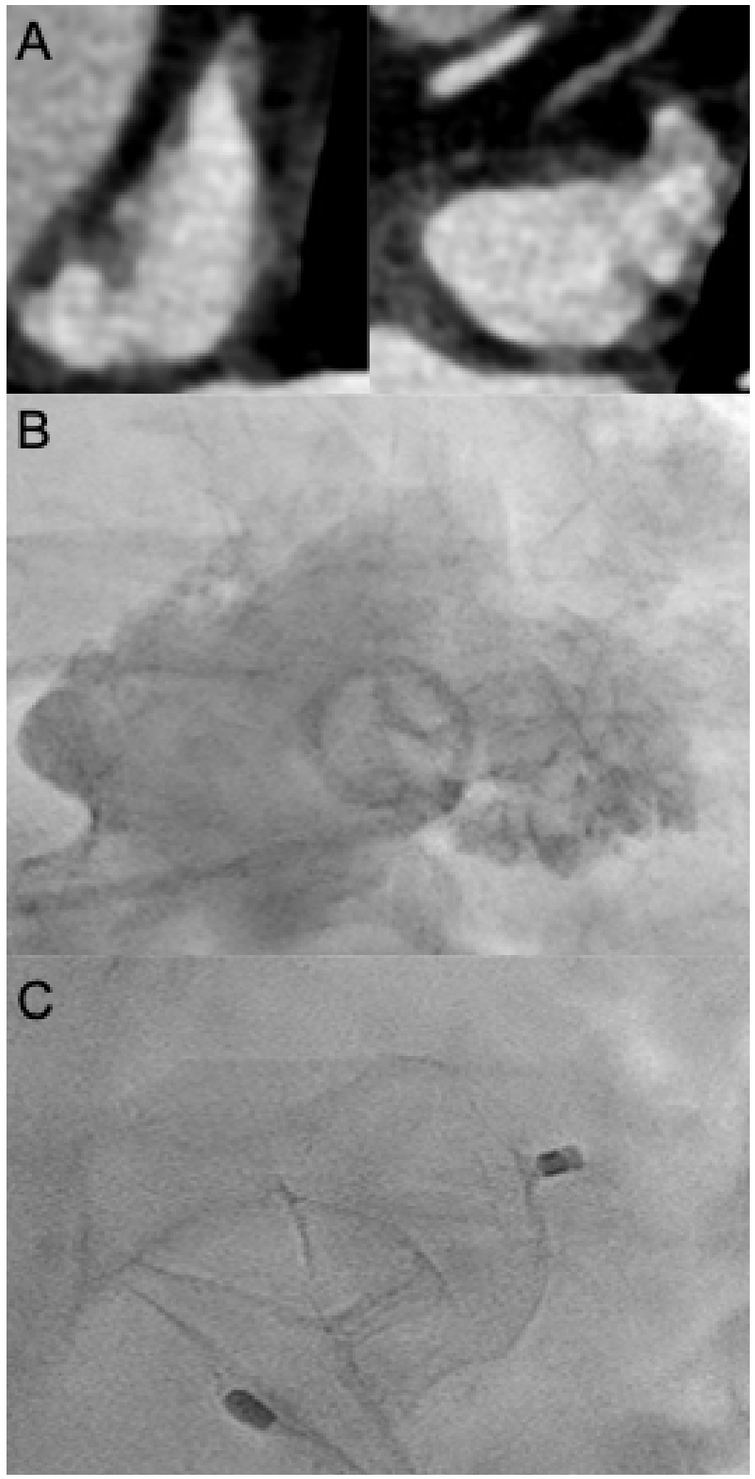
Atrial fibrillation (AF) is very frequent in our aging society[1]. Oral anticoagulation is needed to prevent stroke in patients with[2]. However, bleeding is frequent in patients on oral anticoagulation[3]. Therefore, alternatives without the need of permanent oral anticoagulation are charming. Percutaneous left atrial appendage occlusion (LAAO) is a safe and efficient alternative to permanent oral anticoagulation[4]. In four year follow-up data of the PRAGUE-17 trial, LAAO was even superior in reducing non-procedural bleeding events as compared to oral anticoagulation[5]. However, LAAO still has technical challenges. Especially inter-individual variability of LAA anatomy can be challenging for optimal device positioning[6]. Incidence of peridevice leaks vary from 11-57%[4]. Peridevice leaks are associated with stroke[7]. Therefore, the need to be avoided. Data and case reports regarding percutaneous LAAO in multilobular are sparse. Therefore we here present a successful sealing of multilobular LAA using the Amplatzer™ Amulet™ occluder (Abbott Medical).

CASE PRESENTATION

A 74 year old lady with oral anticoagulation due to paroxysmal atrial fibrillation, presented with history of gastrointestinal bleeding. The option of LAAO was discussed and screening for feasibility was initiated. CT revealed an multilobular LAA anatomy. Feasibility of successful closure was discussed, and interventional closure procedure was scheduled. Conscious sedation and transesophageal echocardiography in combination with fluoroscopy was applied to guide procedure. Transseptal puncture was performed, and anatomy was confirmed multimodally. LAAO using the Amplatzer™ Amulet™ occluder (Abbott Medical) was conducted.

Position of the device-lobe in the posterior lobe with the disc sealing both lobes of the multilobular was successfully achieved. Closure of the femoral vein was achieved by closure device and Z-suture. Dual antiplatelet therapy with acetylsalicylic acid and clopidogrel for 3 months, followed by indefinite acetylsalicylic acid was prescribed. Optimal sealing of the LAA was confirmed in transesophageal echocardiography three months after procedure. 12 months later, no gastrointestinal bleeding occurred.

All content provided by Dr. A. Polzin unless otherwise noted.



CASE PRESENTATION

The present case show a rare anatomy in LAAO. This multilobular anatomy is very challenging, as the combination of safe occluder positioning and complete sealing of the multilobular LAA was needed. Indeed the combination of disc and lobe in the Amplatzer™ Amulet™ occluder allowed us to place the lobe of the occluder in the posterior lobe, assuring a stable position and placement of the disc above the multilobular entrance **(Figure 1)**. Complete closure was successfully achieved in this position.

Figure 1:
A. CT images of multilobular anatomy.
B. Fluroscopy contrast image of multilobular anatomy
C. Closure of multilobular anatomy using the Amplatzer™ Amulet™ occluder (Abbott Medical)

CONCLUSION

This case shows the technical feasibility of complete sealing of multilobular LAA using the Amplatzer™ Amulet™ occluder (Abbott Medical).

All content provided by Dr. A. Polzin unless otherwise noted.

PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE WITH SUPERIOR VASCULAR ACCESS

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ABSTRACT

Recent prospective multicenter studies have shown that a small but sizable percentage of attempted percutaneous left atrial appendage (LAA) closure (LAAC) cannot be completed. Potential reasons include inferior venous system anomalies. In this case report we describe a percutaneous LAAC, initially aborted due to the impossibility to access right atrium, and subsequently completed by using a superior vascular access and an Amulet™ steerable delivery sheath ([ASDS] Abbott Vascular).

INTRODUCTION

Percutaneous LAAC is a valid alternative to oral anticoagulation (OAC) for preventing stroke in patients with non-valvular atrial fibrillation (AF). This procedure aims at mechanically excluding LAA from circulation by implanting a device at the LAA ostium. The first two randomized clinical trials comparing LAAC to OAC showed that only 88-95% of attempted procedures ended with the successful implantation of LAAC device[1,2].

Over the following 10 years, a significant improvement of technical success has been reported. However, procedure abortion has not been fully eliminated (0.9-2.7% of all attempted LAAC)[3-5]. The underlying reasons may be several as challenging LAA anatomies[6], delivery sheath-LAA misalignment or inferior venous system anomalies[7]. Few cases of LAAC with transhepatic vascular access have been described in patients with prohibitive femoral approach[7,8]. No previous cases of LAAC with superior vascular access have been reported so far.

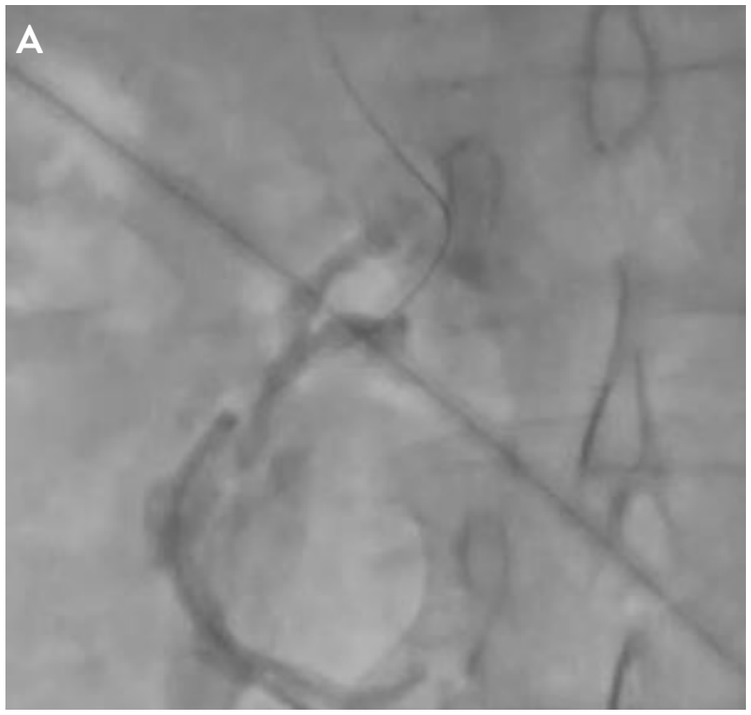


Figure A: Femoral access aborted due to agenesis of the inferior vena cava.

CASE PRESENTATION

We present the case of a 62-year-old man with AF referred to the University Hospital of Bern for percutaneous LAAC due to recurrent strokes under OAC. The first LAAC attempt was aborted due to agenesis of the inferior vena cava with no possibility to access the right atrium despite several attempts **(A)**. We therefore decided to plan 2 months later a new LAAC attempt by using a superior vascular access. The procedure was planned by a preprocedural computed tomography (CT) and was guided by an intraprocedural transesophageal echocardiography (TEE). We percutaneously gained vascular access by means of left axillary vein **(B)** in order to favor a better alignment of delivery sheath with LAA axis **(C)**.

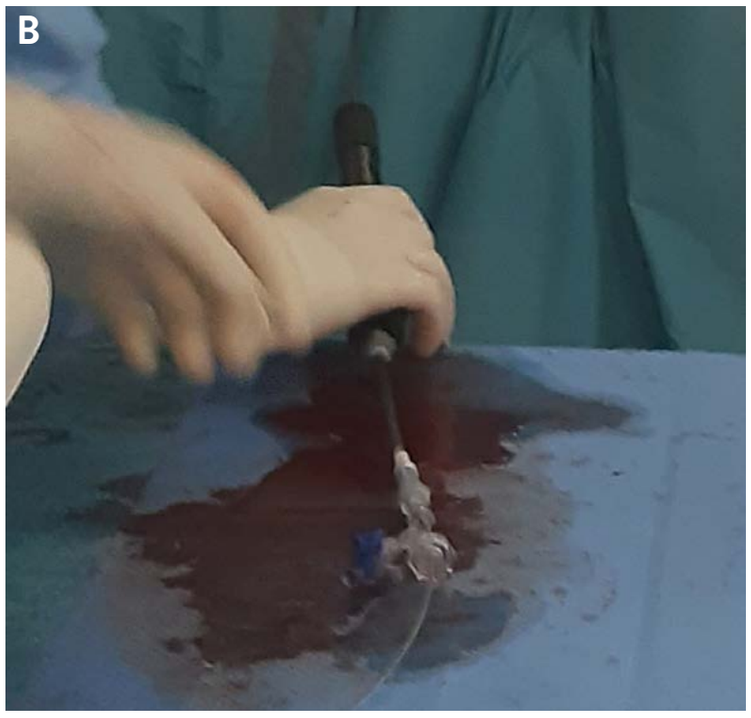


Figure B: Vascular access through the left axillary vein.

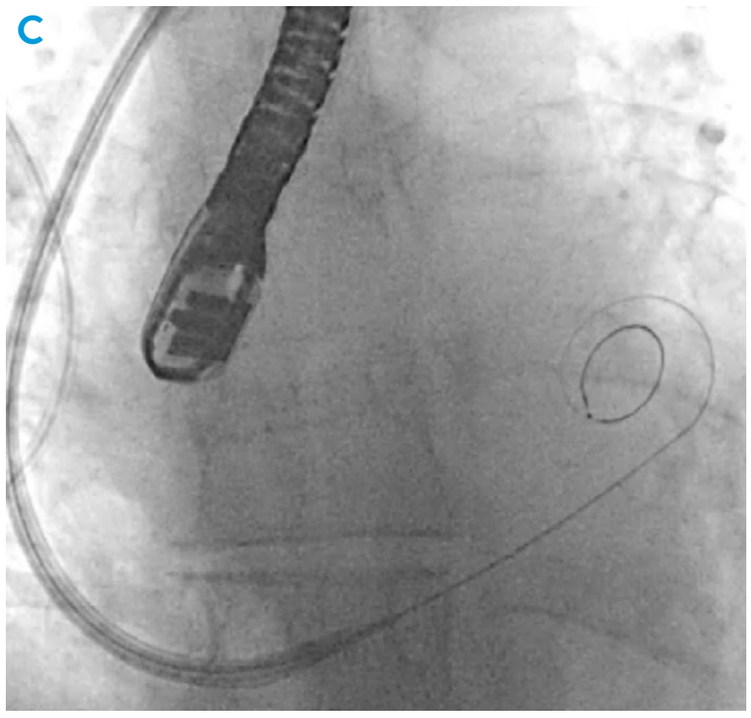


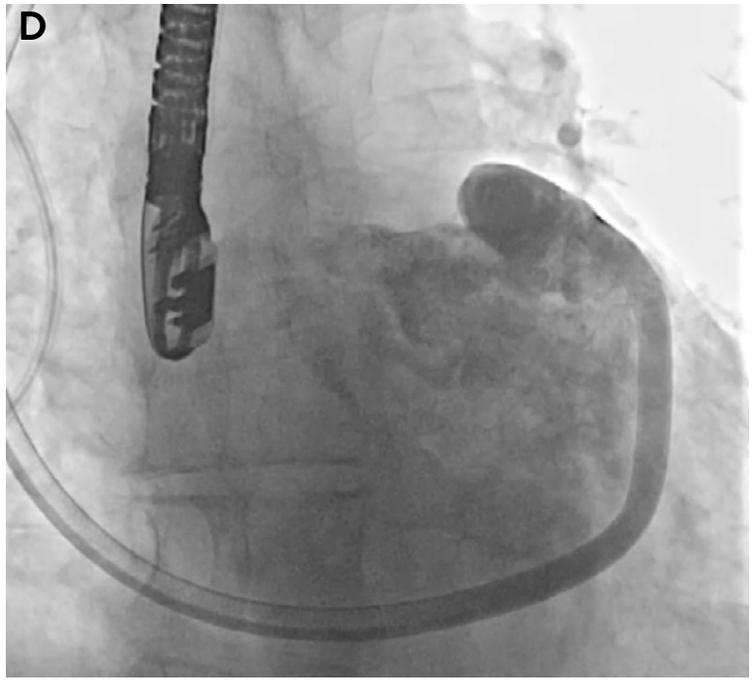
Figure C: Alignment of the Amulet™ steerable sheath with the LAA.

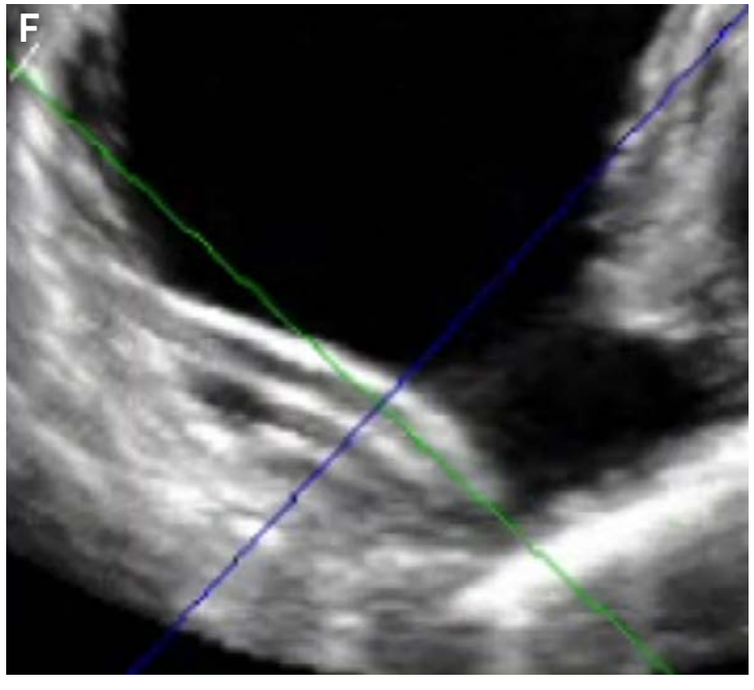
The transseptal puncture was performed at the inferoposterior part of the fossa ovalis with the SupraCross RF Wire and Sheath (Baylis Medical, Montreal, Canada), a transseptal puncture system consisting of a steerable sheath and radiofrequency wire with a flexible, spiral tip to obtain access to the left atrium.

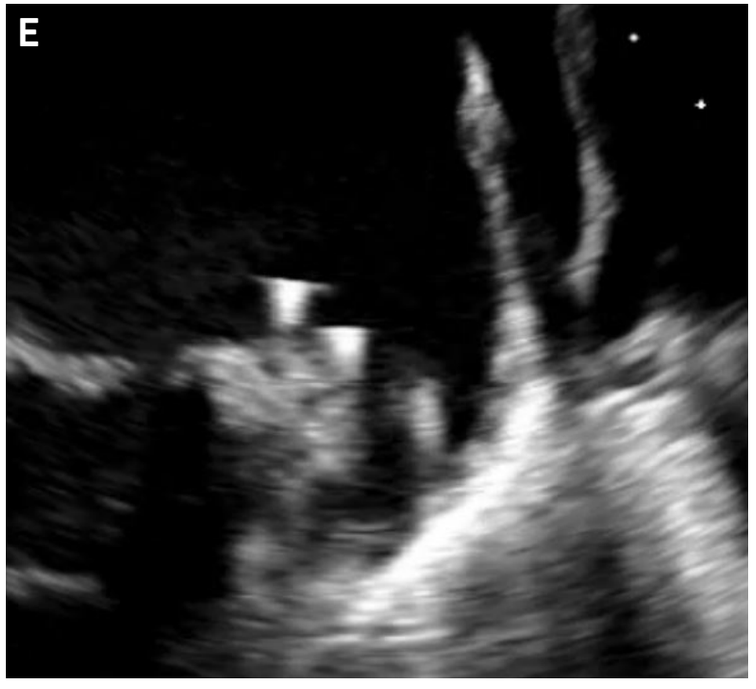
After advancing a 0.035 stiff wire into the left atrial access, Heparin was administered with ACT maintained greater than 250 seconds.

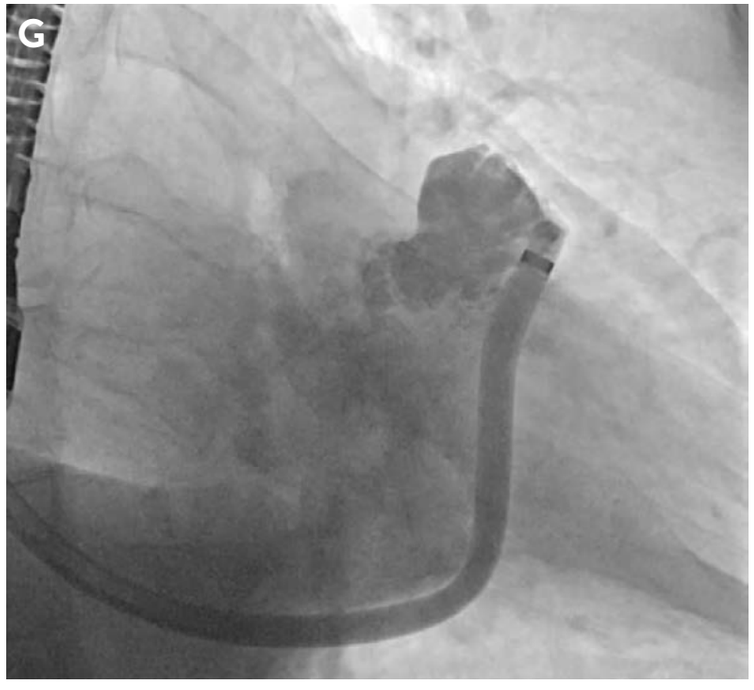
Then, an Amulet™ Steerable Delivery Sheath (ASDS) was delivered to the left atrium **(D-E)**. Then, after confirming a left atrium pressure of at least 12mmHg, a pigtail was advanced into the LAA.

However, due to the superior access used in this procedure, the alignment of ASDS to the main axis of LAA was possible only after deflecting the distal articulation of the ASDS **(F, G)** by rotating the deflexion knob of the sheath (allowing a bidirectional deflection).





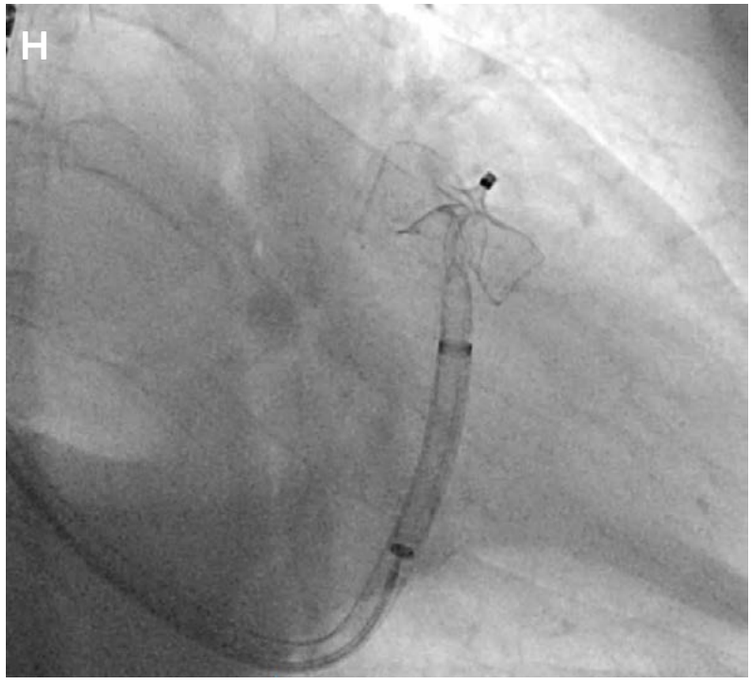


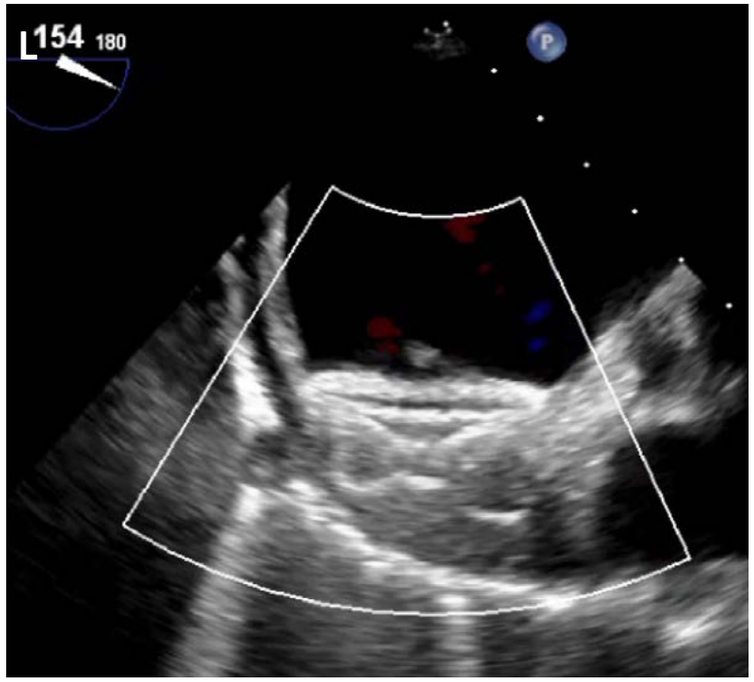


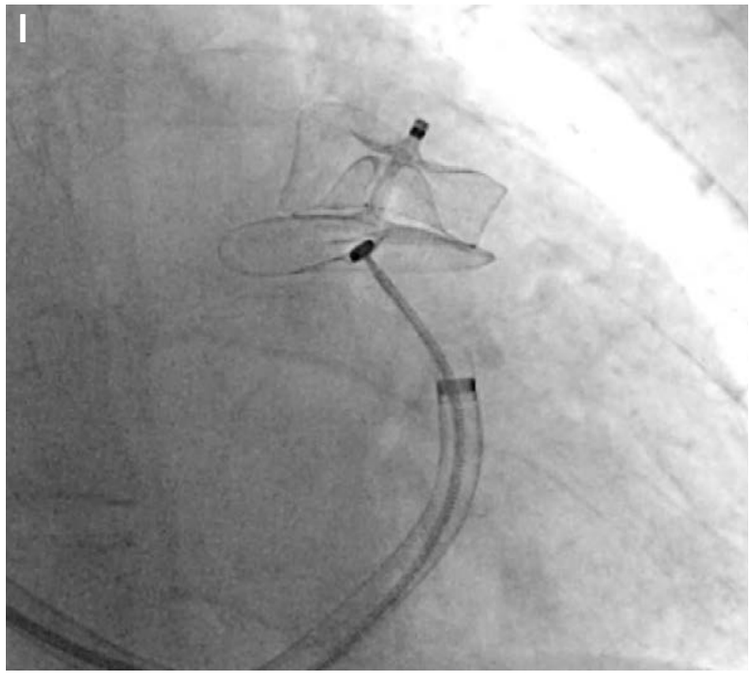
All content provided by Dr. Roberto Galea and Lorenz Räber unless otherwise noted.

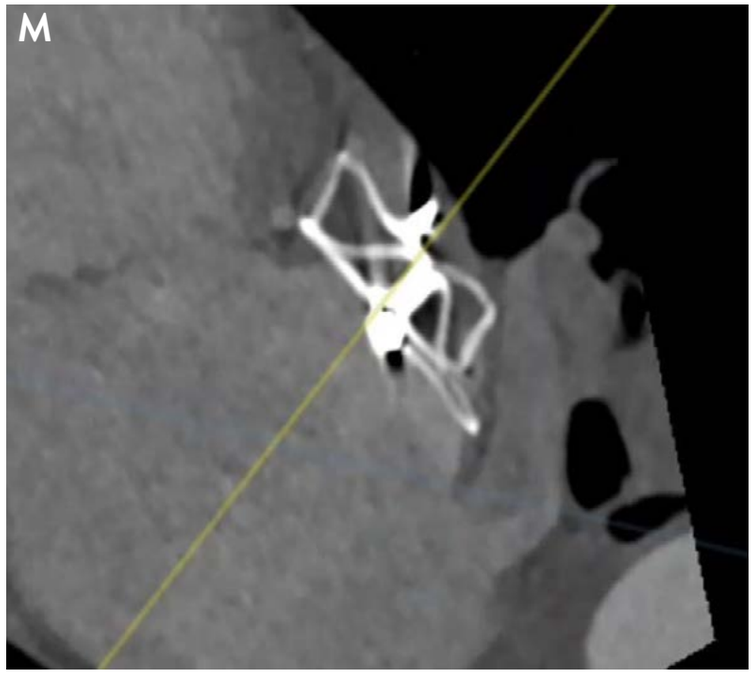
Once an acceptable LAA-ASDS alignment was achieved, an Amulet 31 device was advanced through the ASDS. The advancement of the device through the ASDS required more strength than usual, most likely due to the acute angle of the ASDS **(H)**. The device was successfully released at the first attempt after confirming an acceptable degree of LAA sealing and device stability by using both fluoroscopy **(I)** and echocardiography **(L)**.

The vascular access was closed by Z-shaped suture. The patient was discharged 2 days later under Aspirin and Plavix without further complications. At 45 days no events were reported, the CT showed a good position of device with a good LAA-device alignment **(M)**.









CASE DISCUSSION

The Amulet device has been designed for delivery via femoral vein approach. However, a small percentage of general population (approximately 0.3%) and of individuals with congenital heart disease (0.6–2%) present congenital interruption of the inferior vena cava. As a consequence, patients eligible for LAAC but with prohibitive femoral approach can be observed in clinical practice. Few cases of LAAC with transhepatic approach have been reported so far[7,8]. Yet, the technique to gain and close the vascular access requires special expertise.

To the best of our knowledge, this is the first percutaneous LAAC with superior vascular access ever reported. Unlike the transhepatic approach, the percutaneous vascular access was easily closed by Z-shaped suture without any closure device. However, the use of a steerable sheath during both transseptal puncture and device deployment was necessary in order to complete the procedure. Coaxial alignment of delivery sheath with the LAA axis is crucial to achieve a good LAA sealing and device stability during percutaneous LAAC.

In this case, the use of ASDS allowed to correct the wrong initial axis of the delivery sheath (consequence of the superior approach) in order to successfully release the device in a correct position. The availability of the ASDS may reduce the number of failed LAAC in the future, allowing in some select cases, to perform LAAC even by using a non-femoral vascular access. Furthermore, in this case a left axillary vein approach was used in order to facilitate the alignment of the delivery sheath with the LAA.

However, the high degree of tension developed by the delivery system during the device advancement might require further measures (e.g. formation of “ball shape” in left atrium and subsequent alignment to LAA) to prevent potential complications.

CONCLUSION

In the last decade aborted percutaneous LAAC have significantly reduced in clinical practice. However, they have not yet fully eliminated. The use of the new technology may further reduce the number of failed LAAC in the future, by facilitating the LAA-delivery sheath alignment, and allowing to perform LAAC even by using a non-femoral vascular access.

All content provided by Dr. Roberto Galea and Lorenz Räber unless otherwise noted.

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