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LAA 2015 Abstracts

How to Close the Left Atrial Appendage

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Anticoagulation for stroke prevention in atrial fibrillation is difficult in clinical practice - with Coumadin and also with NOACS. Left atrial appendage closure has been shown to be superior to anticoagulation regarding stroke prevention, bleeding complications and even mortality. Several devices now have CE mark and/or FDA approval and many others are already in clinical trials.

LAA Frankfurt is a 2-day course, designed to give attendees an overview on all aspects of this treatment modality. During the course we cover clinical studies and demonstrate how to perform the procedure step by step and how to prevent and manage complications. Live case transmissions are a core of this course and allow direct attendee-operator interaction to maximize the learning experience.

LAA 2016 will take place November 18-19, in Frankfurt, Germany. If you would like to join this year, please visit our website for more information at http://www.csi-congress.org/laa-workshop.php?go=0.

LATVIAN LAA CLOSURE REGISTRY FIVE YEARS OF EXPERIENCE IN HIGH-RISK PATIENTS

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Background: Left atrial appendage (LAA) closure with the Watchman device and AMPLATZER Cardiac Plug (ACP) has been shown to be a safe and effective alternative to oral anticoagulant therapy. In real-world practice in Latvia, LAA closure is preformed in AF patients with high stroke and bleeding risk, distinction from the two randomized controlled trial of device closure for patients with atrial fibrillation. LAA 2015

Objectives: The purpose of the Latvian LAA clo prevention in high-risk patients with atrial fibrillation (AF).

Methods: This is a single centre prospective non-randomized longitudinal cohort study of LAA closure with the Watchman device and ACP during five years. The registry collected data about clinical condition, efficacy and safety events (ischemic/hemorrhagic stroke, death, systemic embolism, device thrombosis or embolization, pericardial tamponade) from May 2010 to September 2015.

Results: In total 29 LAA closure cases were studied. Successful LAA closure was achieved in 96.6% of cases (n=28). The Watchman device was implanted in 50% and the ACP in 50% of cases. Mean CHA2DS2-VASc score was 6.3 (1.6) and HAS-BLED score - 3.3 (1.0). The main indication for closure was recurrent ischemic stroke and low compliance with warfarin usage. Serious peri-procedural safety events (device embolization of a Watchman device) occurred in one patient (n=1). Mean follow-up time was 38 (19.8) months, patients followed n=26. During 45 post-procedural days there was one (n=1) device thrombosis without clinical sequelae. After day 45, ischemic stroke occurred in

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2 patients (2.3 per 100 patient-years) and non-cardiovascular death (from liver cancer) in one patient (1.2 per 100 patient-years).

Conclusions: LAA closure is a safe and effective method for thromboembolic stroke prevention in patients with atrial fibrillation and high risk of stroke and bleeding.

CROSS-SECTIONAL COMPUTED TOMOGRAPHIC SUPERIOR TO 2D AND 3D TEE FOR LAA CHARACTERIZATION OF SIZE AND THEREFORE DEVICE SELECTION

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Background: Standardized LAA sizing is based on 2D transesophageal (TEE) measurements of the left atrial appendage (LAA). However, 3DTEE and CT have proven superior to 2DTEE for multiple structural interventional procedures.

Objective: The aim of this study is to evaluate LAA ostium width and length by 2DTEE, 3DTEE, and CT to determine the optimal imaging modality for accurate device selection.

Methods: From May through August 2015, 22 patients underwent LAA occlusion with WATCHMANTM. All patients received pre- procedural CT scan, and intraprocedural 2D and 3D TEE. Maximal width and length of LAA were obtained at 0, 45, 90, 135 degrees by 2D /3DTEE. Paired t-tests were applied to look for differences between CT sizing and each TEE methodology. Bland-altman plots were applied to compare each TEE type to CT.

Results: 22 patients underwent successful implantation of the WATCHMANTM device with CT guided sizing. CT maximal LAA width was larger than 2DTEE ($p<0.001$) and 3DTEE ($p=0.002$). CT maximal LAA length was longer in 21 of 22 patients versus 2D TEE ($p<0.001$). There were no LAA ruptures. Each patient required only 1 device size. There were 3 peri-watchman leaks (< 5mm) secondary to accessory LAA pedunculation and not device sizing. 2D TEE maximal width would have required bigger device in 9 / 22(40.9%) patients. 3DTEE maximal width would have required bigger device in 7 / 22(31.8%). 2D TEE length would have excluded 5 patients from LAA occlusion.

Conclusion: CT guided LAA sizing is superior to 2D and 3DTEE assessment.

DELIVERABILITY, CONFORMABILITY, AND HEALING RESPONSE OF WATCHMAN FLX LAAC DEVICE

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Background: WATCHMAN FLX (WM-FLX) is the next generation WATCHMAN (WM) device.

Objective: The aim of this study is to compare WM-FLX and WM for implant deliverability, LAA conformability, and for biologic healing response at 45 and 90 days in the canine model.

Methods: LAA ostium was measured under TEE to determine device sizing. WM-FLX devices were implanted in 12 canines to evaluate the healing response. Half were terminated at 45d and half at 90d, respectively.

Results: 100% of WM-FLX canines (6/6) and 75% of WM canines (6/8) were successfully deployed (one excluded due to pericardial effusion, one for unfavorable LAA). The WM-FLX cohort required fewer partial and full recaptures. WM-FLX had no observed peri- device jets. (Table 1).

Table 1: Deliverability and Conformability Comparison

	WM	WM-FLX
Total devices/dogs used	10/6	6/6
Full recaptures	4	2
Partial recaptures	3	2
Dogs with Peri-device jet (<2mm)	2	0

WM-FLX showed a similar biologic healing response when compared to WM at both 45d and 90d. Endocardial tissue growth was complete to near-complete in all devices with the exception of single canine from the WM group at 90d in which there was minimal thrombus associated with slight protrusion of the device into the left atrium. Inflammation was minimal in all devices.

Conclusion: WM-FLX showed an improvement in both deliverability and LAA conformability, and had a similar healing response compared to WM.

RATIONALE OF CEREBRAL PROTECTION DEVICES IN LEFT ATRIAL APPENDAGE OCCLUSION

Felix Meincke[1], Felix Kreidel[1], Tobias Spangenberg[1], Christian Frerker[1], Oscar Sanchez[2], Elena Ladich[2], Karl-Heinz Kuck[1], Alexander Ghanem[1]
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Background: Periprocedural stroke has been reported after interventional left atrial appendage occlusion (iLAAO). In transcatheter aortic valve replacement (TAVR), the use of a cerebral protection device has been shown to reduce cerebral lesions assessed with magnetic resonance imaging. Our aim was to assess the feasibility of cerebral protection devices in iLAAO and to analyze the amount and type of debris captured.

Methods: In five consecutive patients undergoing iLAAO, the Sentinel CPS® cerebral protection device was used. For iLAAO, the Watchman® device was used in two patients and the Amulet® in three. After iLAAO, the filters underwent histopathological examination.

Results: A total of 10 filters (one proximal and one distal filter for each patient) were collected and underwent histopathological analysis (CV Path Institute Inc.). Debris was found in all patients (9/10 filters). Acute thrombus was found in 3 patients (2 Watchman®; 1 Amulet®), organizing thrombus in 4 patients (1 Watchman®; 3 Amulet®). Two Amulet® patients had endocardial or myocardial tissue in their filters. None of the filters included calcifications or other foreign material.

The maximal diameter of the collected material was 0.68 (±0.9) mm.

Conclusion: As expected, iLAAO can cause embolization of thrombotic material and other debris, either preexisting (e.g. embolization of echocardiographically undetected LAA thrombus) or induced by the procedure. This finding strongly encourages further investigations of the underlying mechanisms for embolization of different types of material, as well as the clinical impact of microemboli. Potential differences in thrombogenic potential between devices should also be addressed in future investigations. The potential for thrombo- embolism should be taken into account for device design and implantation techniques.

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ANTICOAGULATION MANAGEMENT AFTER LEFT ATRIAL APPENDAGE CLOSURE WITH THROMBUS FORMATION AND HIGH BLEEDING RISK

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Background: Device associated thrombus formation is a feared complication of left atrial appendage closure (LAAO). Anti- coagulation management in this setting remains a challenge, as patients frequently suffered from comorbidities that increase bleeding risk.

History and Indication For Intervention: A 75- year-old male (82 kg) with persistent atrial fibrillation and past medical history of hypertension, dyslipidemia, chronic renal failure (creatinine clearance 25-30 ml/min, serum creatinine 2.2 mg/dL) and peripheral arterial disease (CHADS-VASc= 5) had to stop oral anticoagulation because of gastro-intestinal bleeding under acenocumarol and apixaban (2.5 mg bid). Gastroenterology studies were performed, showing duodenal angiodysplasia and gastric and sigma polyps. Several trials of electrocoagulation along with octreotide treatment were tried unsuccessfully. Patient experienced several bleeding episodes with secondary iron-deficiency anemia. He underwent several transfusion and treatment with endovenous iron and EPO.At the same time, echocardiogram showed severe left ventricular dysfunction (EF 25-30%) in the context of tachymyo- cardiopathy, despite optimization of antiarrhythmic and chronotropic drugs.

Due to these problems, oral anticoagulation was discontinued, and pulmonary vein ablation and percutaneous left atrial appendage closure were planned.

Intervention: Pulmonary vein isolation was conducted under general anesthesia, using a standard point-by-point ablation with irrigated catheter (Navistar Thermocool, Biosense Webster, CA, USA). LAAO was performed with Watchman device (Atritech, Inc, Plymouth, Minnesota, MN) implantation, immediately after the ablation procedure. The ablation catheter was removed and the initial sheath was replaced by a 14F transseptal access sheath (Atritech, Inc, Plymouth, MN), which was positioned in the LAA. The Watchman device access sheath and dilator was advanced over the wire into left atrium. Size and shape of the LAA was determined by using monoplane fluoroscopy (with pigtail catheter and additional angiograms, RAO 30o) and 3-dimensional TEE guidance. LAA ostium diameter varied between 19-23 mm in different angles (from 0o to 135o), and LAA depth was 26 mm. Under fluoroscopy guidance, delivery catheter was advanced into the access sheath until the most distal marker band, and deployed as per manufacturer's recommendations. Release criteria (position, anchor, size and seal) were met, and Watchman device (no 30) properly placed, stable during tug test, without any leak, and high compression.

A COMPARISON OF 2-D AND 3-D ECHOCARDIOGRAPHY IMAGING DURING PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE (LAAO)

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Background: To chose an appropriate occluder size for left atrial appendage occlusion (LAAO), accurate assessment of the ostium and landing zone dimensions is essential. To date, the utility of 3-D versus 2-D has not been examined.

Objective: The aim of this study was to compare 2-D and 3–D echocardiography imaging performed during LAAO by two independent echocardiographers and to assess reproducibility of either method.

Methods: We analyzed 33 consecutive patients who underwent LAAO in our clinic. During LAAO the patients were anesthetized and the TEE was performed. Two independent echocardiographers measured LAA ostium and landing zone via 2-D and 3-D TEE.

Results: Mean values of ostial diameters measured in 2-D TEE by two independent echocardiographers were 23.8±4.4 vs 25.2±5.4 (P=0.04) and mean landing zone diameters were 18.3±4.4 vs 19.9±4.0 (P=0.005). In 3-D TEE mean ostial diameter was 29.5±5.3 vs 30.4±6.5 (P=0.07) and the landing zone 21.9±3.8 vs 22.2±3.9 (P=0.23). When the 2-D and 3-D measurements were compared, the ostial and landing zone diameters differed significantly (P<0.0001 and P<0.001 respectively).

Conclusions: There are significant differences between 2-D and 3-D TEE measurements of the ostial and landing zone diameters. 3-D measurements may be more reproducible than 2-D measurements.

LEFT ATRIAL APPENDAGE CLOSURE USING LEFT FEMORAL VEIN APPROACH

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Introduction: Atrial Fibrillation (AF) is the most common tachyarrhythmia and is associated with major complications such as thromboembolic events. Oral Anticoagulation (OAC) therapy remains an important component of AF treatment to avoid thrombo- embolism. Left Atrial Appendage (LAA) closure may be considered in patients with AF with high stroke risk and contraindications for long term OAC therapy. Devices for LAA closure are usually placed trans-septally using the Right Femoral Vein (RFV) approach (1; 2). Alternative approaches for accessing the left atrium have been reported, (2-6) but there are no reports on usage of the Left Femoral Vein (LFV) for LAA closure by using watchman device, that is unusual for septal puncture(7). In this report, we describe a LAA closure in an 83 year old patient using the LFV approach.

History and Physical Examination: An 83 year old male patient, with permanent AF with CHADS2 score 3, gastrointestinal bleeding (HAS-BLED = 5) was admitted at our hospital. The medical history included myocardial infarction, percutaneous coronary angio- plasty, dilated ischemic cardiomyopathy, moderate left ventricular dysfunction, NYHA class II, moderate renal failure and hypertension.

Imaging: On routine pre-procedural Echocardiogram, dilated cardiomyopathy and moderate ejection fraction dysfunction were observed. CT angiography done to observe vascular anatomy, demonstrated deployment of right common iliac vein towards left side (Fig 1 a,b). TransEsophageal Echocardiogram (TEE) used during procedure was very helpful to identify exact point (fossa ovalis) for puncture of interatrial septum(8) to approach LAA.

Indication For Intervention: The patient was considered a candidate for LAA closure using a Watchman device in order to avoid OAC therapy, according to current guidelines (9).

Intervention: Classically, the puncture site is reached by pulling the trans-septal sheath down into respectively the right atrium and Fossa Ovalis (FO) while observing the two drop movement. When using the LFV approach, this maneuver is very difficult and usually unsuccessful (10), particularly due to the angulation at the junction between the left common iliac vein and inferior vena cava. This angulation turns the needle away from the interatrial septum, thus hampering good contact with the wall of FO. In our case, we were unable to see the two drop movements into the right atrium and FO even when using needles with different curves. Then, we combined fluoroscopic and TEE images to confirm the exact position of the trans-septal sheath and subsequently steer it into the FO (Fig. 2 b, d). Using this approach we successfully performed puncture and implanted the Watchman device (Fig. 2 g).

Result: There were no complications and the patient was discharged on the third postoperative day. After two years of follow-up the patient remains asymptomatic, free of OAC therapy and without any cerebrovascular events.

Conclusion: In conclusion, trans-septal puncture guided by a combination of fluoroscopic and TEE images can be safely carried out using the LFV approach as an alternative option when the RFV is not accessible.

THORACOSCOPIC ATRICLIP CLOSURE OF LEFT ATRIAL APPENDAGE AFTER FAILED LIGATION VIA LARIAT

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Sam G. Aznaurov, MD: None Stephen K Ball, MD: None

Clinical History And Imaging: A 68-year-old male with paroxysmal AF was evaluated for ligation of the LAA via LARIAT sub-xiphoid approach. His CHA2DS2-VASc score was 4 for hypertension, prior cerebrovascular accident, and age >65 years. He was intolerant of anticoagulation with both dose-adjusted warfarin and rivaroxaban, due to recurrent, transfusion-dependent gastroin- testinal hemorrhage. His HAS-BLED score was 4. Pre-procedure gated CT angiography revealed an anteriorly directed LAA of chicken wing morphology, with a small secondary lobe near the ostium. He underwent LAA ligation utilizing a LARIAT ligature, via standard trans-septal and sub-xiphoid pericardial approach under general endotracheal anesthesia. The suture delivery device was cinched over the proximal neck of the LAA, and complete closure of the LAA ostium was initially noted (Figure 1a). However, after tightening the LARIAT, repeat contrast angiography of the LAA demonstrated gradual reopening of the LAA ostium and proximal lobe, as the delivery device was removed. A second LARIAT Plus ligature was used to re-snare the proximal neck of the LAA, but reopening of the LAA ostium was seen on repeat contrast angiography (Figure 1d). The patient was referred to the cardiothoracic surgery service for closure of the residual lobe of the LAA with an Atriclip-Pro device.

Intervention: Totally thoracoscopic access was obtained to the left chest under general endotracheal anesthesia. The pericardium was opened posteriorly to the phrenic nerve, and the LAA was visualized. The two previously deployed LARIAT ligatures were seen, and early ischemia of the LAA superior lobe was noted distal to the suture ligation neck (Figure 2). The basal accessory lobe of the

LAA remained unaffected by these ligatures. A 40mm Atriclip-Pro was deployed at the base of the LAA, achieving complete occlusion. The patient tolerated the procedure well, and following an uneventful postoperative course he was discharged to home 3 days later. Followup gated cardiac CT angiography showed complete closure of the LAA by Atriclip-Pro.

Discussion and Learning Points: Device-assisted epicardial closure of the LAA is an evolving option for the prevention of systemic embolism in patients with AF. While this is a safe and effective therapy for patients who are intolerant of anticoagulation, there is limited experience with these devices, and operators need to be aware of the potential for both early and delayed complications. To our knowledge, this is the first reported case of the use of a thoracoscopically deployed Atriclip-Pro device to acutely salvage an incomplete LAA ligature by the LARIAT device.

During deployment, LAA anatomy was such that, even with incomplete closure of the LAA by both the LARIAT and the LARIAT Plus ligatures, the appendage appeared occluded by direct compression from the LARIAT suture delivery device. After the LARIAT delivery catheter was removed off the LAA base and angiography was again performed, a remaining trabeculated infundibulum was noted. In contrast to the smooth-walled residual "stump" which is sometimes seen following epicardial LAA exclusion, this remaining trabeculated portion of the LAA may serve as a potential cardioembolic source. Furthermore, early thrombosis at the site of LAA ligation has been well described following the LARIAT procedure, and is postulated to be the result of

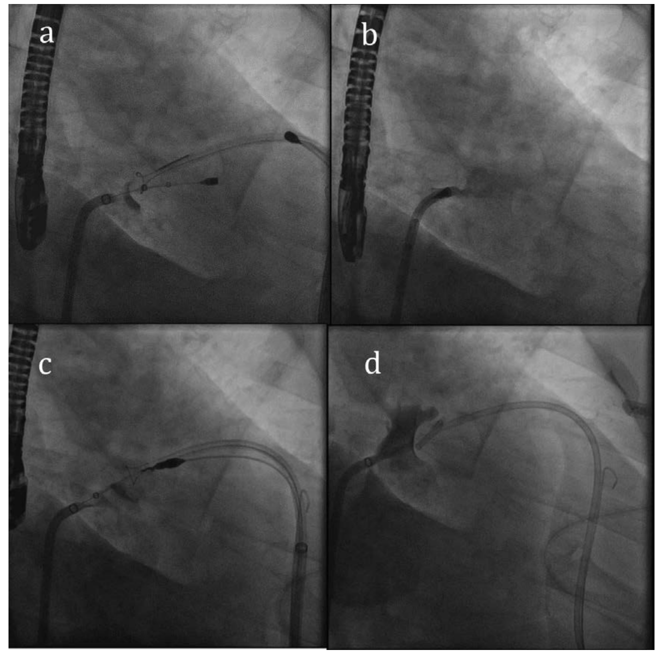

Figure 1. Intra-procedural fluoroscopy during initial deployment of the LARIAT over the neck of the LAA (a), with incomplete closure on post ligation angiogram (b). LARIAT Plus deployment, again over the neck of the LAA (c). Final angiographic appearance of the LAA, with the trabeculated secondary lobe unaffected by LARIAT Plus ligature (d).

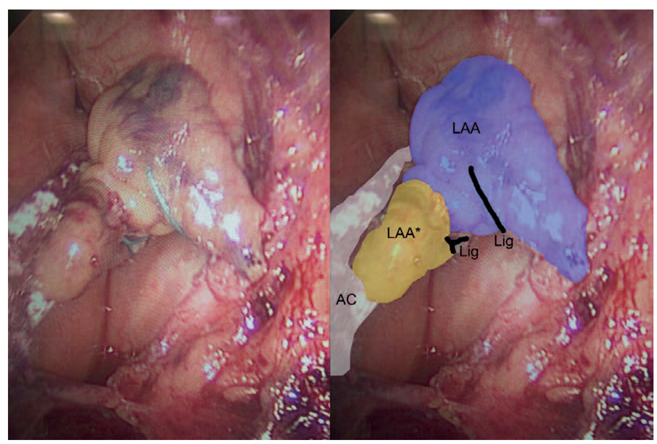

Figure 2. Thoracoscopic appearance of the Atriclip device (AC, white), over the previously ligated left atrial appendage (LAA, blue) as well as the previously unaffected secondary lobe (LAA*, yellow). Previously deployed LARIAT ligatures are also seen (Lig, black).

endothelial injury and inflammation producing a nidus for thrombus formation. Due to the residual risk of LAA thrombosis, the patient was referred to cardiac surgery service for completion of LAA exclusion.

Although totally thoracoscopic deployment of the Atriclip-Pro device is well described, its use in this scenario is novel. This case demonstrates the feasibility of completion of LAA closure following incomplete LAA ligation by sub-xiphoid approach. Additionally, this case highlights the possibility of incomplete LAA closure despite a favorable appearance on angiography during deployment of the LARIAT suture delivery device.