



# Assessment of peri-device leaks after interventional left atrial appendage closure using standardized imaging by cardiac computed tomography angiography

Simon Lindner<sup>1</sup> · Michael Behnes<sup>1</sup>  · Annika Wenke<sup>1</sup> · Benjamin Sartorius<sup>1</sup> · Uzair Ansari<sup>1</sup> · Muharrem Akin<sup>2</sup> · Kambis Mashayekhi<sup>3</sup> · Nils Vogler<sup>4</sup> · Holger Haubenreisser<sup>4</sup> · Stefan O. Schoenberg<sup>4</sup> · Martin Borggrefe<sup>1</sup> · Ibrahim Akin<sup>1</sup>

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## Abstract

Cardiac computed tomography angiography (cCTA) has recently been proposed for evaluation of successful interventional left atrial appendage closure (LAA/LAAC). This prospective longitudinal observational study aims to assess this proposal by applying a standardized imaging protocol to detect and quantify peri-device leaks (PDL) after LAAC. cCTA datasets of consecutive patients 6 months after successful LAAC were acquired on a third generation dual-source computed tomography system and reconstructed with a slice thickness of 0.5 mm. The standardized multi-planar reconstruction LAA occluder view for post-implantation evaluation (LOVE) algorithm was used to assess PDL in relation to LAA morphology and implanted LAAC devices. A total of 49 patients (median age 80 years, 24% female) were included consecutively. Overall PDL rate was 31%. Leak rates among different left atrial appendage morphologies varied largely. Windsock type had the highest incidence of PDL (47%). AMPLATZER™ AMULET™ device type revealed slightly higher PDL rates than WATCHMAN™ type and showed larger leaks. However, no statistical differences were found. PDL can be sized best in LOVE sagittal views, whereas a synopsis of LOVE sagittal, axial and coronal views allows further examination and detection of small leaks. PDL are common after successful interventional LAAC, which can be accurately detected and sized by standardized cCTA imaging protocols.

**Keywords** Left atrial appendage closure · Cardiac computed tomography angiography · Standardized imaging protocol · LOVE · Peri-device leak.

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Simon Lindner and Michael Behnes have contributed equally to this study.

✉ Michael Behnes  
michael.behnes@umm.de

- <sup>1</sup> First Department of Medicine, University Medical Center Mannheim (UMM), Faculty of Medicine Mannheim, University of Heidelberg, European Center for AngioScience (ECAS), and DZHK (German Center for Cardiovascular Research) partner site Heidelberg/Mannheim, Mannheim, Germany
- <sup>2</sup> Department of Cardiology and Angiology, Hannover Medical School, Hannover, Germany
- <sup>3</sup> Clinic for Cardiology and Angiology II, Universitaetszentrum Freiburg Bad Krozingen, University of Freiburg, Bad Krozingen, Germany
- <sup>4</sup> Institute of Clinical Radiology, University Medical Center Mannheim, University of Heidelberg, Mannheim, Germany

## Introduction

The left atrial appendage (LAA) is the main site of thrombus formation in patients suffering from non-valvular atrial fibrillation [1, 2]. To reduce the risk of ischemic stroke, the direct targeting of this problem by catheter-based LAA closure (LAAC) has become an established treatment alternative in recent years, especially since follow-up of the PROTECT-AF study demonstrated the effectiveness of this procedure compared to conventional anticoagulation therapy [3]. However, peri-device leaks (PDL) after LAAC are relatively common [4–6], and the consequences are not fully understood.

Assessment of PDL is usually performed via transesophageal echocardiography (TEE) [4], whereas cardiac computed tomography angiography (cCTA) may reveal the potential as an even more accurate imaging modality [7]. However, in studies assessing TEE examinations, PDL rates vary

largely [5, 6, 8, 9]. cCTA, in contrast, offers higher resolution images and could be superior to TEE in detection and scaling of PDL. A standardized cCTA imaging protocol has recently been proposed by our working group [7, 10] and could prove useful in post implantation evaluation of the LAAC device. Non-invasiveness and higher resolution of cCTA compared to TEE evaluation of LAAC paired with higher objectivity and reliability of a standardized protocol are aspects in favor of cCTA [7, 10].

Therefore, this pilot study aims to evaluate the feasibility of a standardized cCTA protocol—LAA occluder view for post-implantation evaluation (LOVE)—for the assessment of the incidence and accurate size of PDL in consecutive patients 6 months after successful LAAC for the first time. PDL are aimed to be assessed in relation to LAA morphologies and the implanted occlusion devices.

## Materials and methods

### Study population

Consecutive patients with non-valvular atrial fibrillation and indication for oral anticoagulation due to a  $\text{CHA}_2\text{DS}_2\text{-VASc}$  score  $\geq 2$  were included in this prospective, non-randomized, observational, longitudinal single-center study from June 2014 to December 2017. Following the 2016 guidelines of the European Society of Cardiology (ESC) [11], sex category as independent risk factor was excluded from the original  $\text{CHA}_2\text{DS}_2\text{-VASc}$  score. Inclusion criteria were age  $\geq 18$ , a relative or absolute contraindication for oral anticoagulation, which was major or recurrent bleeding, HAS-BLED score  $\geq 3$  or intolerance to oral anticoagulation. Exclusion criteria were a single episode of atrial fibrillation or a treatable cause, planned catheter ablation of atrial fibrillation or electrical cardioversion within 30 days prior or after LAAC, congestive heart failure at New York Heart Association (NYHA) stage IV, myocardial infarction within the last 3 months, atrial septum defect (ASD) or interventional or surgical occlusion of ASD, mechanical heart valve, status after heart transplant, symptomatic carotid stenosis, transient ischemic attack (TIA) or stroke within the last 30 days, intracerebral bleeding within the last 3 months, acute infection, existing or planned pregnancy, and existing cardiac thrombus.

The LAAC device implantation was performed by experienced interventional cardiologists and the selection of one of the two devices—WATCHMAN™ (Boston Scientific, Natick, MA, USA) or AMPLATZER™ AMULET™ Cardiac Plug (St. Jude Medical, St Paul, MN, USA)—was based on individual anatomic considerations. The detailed procedure and post-procedural measures have been previously described by our study group [12]. After LAAC,

100 mg/day of acetylsalicylic acid (ASA) was prescribed indefinitely and 75 mg/day clopidogrel for at least 6 months with a loading dose of 600 mg or 250 mg if clopidogrel had been taken before.

### Cardiac computed tomography angiography imaging at 6 months of follow-up

cCTA was scheduled 6 months after successful LAAC. All cCTA scans were performed using a  $2 \times 192$ -slice third generation dual-source CT (Siemens Force, Siemens Healthineers, Forchheim, Germany) using a dual-energy scan mode. The dual-energy approach was, however, not required for the assessments in this study. Acquisition parameters for the dual energy cCT were tube voltage 90 kV (tube A), 150 kV with tin filter (tube B) with topogram dependent tube current modulation for both tubes; detector collimation  $2 \times 192 \times 0.6$  mm; slice thickness 0.6 mm, increment 0.5 mm. All cCTA acquisitions were performed with retrospective ECG-gating and bolus triggering technique with a region of interest placed in the descending aorta and 100 HU threshold. For i.v. contrast 80 cc of iodinated contrast material (Imeron 400, Bracco, Milan, Italy) were administered via an 18G cubital catheter with an injection rate of 5 ml/s followed by a 50 ml saline flush. A systematic approach to evaluate implanted LAAC devices has been recently described by the so called LOVE views, revealing optimal device-related angulation allowing optimal evaluation of the device post implantation [7]. All images were assessed by a single radiologist using the LOVE sagittal, axial and coronal views.

### Patients with chronic kidney disease

Stage of chronic kidney disease (CKD) was defined according to the KDIGO classification [13] by glomerular filtration rate (GFR)  $< 60$  ml/min. Severe CKD was defined as GFR  $< 30$  ml/min. All patients with chronic kidney disease had 1 l of balanced intravenous electrolyte solution administered before and after imaging. Their renal function was followed up by their respective general practitioner for 2 days after administration of contrast agent.

### Definitions

The recently described LOVE views were applied in all patients to evaluate the presence and extent of PDL [7]. PDL were defined as a contrast enhancement trail adjacent to the LAAC device, representing communication with the lumen of the left atrium. A PDL was classified by width into minor ( $< 1$  mm), moderate (1–3 mm) and major ( $> 3$  mm) leak.

LAA morphology of each patient was assessed and classified into one of the four types suggested by Wang et al. [14], namely windsock, chicken wing, cauliflower and cactus.

All patients were followed-up at cCTA visits regarding anticoagulant therapies and adverse clinical events including arterial or venous thromboembolism, stroke or transient ischemic attack (TIA).

### Study endpoints

PDL incidence and diameter were analyzed for each morphologic type of LAA individually. PDL incidence and diameter was also assessed for both types of LAAC devices (WATCHMAN™ and AMPLATZER™ AMULET™). Adverse events, especially thromboembolic and cardiovascular events, during a follow-up period of 12 months were secondary endpoints of this study.

### Statistical analysis and data availability

Statistical analyses were performed with IBM® SPSS® Statistics Version 21.0.0.0 (IBM, Armonk, NY). Metric variables are given as medians (25th and 75th percentiles) or mean (STD), whereas numerical variables are given as total numbers with group-related percentages. Normal distribution was tested using Kolmogorov-Smirnov-Test. Fisher's exact and Chi square test were used in the analysis of differences in numeric variables of two or more groups respectively. Univariate variance analysis (ANOVA) was used to calculate differences in normally distributed metric variables. A *p* value of <0.05 indicates statistical significance, a *p* value <0.10 indicates a statistical trend. The datasets generated during the current study are available from the corresponding author on reasonable request.

## Results

### Baseline characteristics

A total of 49 patients were included in the study and evaluated by cCTA using the LOVE imaging algorithm 6 months (180 days) after successful LAAC (IQR 178–180 days). Median age was 80 years, 24% were female. Median CHA<sub>2</sub>DS<sub>2</sub>VASc score and median HAS-BLED score were 4. Further baseline characteristics are shown in Table 1.

### Procedural characteristics

Median duration of interventional LAAC procedure was 90.5 min (IQR 70–115). Median contrast agent usage was 145 ml (IQR 110–191) and median duration of fluoroscopy was 8.1 min (IQR 5.2–12.8). Median GFR was 70 ml/min.

**Table 1** Baseline characteristics

Total number of patients	49
Female, n (%)	12 (24)
Age [years] median (IQR)	80 (75–84)
Height [cm] median (IQR)	171 (167.25–176)
Weight [kg] median (IQR)	80 (70.9–89.8)
BMI [kg/cm <sup>2</sup> ] median (IQR)	26.5 (24.6–30.2)
Comorbidities, n (%)	
Hypertension	47 (96)
Diabetes mellitus	11 (22)
Prior stroke	8 (16)
Prior transient ischemic attack	2 (4)
Prior intracranial bleeding	5 (10)
Coronary artery disease	24 (49)
Peripheral vascular disease	3 (6)
Renal failure	16 (33)
Liver disease	4 (8)
AF type, n (%)	
Paroxysmal	23 (47)
Persistent	10 (20)
Permanent	16 (33)
Labile INR, n (%)	3 (6)
CHA <sub>2</sub> DS <sub>2</sub> VASc score <sup>a</sup> median (IQR)	4 (3–5)
HAS-BLED score median (IQR)	4 (3–4)
Prior bleeding, n (%)	
Gastrointestinal	25 (51)
Intracranial bleeding	8 (16)
Urinary	6 (12)
Others	5 (10)
Total	42 (86)

QR Inter quartile rage

<sup>a</sup>Following the 2016 guidelines of the ESC, sex category as independent risk factor was excluded from the original CHA<sub>2</sub>DS<sub>2</sub>VASc score

There were 22 (45%) patients suffering from chronic kidney disease (GFR < 60 ml/min). Of those, four had severe CKD (GFR < 30 ml/min). No acute-on-chronic kidney failure after administration of contrast agent was reported.

### Visualization of PDL

PDL were best visualized and measured in LOVE sagittal views. This has been outlined in (Fig. 1). In contrast, smaller PDL were found in synopsis of sagittal, axial and coronal views (Fig. 2). Screening for PDL should always include the review of all reports. Overall PDL rate was 31%, with a median width of 2.6 mm (IQR 2.1–3.0 mm). Of those PDL, 10% (n=3) were classified as major, 35% (n=11) were classified as moderate. No minor leaks were detected.

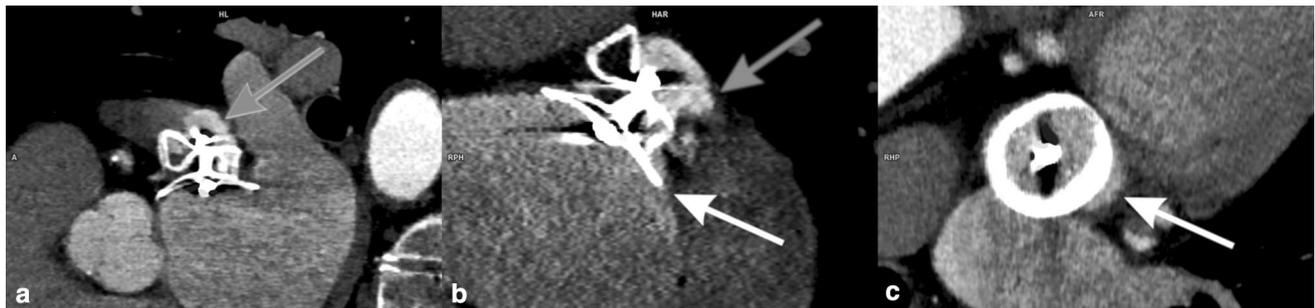
## LAA morphologies and PDL

The rates of different LAA morphologies were 39% windsock, 33% chicken wing, 23% cauliflower and 6% cactus type. PDL was detected in 31% of patients. PDL rate was highest in windsock type (47%). There were lower leak rates in chicken wing (25%) and cauliflower type (18%). Cactus type did not show any PDL. However, those differences did not reach statistical significance. Median PDL sizes related to LAA morphologies also showed no statistically significant differences (2.6 mm in windsock and cauliflower,

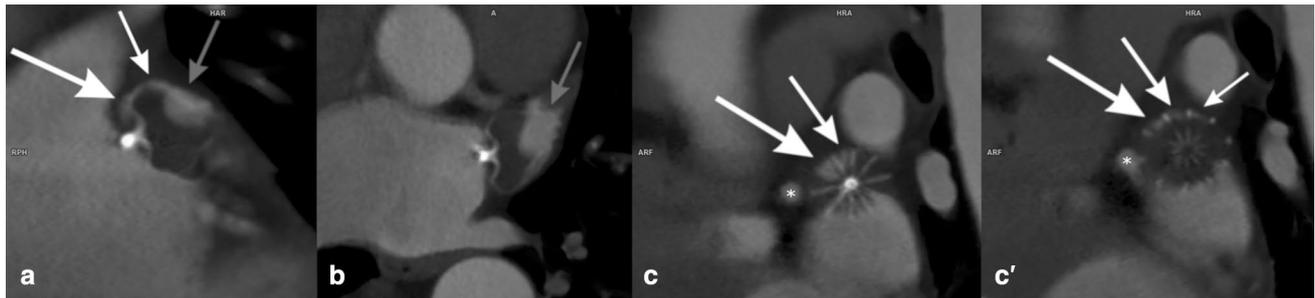
2.5 mm in chicken wing type). Major PDL were found in windsock (11%,  $n=2$ ) and chicken wing type (6%,  $n=1$ ). Respectively, moderate PDL were found in windsock (36%,  $n=7$ ), chicken wing (19%,  $n=3$ ) and cauliflower (18%,  $n=2$ ) (Table 2)

## Devices and PDL

29 WATCHMAN™ devices and 20 AMPLATZER™ AMULET™ devices (59% vs. 41%) were implanted. WATCHMAN™ devices had a lower relative occurrence of PDL



**Fig. 1** Peri-device leak (white arrows) of an AMPLATZER™ AMULET™ plug in **a** coronary, **b** sagittal and **c** axial LOVE-view with contrast medium accumulation in the LAA (grey arrows)



**Fig. 2** Small Peri-device leak (white arrows) of a WATCHMAN™ device in **a** coronary, **b** sagittal and **c** and **c'** axial LOVE-views with contrast medium accumulation in the LAA (grey arrows). The white

asterisk marks the left circumflex artery (LCx) that should not be confused with PDL

**Table 2** Frequency and extent of peri-device leaks according to LAA morphology

	Windsock ( $n=19$ ; 39%)	Chicken wing ( $n=16$ ; 33%)	Cauliflower ( $n=11$ ; 23%)	Cactus ( $n=3$ ; 6%)	$p$ value
Peri-device leak (PDL), $n$ (%)	9 (47)	4 (25)	2 (18)	0 (0)	0.257
Leak diameter, mm, median (IQR)	2.6 (2.0–3.1)	2.5 (1.4–4.43)	2.6 (–)	0 (–)	0.973
Device type (WM / ACP)	7/12	14/2	7/4	1/2	<b>0.010</b>
Major PDL, $n$ (%)	2 (11)	1 (6)	0	0	0.670
Moderate PDL, $n$ (%)	7 (36)	3 (19)	2 (18)	0	0.382

Bold indicates statistical significance ( $p < 0.05$ )

IQR interquartile range. If  $n < 4$  no IQR is given

(27% vs. 35%) and smaller median diameters of occurred leaks (2.2 mm vs. 2.7 mm), however both differences were not statistically significant. More major PDL were found in AMPLATZER™ AMULET™ devices than in WATCHMAN™ devices (10% vs. 3%). Moderate PDL were equally distributed among WATCHMAN™ and AMPLATZER™ AMULET™ devices (24% vs. 25%) (Table 3).

**Morphologies and devices**

Distribution of implanted LAA occlusion devices was significantly different among LAA morphologies. WATCHMAN™ devices were more likely to be implanted in chicken wing and cauliflower types. Respectively, more AMPLATZER™ AMULET™ devices were implanted in windsock and cactus types (Table 2). In individual morphologic types, PDL size showed no significant difference between both device types (Table 4).

**Adverse events**

In the present study cohort, only one patient had a vascular adverse event during the follow-up period of 12 months. The patient suffered from pulmonary arterial embolism and subsequently had oral anticoagulation therapy reestablished 3 months after LAAC. This patient had a WATCHMAN™ device implanted and chicken wing type LAA morphology. At mid-term follow-up cCTA, this patient showed a PDL of 2 mm width. No other vascular adverse event during the follow-up period was documented, and no stroke or TIA occurred at 12 months.

**Discussion**

The present pilot study evaluates for the first time the feasibility of the standardized cCTA LOVE protocol for the assessment of the incidence and accurate size of PDL in consecutive patients 6 months after successful LAAC. PDL are aimed to be assessed in relation to LAA morphologies and the implanted occlusion devices. It was demonstrated that overall PDL has an incidence of 31%. This is accordant to existing literature, where PDL rates vary between 32–36%

**Table 4** Extent of peri-device leaks according to implanted LAAC devices and morphologies

	WATCHMAN™	AMPLATZER™ AMULET™	<i>p</i> value
Windsock	3.1 (4)	2.5 (5)	0.730
Chicken Wing	2.5 (3)	4.9 (1)	0.500
Cauliflower	2.2 (1)	2.9 (1)	1.000
Cactus	(0)	(0)	–

Sizes of PDL in [mm] (n)

[4–6]. A lower incidence (12.5%) was ascertained by Saw et al. [8]. Most PDL documented in this study were moderate (size 1–3 mm), compared to a minor number of major PDL. However, no serious adverse events that could be linked to LAA originated thromboembolism were documented and all patients were treated by dual antiplatelet therapy for at least 6 months.

This study shows varying PDL rates for the different LAA morphologies. Windsock type showed the highest incidence for PDL and major leak. Although no statistical significance could be shown, there seem to be differences in morphologic features and PDL that require further investigation.

This study shows the possible uses of LOVE imaging in the assessment of PDL in patients’ follow-up 6 months after LAAC. Most PDL can be seen best using LOVE sagittal view. When axial LOVE view is combined with perpendicular planes, more detailed assessment of PDL can be made and even small PDL can be detected. Assessment of PDL should thus be part of every cCTA imaging, and implementation of all LOVE views is recommended. Higher resolution measurements of PDL diameters can be performed by cCTA compared to TEE. Further studies are needed to evaluate the additional value of cCTA measurements in this context.

There is only little knowledge on the consequences of PDL. Existing data suggests that PDL have no higher risk for stroke [4, 8] while Lam et al. described thrombus formation in a case of incomplete occlusion [15]. In this cohort, no stroke or TIA occurred, although the prevalence of PDL was high. Further assessment of clinical consequences of PDL is critically important. Standardized LOVE cCTA imaging could facilitate comparability of studies assessing this topic.

**Table 3** Frequency and extend of peri-device leaks according to implanted LAAC devices

	WATCHMAN™ (n = 29; 59%)	AMPLATZER™ AMULET™ (n = 20; 41%)	<i>p</i> value
Peri-device leak (PDL), n (%)	8 (27)	7 (35)	0.428
Leak diameter [mm] median (IQR)	2.2 (1.6–3.0)	2.7 (2.3–4.8)	0.203
Major PDL, n (%)	1 (3)	2 (10)	0.374
Moderate PDL, n (%)	7 (24)	5 (25)	0.946

IQR interquartile range

Possible influences of LAA morphologies on complications of PDL should be evaluated. Further uses of cCTA have also been proposed in the planning of LAAC as well as early and mid-term outcomes of device implantation [16], three-dimensional geometric CT analysis of the LAA could also be effective for prediction of PDL [17]. Non-invasiveness and higher resolution measurements of PDL diameters of CT compared to TEE evaluation of LAAC paired with higher objectivity and reliability of a standardized protocol are aspects in favor of the LOVE cCTA protocol.

### Limitations of this study

This pilot study is the first to evaluate PDL by applying the standardized cCTA LOVE protocol 6 months after successful LAAC. Despite its longitudinal prospective design with consecutive recruitment of LAAC patients, the present study reveals only an observational and hypothesis-generating character with a limited sample size of 49 patients. Only the feasibility of cCTA LOVE imaging was assessed in relation to LAA morphologies and implanted LAAC devices. Further investigations with larger sample sizes are needed to draw any definitive conclusions. Direct comparison of cCTA and TEE regarding the accuracy for detection of clinically relevant PDL were beyond the scope of the present study. However, this should be a focus of future studies, since cCTA allows for an even sharper visualization with less artifacts compared to TEE.

### Conclusion

PDL are common after successful LAAC therapy. Further investigation on consequences of PDL considering the impact of size, LAA morphology and type of implanted LAAC device is needed. A standardized cCTA imaging protocol is an eligible tool to accurately detect and size PDL.

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### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study has been approved by the medical ethics committee II of the Faculty of Medicine Mannheim, University of Heidelberg, Germany.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

**Research involving human and animal participants** This article does not contain any studies with animals performed by any of the authors.

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