

Left Atrial Appendage Occlusion: Analyzing Factors for Peridevice Leak with Dual-Occlusive Devices

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Abstract

Background: This study examines factors influencing peridevice leak (PDL) in patients treated with the Amplatzer Amulet Occluder for left atrial appendage occlusion (LAAO).

Materials and Methods: A retrospective analysis was conducted on 217 patients who underwent successful LAAO with the Amplatzer Amulet Occluder due to atrial fibrillation and anticoagulation contraindications. Follow-up transesophageal echocardiography (TEE) was performed 1-3 months post-procedure to detect PDL and analyze related procedural and anatomical factors.

Results: PDL occurred in 42% of patients, predominantly mild (<3 mm). Key factors associated with increased PDL risk included occluder compression <12%, off-axis device positioning, and device size ≥ 25 mm. Baseline patient characteristics and procedural details did not significantly impact PDL rates.

Conclusion: For optimal LAAO outcomes, pre- and periprocedural assessment of LAA size and device positioning is crucial. Ensuring occluder compression above 15% may minimize PDL risks, especially for larger devices.

Keywords: Left atrial appendage occlusion; dual-occlusive device; 3D transesophageal echocardiography; peridevice leakage; off-axis; compression

Abbreviations

DRT = device related thrombus

LAA = left atrial appendage

LAAO = left atrial appendage occlusion

MAE = major adverse events

PDL = peridevice leaks

(3D-) TEE = (Three dimensional-) transesophageal echocardiography

1. Introduction

One of the most common cardiac arrhythmias, especially atrial tachycardia, is atrial fibrillation. It is presented with a prevalence of 1-2% in population, rising by age continuously (15% in men above 80 years of age) (1, 2). Well known, atrial fibrillation increases the imminent risk of ischemic thromboembolism, developed predominantly in the left atrial appendage (LAA), in all parts of the atrial system (3). Amongst all, stroke is the most feared undesirable event (4).

Oral anticoagulants, such as anti-factor Xa inhibitors, thrombin inhibitors, and vitamin K antagonists, represent a contemporary first-line strategy for prevention of thromboembolism. To minimize bleeding risks, however,

patients should first be evaluated using anticoagulation scoring systems, such as CHA2DS2-VASc (≥ 2) and HAS-BLED (≤ 2) (5-8).

In patients with contraindications to oral anticoagulation, older studies such as PROTECT AF (9), PREVAIL (10) and Prague-17 (11) have already demonstrated the non-inferiority of left atrial appendage occlusion (LAAO) compared to anticoagulation, which is reflected in a Class IIB recommendation in the 2024 ESC Guideline (12) and Class IIA recommendation in the 2023 ACC/AHA/ACCP/HRS Guideline (13). Current randomized studies could upgrade these recommendations in favor of LAAO in the coming years (14).

There are two main types of LAA closure devices: the single-occlusive device, represented by, among others, the Watchman (Boston Scientific, Boston), and the Amplatzer Amulet as a dual-occlusive device (Abbott, Boston) (22). Since the inception of interventional LAAO, the occurrence of peridevice leaks (PDL) and device-related thrombus (DRT) has remained a challenge in some cases.

Ironically, PDLs, have been identified as influencing factors for systemic thromboembolism (15) and the formation of DRT (16), which in turn has emerged as a primary cause of ischemic strokes (17). In cases of severe PDL a second occluder might even become an option (18) next to vascular

plugs, embolic coils or radiofrequency ablation leading to a second intervention for the patient with possible additive adverse events.

Factors influencing the formation of PDL include, among others, LAA size and anatomy, device undersizing, off-axis implantation (19), and volume loading (20).

As an experienced center in the implantation of dual-occlusive devices, specifically the Amplatzer Amulet, we investigated factors influencing the formation of PDL in this study, with the aim of anticipating these factors in the future and ideally preventing the development of PDL in advance.

2. Materials and Methods

2.1 Study Design

In this single-center study, we examined a total of 217 consecutive patients who underwent a successful LAAO with the Amplatzer Amulet Occluder between September 2015 and January 2023 due to atrial fibrillation and contraindications to oral anticoagulation. All patients attended a follow-up 3D transesophageal echocardiography (TEE) 1-3 months post-procedure (22). The primary objective of this investigation was to identify factors influencing the development of PDL. We collected data on baseline characteristics, clinical and laboratory features, pre-LAAO medication, bleeding risk factors, LAAO indications, implantation characteristics, and periprocedural adverse events up to discharge according to the Munich consensus document (21). Additionally, TEE characteristics of the LAA were documented during the procedure and at the first follow-up TEE as described below. All patients had no severe leaks on periprocedural TEE and met the criteria for device success.

2.2 Procedural data

At least 24 hours before the index LAAO procedure, patients underwent TEE to screen for thrombi in the LAA and to assess the overall feasibility of occluder implantation. All procedures were performed under general anesthesia using contrast angiography and TEE (GE Vivid E9 BT12). We recorded the volume of contrast medium (ml), fluoroscopy time (minutes), and radiation dose (cGy*cm²) using DAVID hemodynamic software. The procedure duration, measured in minutes, concluded with patient extubation. The procedure was conducted in accordance with the manufacturers' guidelines.

2.2 TEE Review

An experienced examiner retrospectively analyzed high-quality 3D-TEE images using the GE EchoPAC BT12 software based on the stored images to provide the most detailed insights possible into the research question. Incomplete data sets were excluded.

In the first step, the morphology of LAA was assessed from the periprocedural TEE using the 12-channel multislice mode, which allows

for a 3D reconstruction of the LAA, following the established definitions (22).

Next, the orifice area, representing the immediate opening of the LAA, and the landing zone, extending from the left circumflex coronary artery to 10 mm into the LAA from the left superior pulmonary vein, were measured. The mean diameter (D average) was calculated using the perimeter (Dper) with the formula "Dper = P/π". The depth of the LAA was defined as the shortest orthogonal distance from the landing zone to the LAA roof (21).

In the follow-up TEE, the focus was on detecting PDL, which were classified as mild (< 3 mm), moderate (3-4.9 mm), or severe (> 5 mm). Additionally, DRT, transseptal shunts, off-axis positioning of the occluder, and occluder compression in the LAA were evaluated.

Color-flow Doppler was used to detect leaks around the LAA occluder in the form of residual color jets that were visible despite the occluder being in place. The same methodology was applied to identify transseptal shunts. Device-related thrombus was defined as an echogenic, well-demarcated formation on the occluder.

Off-axis positioning was identified when the disc and the central waist, which connects to the main body of the occluder, did not form a right angle, implicating a tilting of the occluder. Occluder compression was defined as the maximum extent of the occluder within the LAA and was calculated as the ratio of the implanted occluder size, documented as a percentage.

2.3 Statistical Analysis

Continuous variables were expressed as means ± standard deviations and analyzed using the Student's t-test for normally distributed data. For non-normally distributed data, the Mann-Whitney U test was employed. Categorical variables were reported as absolute counts and percentages, with comparisons made using the chi-square test. Statistical significance was defined as a two-sided p-value of < 0.05. All statistical analyses were conducted using SPSS version 29 (IBM Corp., Armonk, NY, USA).

3. Results

3.1 Patient Characteristics

Among the total cohort of 217 patients who received an Amplatzer Amulet Occluder, 91 patients, or 42%, exhibited at least one mild leak (< 3 mm). The average age of the cohort was 77.41 ± 7.19 years, with the majority being over 75 years old (69%). Just over half of the patients were male (51%).

As shown in Table 1, none of the aforementioned parameters, including comorbidities, medication, laboratory values, the CHA2DS2-VASc score, the HAS-BLED score, or atrial fibrillation classification, had a significant impact on the occurrence of leaks.

Table 1. Patient Characteristics				
	Overall Cohort n= 217 (%)	Leaks n= 91 (%)	No leaks n= 126 (%)	p value
Age (years)	77.41±7.19	77.73±7.07	77.18±7.29	0.58
Age≥75 (years)	149 (69)	66 (73)	83 (66)	0.30
Male	110 (51)	49 (54)	61 (48)	0.43
Body mass index (kg/m ²)	27.05±4.74	26.33±4.09	27.57±5.11	0.13
Height (cm)	170.09±9.20	170.79±8.70	169.59±9.55	0.35
Weight (kg)	78.51±15.57	77.02±13.45	79.58±16.93	0.23
CHA ₂ DS ₂ VASC score	4.55±1.52	4.55±1.57	4.56±1.48	0.98
HASBLED score	3.80±1.09	3.73±1.02	3.86±1.13	0.38
Atrial fibrillation				
Paroxysmal	117 (54)	47 (52)	70 (56)	0.57
Persistent	24 (11)	10 (11)	14 (11)	0.98
Permanent AF	76 (35)	34 (37)	42 (46)	0.54
Clinical features				
Coronary artery disease	87 (40)	38 (42)	49 (39)	0.67
Myocardial infarction	29 (13)	11 (12)	18 (14)	0.64
PCI	50 (23)	24 (26)	26 (21)	0.32
CABG	18 (8)	7 (8)	11 (9)	0.78
Heart failure	68 (31)	30 (33)	38 (30)	0.66
Arterial hypertension	180 (83)	74 (81)	106 (84)	0.59
Pacemaker	36 (17)	18 (20)	18 (14)	0.28
Diabetes mellitus	59 (27)	19 (21)	40 (32)	0.08
Hyperlipidemia	86 (40)	35 (38)	51 (40)	0.77
COPD	38 (18)	15 (16)	23 (18)	0.74
Nikotin	53 (24)	19 (21)	34 (27)	0.26
Hemoglobin (g/dl)	11.70±2.32	11.50±2.38	11.85±2.27	0.26
Creatinine (mg/dl)	1.29±0.90	1.31±0.94	1.28±0.87	0.83
GFR (ml/min)	58.96±23.18	58.49±23.26	59.30±23.21	0.80
Quick (%)	87.26±22.19	86.70±22.47	87.66±22.07	0.76
INR	1.12±0.22	1.12±0.20	1.12±0.23	0.94
PTT (sec)	26.89±5.98	26.83±5.39	26.93±6.42	0.90
Medication before LAAO				
ASA	39 (18)	17 (19)	22 (17)	0.82
Clopidogrel	15 (7)	7 (8)	8 (6)	0.70
ASA + Clopidogrel	4 (2)	2 (2)	2 (2)	0.74
Vitamin K antagonist	16 (7)	4 (4)	12 (10)	0.15
Noval oral anticoagulant	108 (50)	46 (51)	62 (49)	0.85
Low molecular weight heparin	24 (11)	11 (12)	13 (10)	0.68
Beta blocker	166 (77)	68 (75)	98 (78)	0.60
Statin	110 (51)	42 (46)	68 (54)	0.26
Diuretic	146 (67)	65 (71)	81 (64)	0.27
ACE inhibitor	53 (24)	25 (27)	28 (22)	0.37
Sartane	85 (39)	37 (41)	48 (38)	0.70
Risk factors for bleeding				
Previous stroke	47 (22)	21 (23)	26 (21)	0.67
TIA	7 (3)	4 (4)	3 (2)	0.41
Prior major bleeding	112 (52)	51 (56)	61 (48)	0.27
Renal disease	92 (42)	35 (38)	57 (45)	0.32
Liver disease	15 (7)	6 (7)	9 (7)	0.86
Labile INR	5 (2)	1 (1)	4 (3)	0.32
Age>65	204 (94)	87 (96)	117 (93)	0.40

CAD: coronary artery disease; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; COPD: chronic obstructive pulmonary disease; GFR: glomerular filtration rate; INR: international normalized ratio; PTT: prothrombin time; ASA: acetylsalicylic acid; ACE: Angiotensin-Converting-Enzyme; TIA: transitory ischemic attack

The primary indication for LAAO was previous bleeding events, with the majority being major bleeds (52%). The occurrence of leaks did not differ significantly in this regard (see Table 2).

	Overall Cohort n= 217 (%)	Leaks n= 91 (%)	No leaks n= 126 (%)	p value
Previous major bleeding	112 (52)	51 (56)	61 (48)	0.27
Intracranial bleeding	33 (15)	13 (14)	20 (16)	0.75
Gastrointestinal bleeding	69 (32)	34 (37)	35 (28)	0.14
Other	12 (6)	5 (6)	7 (6)	0.99
Previous minor bleeding	94 (43)	36 (40)	58 (46)	0.34
Gastrointestinal bleeding	50 (23)	20 (22)	30 (24)	0.75
Hematoma	13 (6)	3 (3)	10 (8)	0.16
Other	42 (19)	16 (18)	26 (21)	0.57
Renal or hepatic disease	38 (18)	17 (19)	21 (17)	0.70
High risk of falls or prior falls	18 (8)	7 (8)	11 (9)	0.78
Physician/patient refusal of oral anticoagulation	2 (1)	1 (1)	1 (1)	0.82
For some patients more than 1 indication was reported				

3.2 Procedural Data

The procedure time averaged 70.36 ± 30.87 minutes, with a contrast medium usage of 80.30 ± 39.96 ml, fluoroscopy time of 11.82 ± 33.20 minutes, and radiation dose of 1692.15 ± 1689.60 cGy*cm². There were no significant differences between groups with and without leaks.

Hospital stay averaged 6.27 ± 3.95 days, with no significant differences between the groups.

The most significant factor influencing leaks was the size of the implanted occluder. Occluders in the leak group were significantly larger (23.51 ± 3.81 mm for leaks vs. 22.25 ± 3.90 mm for no leaks; $p = 0.02$). Specifically, occluders > 25 mm were significantly more associated with leaks (51% for leaks vs. 37% for no leaks; $p = 0.04$) (see Table 3).

	Overall Cohort n= 217 (%)	Leaks n= 91 (%)	No leaks n= 126 (%)	p value
Procedure time (min)	70.36 ± 30.87	70.03 ± 31.05	70.60 ± 30.86	0.90
Contrast medium (ml)	80.30 ± 39.96	79.53 ± 44.34	80.87 ± 36.64	0.81
Fluoroscopy time (min)	11.82 ± 33.20	12.75 ± 36.55	11.17 ± 30.75	0.73
Radiation dose (cGy*cm ²)	1692.15 ± 1689.60	1493.27 ± 1484.03	1832.64 ± 1813.51	0.15
More than 1 device tried	2 (1)	1 (1)	1 (1)	0.82
Final Occluder implanted (mm)	22.77 ± 3.90	23.51 ± 3.81	22.25 ± 3.90	0.02
Final Occluder > 25 mm	92 (42)	46 (51)	46 (37)	0.04
Hospital stay (days)	6.27 ± 3.95	6.46 ± 3.95	6.13 ± 3.97	0.54

3.3 Periprocedural Adverse Events

As shown in Table 4, the incidence of major adverse events (MAEs) was minimal. Cardiac tamponade and major bleeding were the most frequent,

occurring in 2 cases each, but there were no significant differences between the groups. The most common minor adverse events were vascular complications, occurring in 6% of cases, also without significant differences between the groups.

Table 4. Periprocedural adverse events				
	Overall Cohort n= 217 (%)	Leaks n= 91 (%)	No leaks n= 126 (%)	p value
Major adverse events				
Stroke	0	0	0	1
Cardiac tamponade	2 (1)	1 (1)	1 (1)	0.82
Major bleeding	2 (1)	0	2 (2)	0.23
Device embolization	1 (0.5)	0	1 (1)	0.39
Other adverse events				
Minor bleeding	13 (6)	3 (3)	10 (8)	0.16
Air embolism (transient ST elevation and/or chest pain)	2 (1)	1 (1)	1 (1)	0.82
Pericardial effusion	11 (5)	3 (3)	8 (6)	0.31
Vascular complication	14 (6)	4 (4)	10 (8)	0.30
Acute kidney injury	3 (1)	1 (1)	2 (2)	0.76

3.4 TEE Analyses

The periprocedural anatomical characteristics of the LAA, including morphology, landing zone, orifice area, and depth, did not significantly impact the occurrence of leaks (see Table 5).

Table 5. Periprocedural left atrial appendage characteristics				
	Overall Cohort n= 217 (%)	Leaks n= 91 (%)	No leaks n= 126 (%)	p value
Morphology				
Windsock	137 (63)	60 (66)	77 (61)	0.47
Chicken wing	20 (9)	10 (11)	10 (8)	0.44
Cactus	51 (24)	17 (19)	34 (27)	0.16
Cauliflower	9 (4)	4 (4)	5 (4)	0.88
Diameter: Landing Zone (mm)	18.30±3.68	18.77±3.79	17.95±3.57	0.11
Diameter: Orifice Area (mm)	23.86±4.44	24.34±4.01	23.51±4.72	0.18
Depth (mm)	15.57±4.58	15.52±4.34	15.60±4.77	0.89

However, the TEE follow-up (Table 6) revealed different results. Minor leaks accounted for 34% of all leaks, followed by 6% moderate leaks and 2% severe leaks. The most significant factors influencing leaks were off-axis positioning of the occluder (32% for leaks vs. 12% for no leaks; $p < 0.01$) and insufficient occluder compression ($12.98 \pm 6.68\%$ for leaks vs. $16.24 \pm 8.17\%$ for no leaks; $p < 0.01$) within the LAA. Specifically,

compression $< 12\%$ showed notable differences (48% for leaks vs. 30% for no leaks; $p < 0.01$), although significance was lost for compression $< 15\%$ (59% for leaks vs. 46% for no leaks; $p = 0.053$). However, the combination of an occluder ≥ 25 mm and compression $< 15\%$ resulted in a significantly increased risk of leakage (27% for leaks vs. 12% for no leaks; $p < 0.01$).

Table 6. Complications and LAO characteristics at transesophageal echocardiographic follow-up				
	Overall Cohort n= 217 (%)	Leaks n= 91 (%)	No leaks n= 126 (%)	p value
Device-related thrombus	5 (2)	1 (1)	4 (3)	0.32
Transseptal shunt	66 (30)	27 (30)	39 (31)	0.84
Peridevice leakage				
Severe leak (> 5 mm)	4 (2)			
Moderate leak (3-4.9 mm)	13 (6)			
Minor leak (< 3 mm)	74 (34)			
Off-axis position	44 (20)	29 (32)	15 (12)	< 0.01
Occluder compression (%)	14.88±7.73	12.98±6.68	16.24±8.17	< 0.01
Occluder compression $< 12\%$	82 (38)	44 (48)	38 (30)	< 0.01
Occluder compression $< 15\%$	112 (52)	54 (59)	58 (46)	0.05
Final Occluder > 25 mm + Occluder compression $< 12\%$	28 (13)	20 (22)	8 (6)	< 0.01
Final Occluder > 25 mm + Occluder compression $< 15\%$	40 (18)	25 (27)	15 (12)	< 0.01

Transseptal shunts occurred in 30% of cases, but there was no statistical significance between the groups. Interestingly, DRT were more frequent in the group with no leaks (n=4 (3%) for no leaks vs. n=1 (1%); p = 0.32), although this difference was not statistically significant.

4. Discussion

In our retrospective study, we examined a cohort of patients who received the Amplatzer Amulet Occluder, focusing on risk factors for the development of PDL in the first TEE, performed 1–3 months after the index procedure. To avoid interobserver variance, the 3D-TEE images from the hospital's Picture Archiving and Communication System (PACS) were re-evaluated by an experienced cardiologist.

The results revealed three major risk factors for the development of PDL with the Amplatzer Amulet Occluder:

1. A compression of the occluder less than 12% within the LAA
2. A final occluder size of ≥ 25 mm (see image 01)
3. An off-axis position of the disc relative to the occluder's body (see image 02)

Baseline characteristics, such as age, gender, comorbidities, pre-procedure medication, LAAO indications, as well as procedural data and complications during the hospital stay, did not play a significant role as risk factors in our cohort.

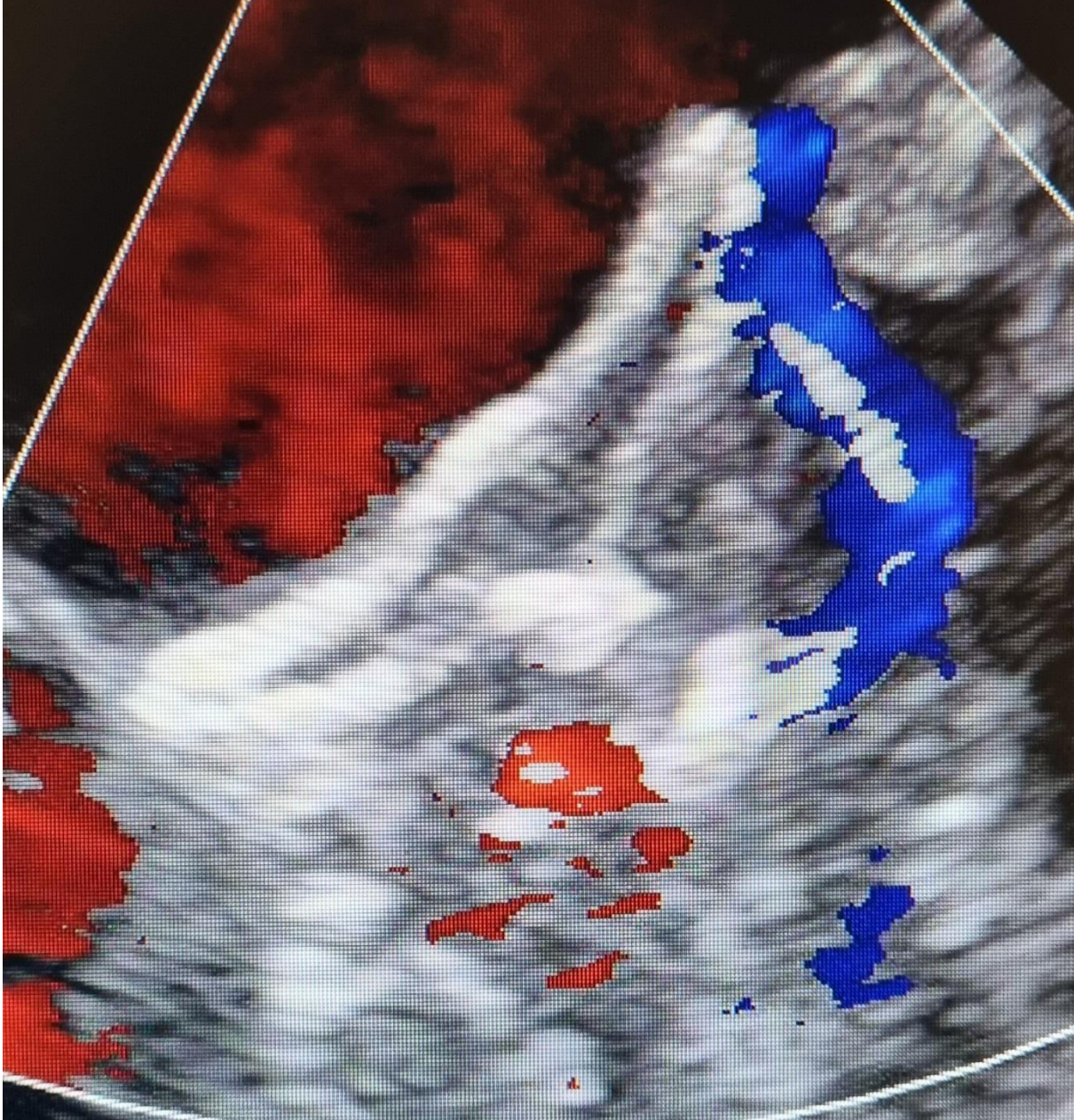


Image 01: TEE 100° view, large occluder, 31 mm Amplatzer Amulet, 25 % compression, mild leak

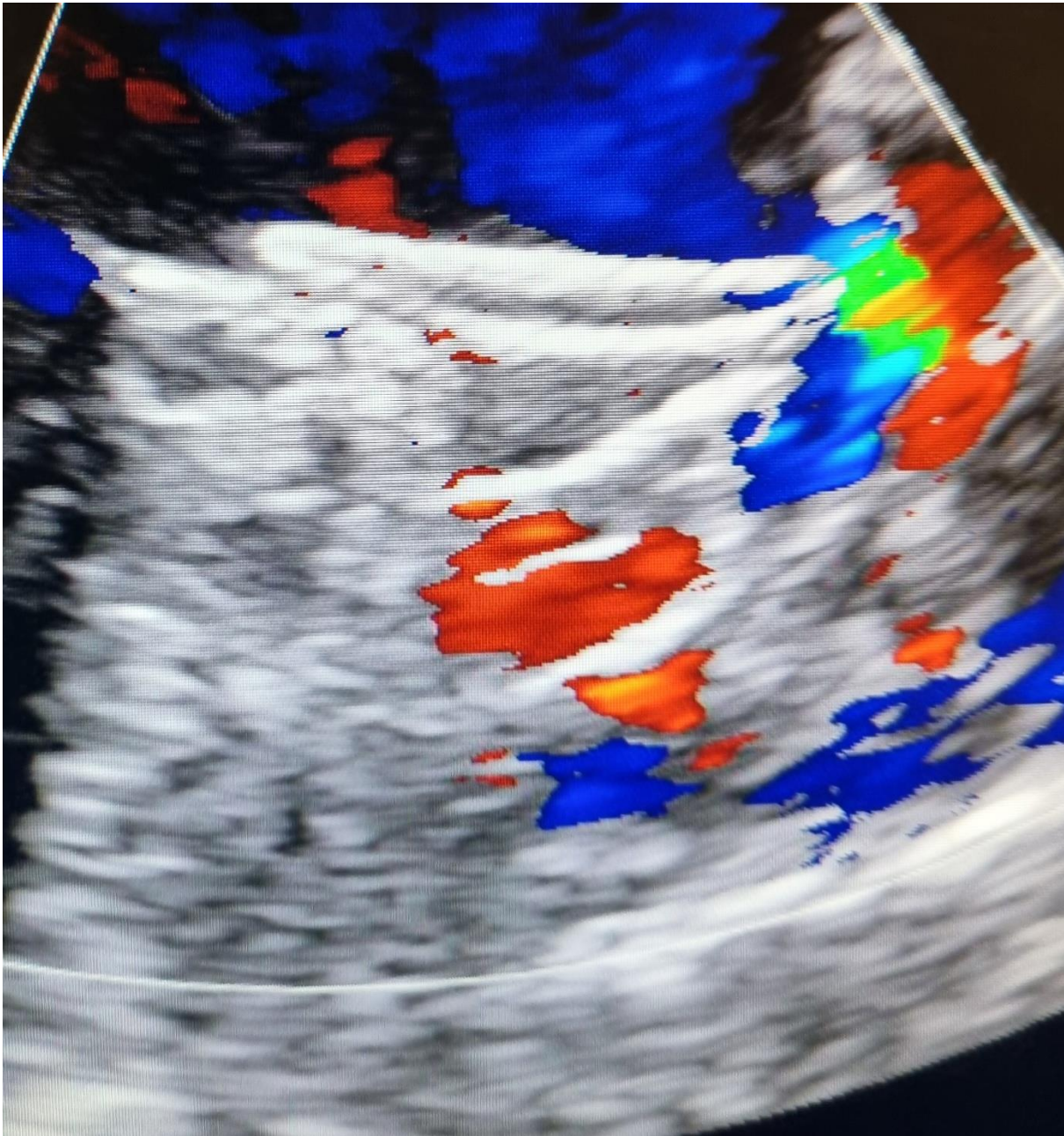


Image 02: TEE 90° view, off-axis position, 28 mm Amplatzer Amulet, 23 % compression, moderate leak

In contrast, Price et al. (15), in the Amulet IDE Trial, identified a higher CHA₂DS₂-VASc score and non-paroxysmal atrial fibrillation as significant risk factors for PDL. It is worth noting that these factors were only associated with single-occlusive devices. Besides, Mansour et al. (23) also identified male gender as a significant factor in a small study.

Similar to our findings, Nguyen et al. (24) and Lakkireddy et al. (19) found that a “chicken wing” LAA anatomy did not pose a risk factor for PDL, although one might have expected that the chicken wing morphology, characterized by a bent body, could complicate correct positioning of the Amplatzer Amulet device.

The incidence of severe leaks (>5mm) in our study was 2%, which aligns with rates from the Amulet IDE Trial (1.1%) (26) and Mansour et al. (3.8%) (23) but was higher than in an earlier study by Saw et al. (25), where a rate of 0.6% was reported for the Amplatzer Cardiac Plug, the predecessor of the Amulet.

There are conflicting results concerning the relevance of compression in PDL development. While we observed significantly more leaks with a compression rate below 12%, the Amulet IDE Trial (26) did not identify a significant difference even in severe leaks, whether with single- or dual-occlusive devices. Nguyen et al. (24), however, supported our findings, identifying a compression rate of less than 10% as a significant factor. Periprocedurally, we calculate the diameter derived from the perimeter and add 15% to this diameter for optimal occluder compression within the LAA, as recommended in the instructions for use.

One possible explanation for undersizing could be insufficient periprocedural volume preload due to pre-procedure fasting, which is standard for interventional procedures. Both Zhang, Cong et al. (2019) (27) and Al-Kassou, Tzikas et al. (2017) (20) demonstrated in the past significant differences in LAA volume based on patients' volume status using 3D-TEE.

An off-axis position of the occluder within the LAA, often indicating a tilted position of the occluder's body, has been identified as a contributing factor to PDL in several studies for both the Watchman and Amplatzer Amulet Occluders (19, 28, 29). We were able to confirm this finding with significant results in our cohort as well (32% for leaks vs. 12% for no leaks; $p < 0.01$).

Furthermore, the occluder's size was critical in our study. A larger occluder (≥ 25 mm in diameter) exhibited lower compression rates. In our cohort, although compression below 15% alone did not maintain statistical significance for PDL (59% for leaks vs. 46% for no leaks; $p = 0.053$) and only became significant below 12% ($p < 0.01$), a combination of a final occluder size of ≥ 25 mm and occluder compression $< 15\%$ was associated with significantly more leaks (27% for leaks vs. 12% for no leaks; $p < 0.01$). This highlights the impact of LAA size on PDL development. In the Amulet IDE Trial (26), orifice diameter was a significant factor for severe PDL with the Watchman (severe PDL: 20.5 ± 5.1 mm vs. no PDL: 18.1 ± 3.1 mm, $p = 0.040$), but not with the Amplatzer Amulet (severe PDL: 20.0 ± 6.4 mm vs. no PDL: 18.6 ± 4.7 mm, $p = 0.21$). Although we also observed larger orifice diameters in the leakage group, this was not statistically significant (24.34 ± 4.01 for leaks vs. 23.51 ± 4.72 for no leaks; $p = 0.18$). In general, our cohort exhibited larger ostia than those in the Amulet IDE Trial, which might explain why, beyond a certain LAA size, the round disc may not adequately seal the oval ostium of the LAA, leading to leakage. In concordance, Cochet, Iriart et al. (2018) (30) demonstrated larger maximal landing zone diameter (25.9 ± 5.1 mm vs. 23.3 ± 4.0 mm, $p = 0.003$) to be a significant factor for PDL development with a predominantly posterior-inferior position of the leak within the ostium on CT images. Pracon et al. (2018) (31) further showed that larger occluders (30.0 mm [IQR, 27.0 – 33.0] versus 25.0 mm [IQR, 24.0 – 28.0]; $P < 0.01$) were associated with a higher incidence of DRT.

In a 5-year outcome study, Dukkipati et al. (2022) (32) found a significantly increased risk of ischemic stroke or systemic embolism with smaller leaks (≤ 5 mm) for the Watchman. Over a shorter follow-up of 18 months, Price et al. (2022) (15) in the Amulet IDE Trial observed similar results for both single- and dual-occlusive devices for PDLs < 3 mm and > 3 mm, although the hazard ratio was higher for single-occlusive devices. Thus, even small PDLs are clinically relevant and should be minimized.

In optimizing LAAO planning, modern technology can assist. For example, virtual reality is helpful in improving pre-procedural planning (33). Ideally, the device should fully occupy the left atrial appendage, making 3D-printing a promising option currently under investigation (34).

5. Conclusion

The rate of severe PDLs (> 5 mm) with a dual-occlusive device is low. Large LAAs require precise pre- and periprocedural assessment of LAA anatomy. Specifically, an occluder compression of at least 15% should be ensured when selecting the device, with consideration that inadequate intravascular volume during the procedure can lead to device undersizing.

6. Limitations

The primary limitation of our study is its retrospective design. Additionally, we only had a short follow-up period, examining echocardiographic PDL occurrence but not its clinical consequences concerning adverse events, in the first TEE performed 1–3 months after the index procedure. Our results are also applicable solely to dual-occlusive devices.

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