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Original Article

Transfabric Leaks After Percutaneous Left Atrial Appendage Occlusion Procedures with the WATCHMAN FLX Device

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ABSTRACT

Background: Cardiac computed tomography imaging with contrast is being used increasingly to image left atrial appendage occlusion (LAAO) devices. Contrast flow across a device, also known as a transfabric leak (TFL), may indicate a lack of complete LAAO-device endothelialization. The data on the rate, predictors, and clinical events associated with TFL are limited.

Methods: All patients who underwent an LAAO-device implantation with a WATCHMAN FLX device and received a postimplantation computed tomography scan were included in this single-centre retrospective cohort study. Patients were classified as either having or not having a TFL, according to 3 currently proposed definitions of TFL. Clinical and procedural differences between the 2 groups were determined. An exploratory univariate logistic regression model to evaluate predictors of TFL was constructed.

RÉSUMÉ

Contexte : La tomodensitométrie cardiaque avec produit de contraste est de plus en plus utilisée pour obtenir des images des dispositifs de fermeture de l'appendice auriculaire gauche (AAG). L'écoulement du produit de contraste au travers du dispositif de fermeture, appelé en anglais « transfabric leak » ou TFL, peut indiquer une absence d'endothélialisation complète du dispositif. Il existe peu de données sur la fréquence, les facteurs prédictifs et les événements cliniques associés aux TFL.

Méthodologie : Tous les patients chez qui un dispositif de fermeture de l'AAG WATCHMAN FLX a été implanté et qui ont été soumis à une tomodensitométrie après l'implantation ont été inclus dans cette étude de cohorte rétrospective monocentrique. Les patients ont été classés comme présentant ou non une TFL, en fonction de trois définitions actuellement proposées pour ce type de fuite. Les

Left atrial appendage (LAA) occlusion (LAAO) can reduce the risk of stroke in patients with nonvalvular atrial fibrillation, thereby avoiding the need for long-term oral anticoagulation therapy. Current endocardial LAAO devices are composed of a nitinol frame, with a fabric covering. Endothelialization of the device surface aids in exclusion of the LAA from the systemic circulation and reduces thrombus formation on the device.

Canine models have suggested that endothelialization of the LAAO devices occurs within 4-6 weeks post-implantation.[1,2] Human endothelialization may not be as rapid. Autopsies of 4 humans with LAA devices implanted for at least 2 months demonstrated complete endothelialization in 2 people, and 85% and 90% endothelialization, respectively, in the other 2.[1] Knowledge of the rate and timing of LAAO-device endothelialization is important, as inadequate device endothelialization may result in device-related thrombus (DRT) formation, which has the potential to obviate any reduction in thromboembolic risk associated with LAAO devices.[3]

Traditional imaging with transesophageal echocardiography (TEE) is unable to comment on the presence of LAAO-device endothelialization. Cardiac computed tomography (CT)angiography (CCTA), on the other hand, can assess for contrast flow across the device, also known as transfabric leak (TFL). TFLs occur due to the lack of endothelialization on the surface of the LAAO device. Several radiographic criteria for establishing the presence of TFL have been proposed, although consensus as to the most appropriate definition is absent.[4-6] Knowledge of the presence of and clinical events associated with TFLs is important, as these may help identify patients at risk for experiencing adverse events, including

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Results: A total of 56 individuals were included in the cohort. The rate of TFL varied from 27% to 52%, depending on the radiographic definition employed. No clinically important patient or procedural characteristics were noted between the groups with vs without TFL. No predictors of TFL were identified. Six deaths and one stroke occurred during a median follow-up period of 673 days.

Conclusions: TFLs occur commonly post−LAAO procedures, suggesting that complete endothelialization of LAAO devices in humans may not be similar to that reported in animal models. Additional study into the best imaging approach to identify TFLs, and clinical events associated with TFLs, is necessary to clarify the significance of TFLs.

différences cliniques et interventionnelles entre les deux groupes ont été déterminées. Un modèle de régression logistique univarié a été élaboré pour évaluer les facteurs prédictifs d'une TFL.

Résultats : Au total, la cohorte comptait 56 personnes. Le taux de TFL variait de 27 % à 52 %, selon la définition radiographique employée. Aucune caractéristique d'importance clinique relative aux patients ou aux interventions n'a été observée entre le groupe avec TFL et le groupe sans TFL. Aucun facteur prédictif de TFL n'a été établi. Six décès et un accident vasculaire cérébral sont survenus pendant une période de suivi médiane de 673 jours.

Conclusions : Les TFL surviennent fréquemment après l'intervention de fermeture de l'AAG, laissant croire qu'une endothélialisation complète des dispositifs de fermeture de l'AAG chez les humains pourrait ne pas être comparable à celle observée dans les modèles animaux. Une autre étude portant sur la meilleure technique d'imagerie pour déceler les TFL et les événements cliniques associés est nécessaire pour clarifier l'importance des TFL.

device-related thrombus, and stroke upon cessation of postprocedure antithrombotic or anticoagulant therapy.

This retrospective study utilizes CCTA to evaluate the rate, predictors, and clinical events associated with TFL.

Methods

Sunnybrook Health Sciences Centre is a large, regional cardiac centre in Toronto, Ontario, Canada that has been performing LAAO-device implantation procedures since November 2015. Consistent with clinical practice in Canada, patients with nonvalvular atrial fibrillation and contraindication to or failure of anticoagulation therapy were selected for LAAO-device implantation procedures. All patients who underwent LAAO procedures between February 2020 and July 2023, and received a CCTA scan after LAAO-device implantation, were included in this study. This time frame was selected because February 2020 coincided with both the adoption of use of the WATCHMAN FLX device (Boston Scientific, Marlborough, MA), and due to the COVID pandemic and limited availability of access to TEE procedures, with a shift to routine CCTA for postprocedure imaging for all patients without risk for contrast-induced nephropathy. All patients received a WATCHMAN FLX device. The procedural approach has been described previously.[7] The choice and duration of postprocedure antithrombotic and anticoagulant therapy were individualized, based on patient risk for bleeding. Chart review was performed to determine patient and procedural characteristics.

CCTA imaging

Follow-up CCTA imaging typically was performed 4 months after the LAAO device−implantation procedure. CCTA was performed using a third-generation dual-source CT scanner, employing a medium-to-sharp kernel, to minimize artifacts from the metallic components of LAAO devices. Contrast media was administered at a rate of 5 cc/s, followed by a saline flush, to clearly delineate cardiac structures and the LAAO device. Imaging parameters were adjusted based on patient body mass index, to optimize image quality while minimizing radiation exposure, with slice thickness set at 0.5-0.6 mm. Prospective electrocardiogram gating was used to reduce motion artifacts, with 35 seconds delayed flash acquisition on the same field of view.

Image analysis

Multiplanar reconstructions were conducted to assess device position. Images were evaluated using Aquarius iNtuition imaging software (TeraRecon, Durham, NC). This analysis was performed on the best systolic phase (30%-50%). Specifically, the phase selected was the end-systolic. This phase was chosen based on the assumption that it provides the best visualization of the LAA, minimizing variability that could be introduced by the dynamic nature of the left atrial (LA) waveforms. In addition, we performed a delayed phase (35 seconds after the first scan), to detect residual flow. The Hounsfield unit (HU) densities were measured using a simple region-of-interest on ≥ 3 different slices.

Peri-device leaks (PDLs) were identified as contrast enhancement adjacent to the LAAO device (Fig. 1A).[5,6,8] The diameter at the narrowest portion of the PDL was determined.

Hypoattenuated thickening (HAT) on the atrial aspect of the LAAO device was identified.[8] HAT may represent prominent device endothelialization; however, it may be confounded with DRT (Fig. 1B). HAT was considered to be more in keeping with DRT if a characteristic such as an irregular surface, a protruding component, or large size responsive to oral anticoagulation treatment was present.

TFL is residual contrast into the LAA after exclusion of a PDL. The following 3 available definitions of (criteria for) TFL were applied to all CCTA image evaluations: criterion 1^4—LAA HU density $>$ 100 HU and LAA/LA HU ratio $>$ 0.25 (Fig. 1C); criterion 2^5—LA density − LAA density $\leq$ 50 HU; and criterion 3^6—LAA density $>$ myocardial (septal) density. In the absence of a PDL or DRT, CCTA imaging of the LAA demonstrating the absence of TFL was considered to represent complete LAAO device neoendothelialization (Fig. 1D).

All images were evaluated independently by a cardiothoracic radiologist and a cardiothoracic imaging fellow. Discrepancies were adjudicated by a third physician.

Figure 1. Cardiac computed tomography angiography images of the left atrial (LA) appendage (LAA) occlusion device: (**A**) peri-device leak (indicated with a **red dashed line**); (**B**) device related thrombus on the LAA occlusion device; (**C**) transfabric leak suggesting incomplete endothelialization (LAA contrast density = 170 Hounsfield unit; LAA:LA ratio = 0.50); and (**D**) no transfabric leak, suggesting complete endothelialization (contrast density in LAA < 100 Hounsfield unit; LAA:LA ratio < 0.25).

Clinical events

Patients were followed until death or April 2024. The occurrence of death or stroke was ascertained from chart review.

Statistical analyses

Patients were classified as either having or not having a TFL. Descriptive statistics were reported for each group. Differences between the 2 groups were determined using the χ^2 test for categorical variables, the Student t test for parametric continuous variables, and the Wilcoxon rank-sum test for nonparametric variables. An exploratory analysis to assess predictors of TFL was performed with simple univariate logistic regression. Significance levels of 0.05 were used for all statistical tests. Statistical analyses were conducted using SAS software, version 9.4 (SAS Institute, Cary, NC).

Ethics approval was obtained from the Sunnybrook Health Sciences Centre research ethics board, which did not require direct patient consent as this study used deidentified and aggregated patient data.

Results

A total of 90 patients underwent LAAO-device implantation between February 2020 and July 2023, of whom 69 received a postprocedure CCTA scan. CCTA images were available for analysis in 67 of the 69 patients. CCTA was performed on average at 126 ± 48 days following the LAAO device−implantation procedure, with 69% of the cohort receiving a CCTA scan within 4 ± 1 months postprocedure. No differences were present in the following factors: age (75 ± 8 vs 75 ± 9 years, $P = 0.68$); sex (female, 39% vs 41%, $P = 0.77$); **C**ongestive Heart Failure, **H**ypertension, **A**ge ≥ 75 Years, **D**iabetes Mellitus, **S**troke, **V**ascular Disease, **A**ge 65 to 74 Years, **S**ex **C**ategory (CHA_2DS_2VASc score; 4.4 ± 1.6 vs 4.8 ± 1.1 years, $P = 0.16$); size of implanted device (device ≥ 30 mm, 31% vs 25%, $P = 0.43$); and device compression at the time of implantation (maximum compression ≥ 20%, 64% vs 64%, $P = 1.0$) for patients who did vs all patients who did not receive a CCTA scan postprocedure.

PDLs were present in 9 patients, 2 of whom had a PDL > 5 mm. No HAT was present in 33 patients; benign HAT was present in 33 patients; and DRT was present in 2 patients. After excluding patients with PDLs and DRTs, 56 patients were available to undergo assessment for TFLs.

TFL

The proportion of patients who had an absence of TFL, suggesting complete LAAO-device endothelialization, varied, depending on the criterion used to define TFL, as follows: 68%, per criterion 1; 48%, per criterion 2; and 73%, per criterion 3. HAT was present in approximately half of all

patients without TFL (per criterion 1, 53%; per criterion 2, 52%; per criterion 3, 49%).

No clinically important patient or procedural characteristics were noted between the groups with vs without TFL (see Table 1 for criterion 1; see Supplemental Tables S1 and S2 for criteria 2 and 3). The exploratory logistic regression model did not identify any predictors of TFL (see Table 2 for criterion 1; see Supplemental Tables S3 and S4 for criteria 2 and 3). An important finding is that device size and degree of device compression were not associated with TFL.

Clinical events

During the first 3 months post−LAA closure, 57% of the entire cohort received dual-antiplatelet treatment, and 41% received oral-anticoagulant treatment, with no difference noted in the use of antiplatelets or anticoagulants in the groups with vs without a TFL. Thereafter, 86% were on single-antiplatelet therapy, 9% remained on oral anticoagulation therapy, 1% remained on dual-antiplatelet therapy, and 4% remained on no therapy. No change occurred in antiplatelet or anticoagulant therapy in response to the identification of a TFL.

A median follow-up of 673 days (range: 143-1548) was available for the cohort receiving CCTA. During the follow-up period, 6 patients died, 3 (16.7%) in the group with TFL, and 3 (7.9%) in the group without TFL, as defined using criterion 1 ($P = 0.32$). No deaths were attributed to a stroke and/or a cardioembolic event. One stroke occurred in the cohort, in a patient without TFL (2.6%, vs 0% in the group with TFL, $P = 0.48$).

Discussion

Radiographic evidence of TFL was observed in at least one quarter of all patients in this cohort of patients with a WATCHMAN FLX device undergoing CCTA 4 months after LAAO-device implantation. The TFL rate varied by the radiographic definition employed, with less-restrictive definitions suggesting that the rate of TFL, or lack of complete endothelialization, may approach 50%.

The use of CCTA to assess the completeness of LAA exclusion with an LAAO device is increasing. The 3-dimensional nature of imaging, and the concomitant use of intravenous contrast, allows for accurate localization of PDLs and identification of TFL. The multiple radiographic definitions of TFL have different operating characteristics.[4-6] In our study, the rate of TFL ranged from 27% to 52%, depending on the definition employed. The best approach to use to try to identify TFL is unclear, as a true gold-standard to confirm complete endothelialization does not exist.

The presence of TFL does not provide insight into the extent of the LAAO device surface in places where endothelium has not formed. One possibility is that a small uncovered area may have allowed for contrast to pass beyond the LAAO device. Whether a critical surface area lacking endothelium is necessary for DRT formation to occur is not known. We attempted to radiographically define regions without endothelialization during our evaluation of all CCTA images; however, this approach was neither practical nor reproducible.

Additionally, one cannot exclude the possibility of contrast appearing distal to the LAAO device in alternative ways, mimicking a TFL. For example, human autopsy studies have suggested that collateral circulation from the appendage wall may develop post−LAAO device implantation.[1] This situation may result in the appearance of contrast distal to the LAAO device in the presence of complete LAAO-device endothelialization. Another possibility is that limitations to CCTA imaging prevent the detection of smaller PDLs that allow contrast to enter the distal LAA. In the absence of correlative CT findings with histologic findings from surgery or autopsy, alternative imaging modalities, such as optical coherence tomography should be studied to assess both the presence and extent of LAAO-device endothelialization.[9] Our findings appear to be inconsistent with initial canine and recent swine models of LAAO-device endothelialization,[1,2] with the WATCHMAN FLX and the newer-generation WATCHMAN FLX Pro device (Boston Scientific). This latter device has a fluoropolymer coating, which has both low thrombogenicity and more-rapid endothelialization. In a swine model (6 animals receiving the WATCHMAN FLX Pro device, and 6 animals receiving the WATCHMAN FLX device), all animals had nearly 100% visual tissue coverage. When evaluating markers for endothelial maturation

Table 1. Patient and procedural characteristics, for patients with vs without transfabric leak (TFL)[4]

Demographics and clinical characteristics	No TFL (n = 38)	TFL (n = 18)	*P*
Age, y, mean (SD)	74 (10)	78 (8)	0.1
Female	34	39	0.7
Body mass index, mean (SD)	30 (6)	27 (3)	0.01
CHA_2DS_2-VASC score > 4	53	56	0.09
Hypertension	79	78	0.9
Diabetes mellitus	45	33	0.4
Dialysis	5	11	0.4
Liver dysfunction	11	0	0.2
Congestive heart failure	26	33	0.6
Device characteristics			
Compression ≥ 20%	23 (60.5)	11 (61.1)	1.0
Size ≥ 30 mm	11 (28.9)	7 (38.9)	0.5
3-mo postprocedure antithrombotic use			
Dual antiplatelet	53	67	0.53
Oral anticoagulation	47	33	
Timing of imaging			
CCTA postimplant, d, mean (SD)	125 (34)	131 (67)	0.8

Values are %, or n (%), unless otherwise indicated. TFL is defined as left atrial (LA) appendage (LAA) Hounsfield unit (HU) density > 100 HU, and LAA/LA HU ratio > 0.25.

CCTA, cardiac computed tomography angiography; CHA_2DS_2-VASC, **C**ongestive Heart Failure, **H**ypertension, **A**ge ≥ 75 Years, **D**iabetes Mellitus, **S**troke, **V**ascular Disease, **A**ge 65 to 74 Years, **S**ex **C**ategory; SD, standard deviation; TFL, transfabric leak.

Table 2. Univariate predictors of transfabric leak (TFL)

Variable	OR (95% CI)	*P*
CHA_2DS_2-VASC score > 4	2.7 (0.9−8.6)	0.09
Diabetes mellitus	0.6 (0.2−2.0)	0.4
Dialysis	2.3 (0.3−17.4)	0.4
Procedural device compression ≥ 20%	1.0 (0.3−3.2)	1.0
Device size ≥ 30 mm	1.6 (0.5−5.1)	0.5

TFL is defined as left atrial (LA) appendage (LAA) Hounsfield unit (HU) density > 100 HU, and LAA/LA HU ratio > 0.25.

CHA_2DS_2-VASC, **C**ongestive Heart Failure, **H**ypertension, **A**ge ≥ 75 Years, **D**iabetes Mellitus, **S**troke, **V**ascular Disease, **A**ge 65 to 74 Years, **S**ex **C**ategory; CI, confidence interval; OR, odds ratio.

(expression of vascular endothelial-cadherin/p120-catenin), greater expression of these markers occurred on the surface of the WATCHMAN FLX Pro, compared to that on the WATCHMAN FLX.[2] Whether this novel coating will allow for rapid and complete LAAO-device endothelialization in humans is unknown. We suggest that future CCTA imaging studies be performed to assess for the presence of TFLs with use of the WATCHMAN FLX Pro device.

Despite the high rate of TFL, the low rate of DRT at 4 months, and of clinical stroke during an average of 2 years of follow-up in our cohort (in patients on predominantly a single antiplatelet agent), provides some reassurance that radiographic evidence of a TFL may not be important clinically. However, a recent publication assessing clinical events in the presence of TFLs with use of the older-generation WATCHMAN 2.5 (Boston Scientific) device suggests that TFL may not be associated with as benign a course as that observed in our cohort.[10] Specifically, the rate of ischemic stroke associated with a TFL during a median follow-up of 1193 days was 7.7%, compared to 1.8% in the absence of a TFL or PDL. The stroke rate for patients with a TFL in this study was similar to the rate that occurred with a PDL.

We suggest that future CCTA studies of a large cohort of LAAO patients be conducted, to assess the rate of TFLs in humans. Serial imaging to assess for resolution of TFL may provide additional information on the natural history of LAAO-device endothelialization in humans. Similar imaging studies coupled to clinical follow-up evaluating long-term clinical events (DRT and stroke) associated with TFLs are encouraged, as are imaging studies of PDLs. This point is important in light of the findings from the publication by Chen et al. suggesting that TFLs may not be associated with a benign course and have a prognosis similar to that of a PDL.[10] Indeed, if TFLs are shown to be associated with an increased incidence of clinical events, then such a finding may result in a shift away from use of TEE for post—LAAO-device implantation surveillance imaging, to use of CCTA, to provide better long-term prognostication of LAAO patients. In addition, confirmation of an increased incidence of adverse clinical events associated with TFLs should prompt further study, to clarify whether concomitant therapy can mitigate the clinical events associated with TFLs. We also suggest that the correlation of procedural characteristics with the presence of TFL be investigated. For example, data from our small-sized cohort do not suggest that a larger device size, or greater device compression predicts TFL. An association between device surface area, due to the use of larger devices, and/or the scalloping effect related to a highly compressed device, plausibly might be observed in a larger dataset. These additional data may allow for a bespoke approach to both device-sizing and use of imaging to guide the duration of use of anticoagulation and/or antithrombotic agents in patients post—LAAO closure, with the aim of minimizing the incidence of DRT and subsequent stroke.

Our work has limitations—specifically, that these data were derived from a single centre, the cohort sample size was small, and imaging occurred only at 1 time point (approximately 4 months). CCTA imaging also was assessed at 1 part, rather than at multiple parts, of the cardiac cycle, which may have limited our ability to detect small PDLs, resulting in misclassification of small PDLs as TFLs. Strengths of the study include the uniform imaging approach, the availability of data from a longer follow-up period, and evaluation of several available definitions of TFL. In addition, to the best of our knowledge, our report is the first to evaluate TFLs occurring with use of the WATCHMAN FLX Pro device.

Conclusions

TFLs occur commonly after LAAO procedures, suggesting that complete endothelialization of LAAO devices in humans may not be similar to that reported in animal models. Additional study into the best imaging approach to use to identify TFLs, and clinical events associated with TFLs, is necessary to clarify the significance of TFLs.

Ethics Statement

Ethics approval was obtained from the Sunnybrook Health Sciences Centre research ethics board.

Patient Consent

The authors confirm that patient consent is not applicable to this article as this is a retrospective case report using deidentified and aggregated patient data; therefore, the research ethics board did not require that consent be obtained from the patients.

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Disclosures

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Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2024.09.011.