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Editorial

Role and Assessment of Peri-Device Leaks After Left Atrial Appendage Occlusion

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See article by Nguyen et al., pages 405–412 of this issue.

Percutaneous left atrial appendage (LAA) occlusion (LAAO) represents a valid alternative in patients with nonvalvular AF (NVAF) and absolute or relative contraindications for oral anticoagulation. Like other percutaneous structural heart interventions, LAAO is a relatively novel technique, with limited procedural and follow-up data. Several questions—such as optimal patient selection, accurate LAA sizing, improved device selection, ideal antithrombotic therapy, and the role and management of device thrombosis and peri-device leaks (PDL) after LAAO—remain unanswered. Indeed, not only the impact but also the diagnosis of PDL is currently one of the most controversial questions in the LAAO field. The arbitrary nature of PDL definitions is probably one of the main factors contributing to this controversy. A relevant PDL was defined by the presence of a color Doppler jet by transesophageal echocardiography (TEE) greater than 3 mm in the **P**ercutaneous **L**eft **A**trial **A**ppendage **T**ranscatheter **O**cclusion (PLAATO) trial[1] and > 5 mm in WATCHMAN LAA Closure Technology for Embolic **Pro-tec**tion in Patients with **A**trial **F**ibrillation (PROTECT-AF).[2] These definitions were initially proposed for "single-lobe" LAAO devices like the Watchman (Boston Scientific, Marlborough, MA) but were posteriorly adopted for all other "disc-and-lobe" LAAO devices such as the Amplatzer Cardiac Plug (ACP) or Amplatzer Amulet (St Jude Medical, Abbott Laboratories, Lake Bluff, IL). At present, most of the published data, including the large registries EWOLUTION,[3] ACP Multicenter Registry,[4] and Amulet Observational Study[5] used the 3- to 5-mm arbitrary cut-off. Although these initial cut-off values were based on surgical LAAO data,[6] it seems reasonable to ask if the use of arbitrary cut-off values is still valid for percutaneous LAAO and, more importantly, whether the same cut-off values are valid for any other imaging modality. Also, for "disc-and-lobe" devices, should PDLs be measured at the level of the lobe or the disc? Parts of these questions were recently discussed by a group of LAAO experts and published in the Munich Consensus Document.[6] Although the 5-mm cut-off was still used to define a technical success for the procedure, experts were more open when defining the presence of PDLs or the role and their management after LAAO. They concluded that residual flow is not an uncommon finding after LAA exclusion, irrespective of the applied approach. As its clinical significance was still poorly understood, any criterion to classify the size of the residual leak appeared to be highly arbitrary. Therefore, the consensus was to assess this parameter in studies on any type of LAA exclusion following a consistent methodology with TEE or cardiac CT. Accurate assessments of uncovered lobes, descriptions of device position, and locations of PDL are warranted. Multiple views (0°, 45°, 90°, and 135°), using a Nyquist limit to detect low velocity flow (20 to 30 cm/s), were recommended for TEE and documentation of the largest PDL and achieved angle of measurement by TEE or CT.

In this issue of the *Canadian Journal of Cardiology*, Nguyen et al[7] present a comprehensive analysis of PDLs in a series of 77 patients undergoing LAAO with different devices (ACP, Amulet, and Watchman). Patients were followed by TEE and/or cardiac CT. PDL was defined by the movement of contrast into the LAA beyond the device on CT or color Doppler flow around the device by TEE. To determine risk factors for leaks, the authors also assessed the compression and the off-axis position of the device at follow-up. The main finding of the study was the high incidence of PDL by CT (from 68.5% at 3 months to 56.7% at 12 months). In addition, among the 28 patients with both CT and TEE available at 3 months, the detection of PDL varied according to the imaging modality from 7.1% with TEE to 64.3% with CT. A device compression ratio of less than 10% was the only parameter associated with occurrence of PDL. The authors did not observe any association between PDLs and thromboembolic events, an observation limited by a lack of statistical power. The relatively small size of the sample was the main limitation of the study, whereas the comprehensive imaging follow-up with multiple CTs and/or TEE and the larger number of patients included compared with previous similar manuscripts represent its main

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strengths. One of the most relevant points of discussion was the selection of imaging modality for follow-up. Cardiac CT seems to be more sensitive than TEE for detecting LAA patency. In a small cohort of 24 patients, Jaguszewski et al.[8] detected persistent LAA contrast filling in 62% of patients, although leak-sizes were small (1.5 ± 1.4 mm). In addition, PDLs were almost exclusively localized at the posterior portion of the LAA orifice (> 90%). Similarly, Saw et al.[9] showed, in a cohort of 45 patients, residual contrast after LAAO in 63.6% of patients 1 to 6 months after LAAO.

To date, most of the published studies did not detect any association between PDL and clinical events. The only potential association was published by Katzet al.[10] in patients undergoing surgical LAAO and showed that 50% of the unsuccessful closures had spontaneous echo contrast or thrombus in the LAA, and 22% had subsequent thromboembolic events. Viles-Gonzalez et al[11] reported that despite a high incidence of PDL at 12 months with the Watchman device (32%) in the PROCTECT-AF cohort, there was not an increased risk of thromboembolic events. Similarly, large registries with more than 1000 patients such as the ACP Multicenter Registry,[4] Amulet Observational study,[5] and EWOLUTION,[3] failed to show any association between PDLs and clinical events. Some authors have suggested that there may be an increased rate of device thrombosis in patients with incomplete LAAO.[12] In fact, an association between device-related thrombosis (DRT) and a higher incidence of cerebrovascular events has recently been reported.[13,14] Based on the initial LAAO trials, DRT was not associated with a higher incidence of thromboembolic events. However, with the growing number of interventions and more specific analysis, a DRT/thromboembolic event association has been established. In this sense, report, classification, and analysis of any existing PDL with any imaging modality in large trials will be necessary to confirm whether an absence of clinical impact is real or due to suboptimal analysis.

In any case, limitations on PDL data and the intuitive thought that complete sealing should be better than any degree of leak highlights another relevant point from the Nguyen manuscript: How to prevent occurrence of PDL. The authors concluded that PDLs are more prevalent in patients with low device compression ratio (< 10%). Similarly, other authors reported that occurrence of PDL is associated with a lower degree of device oversizing.[8,15] Saw et al.[9] identified 3 mechanism of PDL: off-axis position defined by the absence of perpendicularity between the LAA landing zone and the lobe of the occlude; the presence of a gap due to the lack of expansion of the device against the LAA wall at the landing zone; and the absence of device sealing as a result of incomplete endothelization. Improved device sizing, increased operator experience, as well as device evolution will be necessary to achieve better procedural outcomes in terms of not only device selection but improved device orientation.

The current paper confirms that the incidence of PDLs after LAAO varies with the imaging modality. The incidence of PDLs ranged from more than 60% to less than 10%, based on cardiac CT or TEE, respectively. Although TEE has been the preferred follow-up method in large LAAO registries, novel large trials and registries will be necessary to compare both imaging modalities and discern which provides more clinically meaningful information.

Disclosures

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