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Impact of peri-device leakage after interventional occlusion of the left atrial appendage: Results from the ORIGINAL registry (saxOnian RegIstry analyzinG and followINg left atrial Appendage cLosure)

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Background: Oral anticoagulation for prophylaxis of central and peripheral embolisation is limited in its use in patients with atrial fibrillation (AF) and bleeding events. As an alternative to anticoagulation, the interventional closure of the left atrial appendage (LAAO) is available. A common clinical dilemma is the treatment of patients with potential peri-device leakage following LAA occlusion. The specific definition of the severity of the leak and the long-term clinical implications have not yet been sufficiently investigated.

Methods: The multi-centre ORIGINAL registry was initiated 2014. The aim of this registry is to analyze the safety and efficacy of the procedure in patients with a high risk of bleeding in everyday clinical practice and to evaluate hemorrhagic and thromboemb. events in the long term follow-up. Patients with an indication for LAA occl. were included in the registry after informed consent. The impl., follow-up and anticoagulation regimens are performed according to the standard of the participating centers. 521 patients with AF underwent an implantation of an LAA closure device between Jul. 2014 and Nov. 2018. A mean follow-up of 463 days could be reached in 386 patients.

Results: The periprocedural complication rate was 3.8% of which 5 patients experienced pericardial effusion (successful treatment with pericardial puncture or surgical), 2 patients had periprocedural stroke and 1 patient suffered from air embolism. In 27 patients a peri-device flow due to incomplete occlusion was detected by TEE (5.4% of the implantations). The size ranged between 1 and 8 mm (mean 2.28 mm (SD=2.11)). The eccentricity index (EI) of the LAA in these patients was 1.22 (SD 0.17), and thus the LAA rather oval, while those LAA without leakage tend to be more circular (EI 1.08 with SD=0.17). 2 of the patients with leakage (7.4%) experienced stroke or peripheral embolism, respectively. The annual risk for stroke/TIA/peripheral embolism of these patients was 5.84%, the annual risk of the patients without leakage was 2.04%. Patients with a leakage $>$6 mm were treated with rivaroxaban in full therapeutic dosage. One patient underwent an additional procedure.

Conclusion: The evaluation and management of para-device leakage after an interventional LAA occlusion represents a challenge. Currently, limited data are available on the optimal strategy. Those data indicate that residual peri-device flow into the LAA after percutaneous closure with the Watchman device represents no cause for alarm. However, our data suggest, that patients with peridevice leak might be at a higher risk of thromboembolic events. Furthermore, it could be shown, that these patients had rather oval ostium of the LAA, while those LAA without leakage tend to be more circular. This implicates the importance of advanced imaging methods, such as 3D-TEE, which are capable to precisely determine the size of the LAA and the degree of its circularity.