



## Reassuring but not convincing - another registry to support left atrial appendage closure but randomized data remains scarce

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Left atrial appendage closure (LAAC) is considered an established therapy for patients with contraindications to long-term oral anticoagulation [1]. As per study design, LAAC was initially deemed a true alternative to vitamin K antagonists [2,3]. However, with the advent of direct oral anticoagulants (DOACs) and its compelling data from thousands of patients, interventional LAAC was pushed back to become a niche indication for patients with a high bleeding risk.

Contemporary use and effectiveness were well described in two large-scale prospective registries mainly performed in Europe [4,5].

In the present edition of the International Journal of Cardiology Heart & Vasculature, Philips and co-workers present on the Asian-Australian experience with Watchman™ for LAAC in 201 patients [6]. The data documents the continuous effort of the researchers as well as the manufacturer to build evidence for LAAC. Outcome data were well in line with the European experience in the Evolution registry reporting a high procedural success rate with few serious complications and an excellent device performance reflected by a high sealing rate. Moreover, the authors focused on a comparison between Asians and non-Asians without identifying any relevant differences for LAAC. This is of particular importance taking into consideration the increased risk for Asians to suffer from an intracerebral hemorrhage on oral anticoagulation with vitamin K antagonists as well as with dabigatran [7,8].

It is striking to see the consistency of ischemic stroke/systemic embolism rate across all Watchman™ registries and studies ranging between 1.3 and 2% per year. Surprisingly, the annual major bleeding rate was low at 2.2%, in fact much lower as reported in the European experience being 2.7%/year after 2 years of follow-up [9].

Nonetheless, we also need to focus on the weak points of the present data. First, a registry cannot answer the most important question which is the best therapy in this particular patient population at high risk for bleeding thus deemed contraindicated to continued oral anticoagulation. Second, the number of patients is very small ( $n = 201$ ) compared to contemporary registries. Last, the number of participating centers is even smaller ( $n = 9$ ) indicating that LAAC has not been established in the entire Asia Pacific region yet, thus it may be difficult to draw universal conclusions.

Major bleeding remains the most frequent complication after LAAC. Several different therapy regimens have been proposed including short-term dual antiplatelet therapy for six weeks as well as single antiplatelet therapy in high-risk populations [10,11]. Surprisingly, in the WASP registry DOACs were the predominant type of post-implant antithrombotic therapy. Later, non-Asians were mostly switched to single antiplatelet therapy while most Asians remained on dual antiplatelet therapy. Despite the more intense antithrombotic therapy the observed rate of bleeding in Asians was lower also paralleled by a lower thromboembolic event rate. While this may not be explained by differences in patient characteristics, it might be advisable to interpret the data with caution given the small number of patients.

It has to be highlighted that no hemorrhagic stroke occurred in the WASP registry during the 2 year follow-up, which again underscores the value of LAAC for this disease entity in particular for secondary prophylaxis [12].

The present data is certainly reassuring that LAAC is also applicable in this part of the world, but to convince critics of LAAC we urgently require more randomized controlled data to compare medical treatment and LAAC both in patients deemed contraindicated to oral anticoagulation (ASAP-TOO; NCT02928497), [13] as well as in patients at high risk for bleeding (CLOSURE AF; NCT03463317).

### Conflict of interest

BS is consultant to Boston scientific and Abbott, BS and KRJC received research grants and speaker honoraria from BSCI and Abbott, SB has no COI to disclose.

### References

- [1] P. Kirchhof, S. Benussi, D. Kotecha, et al., 2016 ESC guidelines for the management of atrial fibrillation developed in collaboration with EACTS, Eur. Heart J. 37 (2016) 2893–2962.

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- [2] D.R. Holmes, V.Y. Reddy, Z.G. Turi, et al., Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial, *Lancet* 374 (2009) 534–542.
- [3] D.R. Holmes, S. Kar, M.J. Price, et al., Prospective randomized evaluation of the watchman left atrial appendage closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial, *J. Am. Coll. Cardiol.* 64 (2014) 1–12.
- [4] L.V.A. Boersma, B. Schmidt, T.R. Betts, et al., Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry, *Eur. Heart J.* 37 (2016) 2465–2474.
- [5] U. Landmesser, B. Schmidt, J.E. Nielsen-Kudsk, et al., Left atrial appendage occlusion with the AMPLATZER amulet device: periprocedural and early clinical/echocardiographic data from a global prospective observational study, *EuroIntervention* 13 (2017) 867–876.
- [6] K. Phillips, S. Teguso, P. Sanders, et al., Left atrial appendage closure with WATCHMAN in Asian patients: 2 year outcomes from the WASP registry, *Int. J. Cardiol. Heart Vasc.* 23 (2019), 100358.
- [7] A.Y.J. Shen, J.F. Yao, S.S. Brar, M.B. Jorgensen, W. Chen, Racial/ethnic differences in the risk of intracranial hemorrhage among patients with atrial fibrillation, *J. Am. Coll. Cardiol.* 50 (2007) 309–315.
- [8] M. Hori, S.J. Connolly, J. Zhu, et al., Dabigatran versus warfarin: effects on ischemic and hemorrhagic strokes and bleeding in Asians and non-Asians with atrial fibrillation, *Stroke* 44 (2013) 1891–1896.
- [9] L.V. Boersma, H. Ince, S. Kische, et al., Evaluating real-world clinical outcomes in atrial fibrillation patients receiving the WATCHMAN left atrial appendage closure technology, *Circ. Arrhythm. Electrophysiol.* 12 (2019) 1–13.
- [10] F.K. Weise, S. Bordignon, L. Perrotta, et al., Short-term dual antiplatelet therapy after interventional left atrial appendage closure with different devices, *EuroIntervention* 13 (2018) e2138–e2146.
- [11] Korsholm K, Nielsen KM, Jensen JM, Jensen HK, Andersen G. Transcatheter left atrial appendage occlusion in patients with atrial fibrillation and a high bleeding risk using aspirin alone for post-implant antithrombotic therapy. 2017: 2075–2082.
- [12] A. Tzikas, X. Freixa, L. Lull, et al., Patients with intracranial bleeding and atrial fibrillation treated with left atrial appendage occlusion: results from the Amplatzer Cardiac Plug registry, *Int. J. Cardiol.* 236 (2017) 232–236.
- [13] D.R. Holmes, V.Y. Reddy, M. Buchbinder, et al., The assessment of the watchman device in patients unsuitable for oral anticoagulation (ASAP-TOO) trial, *Am. Heart J.* 189 (2017) 68–74.