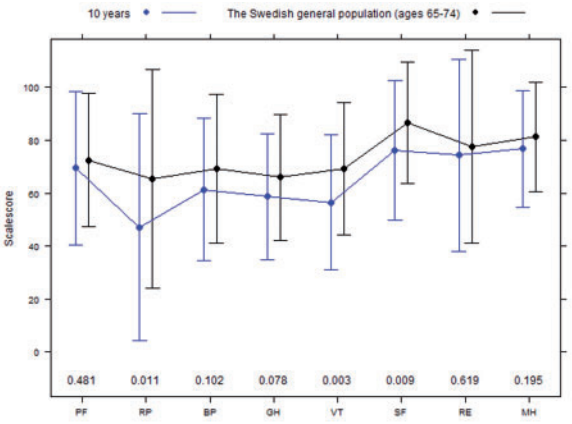
Methods: A total of 39 patients with symptomatic drug-refractory atrial fibrillation, who underwent epicardial pulmonary vein isolation, ganglionated plexi ablation, division of the ligament of Marshall and left atrial appendage excision were evaluated after 10 years for atrial fibrillation recurrence by 24 hour Holter monitoring, quality of life and symptoms by SF 36 and severity of symptom questionnaire and safety.
Results: After 10.8±0.7 years (mean±standard deviation) follow-up, 36 % of patients were free from atrial fibrillation and atrial tachycardia. The quality of life remained improved as compared to baseline for the mental component score, 40.44±12.32 versus 48.19±12.22 ($p = 0.011$), but not for the physical component score (39.41±9.40 versus 43.44±12.31, $p = 0.053$). The quality of life was comparable to the values of an aged matched Swedish normal population in 5 out of 8 subscales at follow-up (figure). The symptom severity scores were also still improved as compared to baseline (12.80±4.27 vs 15.19±4.01, p= 0.036). Apart from 4 strokes no other events occurred.
Conclusions: The clinical benefit with improvement of symptoms and quality of life remains on long-term after minimally invasive surgical ablation and the single procedure success rate is 36 %. Larger randomized trials are warranted to confirm these results and predict which patients will benefit the most from such procedure. Left atrial appendage excision with stapler did not prevent strokes.



Abstract 199 Figure. Comparison of quality of life by SF-36.

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Safety of uninterrupted dabigatran in cardiovascular interventions in the GLORIA-AF registry program

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Background: Non-VKA oral anticoagulants (NOACs), such as dabigatran etexilate (DE), have become an important treatment option for patients with atrial fibrillation (AF). Cardiovascular (CV) interventions such as cardioversion and catheter ablation carry the risk of thromboembolic complications, while ablation is also associated with a risk of peri-procedural bleeding. A recent randomized, controlled clinical trial (RE-CIRCUIT) in patients undergoing AF ablation showed that an uninterrupted DE regimen was associated with fewer bleeding complications than uninterrupted warfarin with no difference in thromboembolic events1. Data from patients followed in routine clinical care inform clinical decision-making; however, prospectively collected data are not readily available.
Purpose: This analysis describes the safety of uninterrupted DE for patients undergoing CV interventions in the prospectively collected clinical practice data from GLORIA-AF.
Methods: GLORIA-AF is a prospective, observational, global registry program of consecutive patients with newly diagnosed non-valvular AF at risk of stroke. In Phase II of the program, DE patients were followed for 2-years. DE was prescribed and used at the discretion of treating physicians. CV interventions in patients on DE treatment that were performed without bridging, and for which information about the intra-procedure DE regimen (interrupted or uninterrupted) was available were included in the analysis. For the major subgroup of patients with an uninterrupted DE regimen, baseline characteristics, stroke/systemic embolism, and major bleeding up to 8 weeks after the intervention were described.
Results: Patients were recruited at 982 sites in 44 countries from Nov 2011 to Dec 2014. During the 2-year follow-up of the 4859 eligible DE patients, 456 CV interventions were identified in the first DE treatment period. The majority of interventions (n=412) were performed with an uninterrupted DE regimen: 299 cardioversions, 38 catheter ablations, 25 pacemaker implantations, 26 angiographic procedures, 24 coronary/peripheral angioplasty ± stenting and other catheter-based interventions in 332 patients. Mean age of these patients was 67.2 (±9.6) years, 64.5% were male, 75.3% had hypertension, 28.6% heart failure and 20.8 % coronary disease. Mean CHA2DS2VASc score was 2.7 (±1.4). Within an average follow-up of 7.52 weeks after intervention, one major bleed and one systemic embolic event occurred on DE (risk 0.25% per intervention for both outcomes, 95% confidence interval (0.01%-1.36%).
Conclusions: In this prospective analysis, the frequencies of major bleeding and stroke/systemic embolism following CV interventions with an uninterrupted DE regimen were very low. This supports the favorable safety and effectiveness profile of DE in clinical practice based settings, complementing randomized trial data.
Reference: 1) Hugh Calkins et al. N Engl J Med 2017; 376:1627-1636

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Left atrial appendage closure for stroke prevention in patients with atrial fibrillation: the difficult task of estimating the possible benefit in real life setting

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Transcatheter left atrial appendage (LAA) closure is an alternative strategy for stroke prevention in atrial fibrillation (AF) patients with an inacceptable risk of bleeding with oral anticoagulation (OAC). Recent observational analyses compared the ischemic stroke rate in AF patients after LAA closure with the rate expected for a same risk score population (if untreated). However, most patients receive various antithrombotic strategies after LAA closure, which should also be taken into account in this type of estimation.
Methods: In patients treated with Watchman or Amplatzer LAA closure devices from 8 French centers, yearly rate of ischemic stroke during follow-up was calculated and compared to that expected for a same risk score population (if untreated). Adjustment was then made for exposure to antiplatelet therapy (APT) treatment, assuming that aspirin provides a 22% reduction in TE risk, and to oral anticoagulation (OAC) assuming that OAC provides a 64% reduction in TE risk. Theoretical yearly rate of bleeding was extrapolated from that reported with the HASBLED score.
Results: A total of 469 consecutive AF patients (299 males, 74.9±8.9 years old, mean CHA2DS2-VASc score 4.5±1.4, HASBLED score 3.7±1.0) received LAA closure from March 2012 to January 2017. There were 272 Watchman devices (58%) and 197 Amplatzer devices (42%) implanted. At discharge, 36% received a single anti platelet APT, 23% received dual APT, 29% received oral OAC and no APT, 5% received OAC plus APT and 8% received no antithrombotic therapy. Mean follow up was 13±13 months during which 70 major cardiovascular events (19 ischemic strokes, 18 major hemorrhages and 33 deaths) were recorded in 69 patients.
The annual rate of ischemic stroke was 3.96%, which translates into a 43% relative risk reduction (95%CI 1 to 67%) as compared with the calculated stroke rate of 6.95% without the use of antithrombotic therapy for similar CHA2DS2-VASc score. After adjustment for exposure to APT and OAC, relative risk reduction was 13% (95%CI -59 to 52%). The annual rate of major bleeding in the study was 3.75%, which corresponds to a 48% relative risk reduction (95%CI 9 to 70%) as compared with the rate that would have been expected based on a comparable HAS-BLED score. As a result, clinical benefit was a relative risk reduction in combined ischemic stroke and bleeding events ranging from 45% (95%CI 20 to 63%) to 34% (95%CI 3 to 56%) after adjustment on antithrombotic use.
Conclusions: AF patients treated with LAA closure and an antithrombotic strategy proposed on an individual basis had a significant reduction in the risk of events (stroke and/or bleeding) compared to their theoretical risk. This estimated benefit was not as dramatic as that seen in other registries and was variable according to the method of adjustment. A better identification of this benefit is needed, which might only be obtained in a specific randomized trial performed in patients with OAC contraindication.