Prospective evaluation of silent cerebral lesions and cognitive function after pulmonary vein isolation with an irrigated gold tip catheter - REDUCE TE Pilot study

Authors:
D Shah, G Szeplaki, J Kautzner, VJHM Van Drieh, F Bourier, M Kuniss, A Bulava, G Nolker, M Khan, T Lewalter, N Klein, B Schmidt, University Hospital of Geneva, Cardiac Electrophysiology Unit - Geneva - Switzerland, Semmelweis University - Budapest - Hungary, Institute for Clinical and Experimental Medicine (IKEM) - Prague - Czech Republic, Haga Ziekenhuis - Den Hague - Netherlands, DHZ - Munich - Germany, Kerckhoff-Klinik - Bad Neuheim - Germany, Eseke Budijovice Hospital - Ceske Budejovice - Czech Republic, HDZ - Bad Oeynhausen - Germany, OLVG - Amsterdam - Netherlands, Peter Osypka Herzzentrum - Munich - Germany, Universitatsklinikum - Leipzig - Germany, Cardiology Centre Bethanien (CCB) - Frankfurt am Main - Germany,

Topic(s):
Rhythm Control, Catheter Ablation

Citation:
Background: Stroke is one of the most feared complications during catheter ablation (CA) of atrial fibrillation (AF). While symptomatic thrombembolic (TE) events are rare, magnetic resonance imaging (MRI) may identify asymptomatic (i.e. silent) cerebral lesions (SCL) following pulmonary vein isolation (PVI). According to previous reports, their incidence after PVI using radiofrequency ablation ranges between 1.7-24‰ although clinical implications are unclear.

In the REDUCE-TE Pilot study, a novel gold-tip externally-irrigated ablation catheter (AlCathFlux eXtra Gold; manufacturer VascoMed, Binzen, Germany) was investigated during PVI in patients with paroxysmal AF with focus on the incidence of SCL.

Methods: REDUCE-TE Pilot was a prospective multi-centre, single arm observational study. Patients with symptomatic PAF with an indication for CA were eligible. Patients had to be on stable oral anticoagulation (OAC) according to clinical routine with either a vitamin K antagonist (VKA) (INR 2-3) or a direct OAC. Main exclusion criteria were a CHA2DS2-VASc= 5, prior ischemic stroke or transient ischemic attack, previous PVI, contraindication for DW-MRI, LA >55 mm, and LVEF<35%. The study included one baseline and one pre-ablation-assessment. A cerebral diffusion-weighted (DW)-MRI and a post-ablation follow-up were performed within 1-3 days after the ablation. Study participation ended with a 3-month follow-up visit.

The primary endpoint was the occurrence of new SCLs after PVI assessed by cerebral DW-MRI. Secondary endpoints included neurocognitive status, procedural success rate, and peri-procedural complications including symptomatic TE.

Results: A total of 104 patients (69% male, 61.5 ± 9.7 years age, LVEF 57.3 ± 6.5 %, CHA2DS2-VASc 1.7 ± 1.2) were enrolled and underwent PVI. Oral anticoagulation consisted of a VKA in 56%, whereas 41% of patients were taking NOACs. Peri-procedural anticoagulation management was left to the investigator’s discretion. Post-procedural DW-MRI examination was performed in n=97 patients. In 9 of them, 11 SCLs were detected by MRI (incidence 9.3%, 95% confidence interval [CI] 4.3%-16.9%). Eight patients showed 1 lesion, whereas one patient showed 3 new lesions. In a per-protocol analysis excluding patients with violation of in- or exclusion criteria or violation of INR criteria, the incidence of SCLs was only 7.1% (CI 2.6-14.7%). Univariate analyses did not detect any significant predictor for new SCLs. Non-significant trends were observed for low ACT values during ablation and INR at ablation out-of-range 2-3. There was no evidence of significant deterioration of neuro-cognitive function after PVI.

Conclusion: The REDUCE-TE Pilot study showed a low incidence (9.3%) of new SCLs after PVI using the AlCath Flux eXtra Gold catheter without evidence of deterioration in neuro-cognitive function. Maintenance of effective anticoagulation throughout the procedure seems to be important for preventing new SCLs.
Abstract:
Prospective evaluation of silent cerebral lesions and cognitive function after pulmonary vein isolation with an irrigated gold tip catheter - REDUCE TE Pilot study

Authors:
D Shah 1, G Szeplaki 2, J Kautzner 3, VJHM Van Driel 4, F Bourier 5, M Kuniss 6, A Bulava 7, G Nolker 8, M Khan 9, T Lewalter 10, N Klein 11, B Schmidt 12

1 University Hospital of Geneva, Cardiac Electrophysiology Unit - Geneva - Switzerland, 2 Semmelweis University - Budapest - Hungary, 3 Institute for Clinical and Experimental Medicine (IKEM) - Prague - Czech Republic, 4 Haga Ziekenhuis - Den Hague - Netherlands, 5 DHZ - Munich - Germany, 6 Kerckhoff-Klinik - Bad Neuheim - Germany, 7 Eseke Budijovice Hospital - Ceske Budejovice - Czech Republic, 8 HDZ - Bad Oeynhausen - Germany, 9 OLVG - Amsterdam - Netherlands, 10 Peter Osypka Herzzentrum - Munich - Germany, 11 Universitatsklinikum - Leipzig - Germany, 12 Cardiology Centre Bethanien (CCB) - Frankfurt am Main - Germany

Topic(s):
Rhythm Control, Catheter Ablation

Background: Stroke is one of the most feared complications during catheter ablation (CA) of atrial fibrillation (AF). While symptomatic thromboembolic (TE) events are rare, magnetic resonance imaging (MRI) may identify asymptomatic (i.e. silent) cerebral lesions (SCL) following pulmonary vein isolation (PVI). According to previous reports, their incidence after PVI using radiofrequency ablation ranges between 1.7–24‰ although clinical implications are unclear.

In the REDUCE-TE Pilot study, a novel gold-tip externally-irrigated ablation catheter (AlCathFlux eXtra Gold; manufacturer VascoMed, Binzen, Germany) was investigated during PVI in patients with paroxysmal AF with focus on the incidence of SCL.

Methods: REDUCE-TE Pilot was a prospective multi-centre, single arm observational study. Patients with symptomatic PAF with an indication for CA were eligible. Patients had to be on stable oral anticoagulation (OAC) according to clinical routine with either a vitamin K antagonist (VKA) (INR 2–3) or a direct OAC. Main exclusion criteria were a CHA2DS2-VASc = 5, prior ischemic stroke or transient ischemic attack, previous PVI, contraindication for DW-MRI, LA >55 mm, and LVEF<35%. The study included one baseline and one pre-ablation-assessment. A cerebral diffusion-weighted (DW)-MRI and a post-ablation follow-up were performed within 1–3 days after the ablation. Study participation ended with a 3-month follow-up visit.

The primary endpoint was the occurrence of new SCLs after PVI assessed by cerebral DW-MRI. Secondary endpoints included neurocognitive status, procedural success rate, and peri-procedural complications including symptomatic TE.

Results: A total of 104 patients (69% male, 61.5 ± 9.7 years age, LVEF 57.3 ± 6.5 %, CHA2DS2-VASc 1.7 ± 1.2) were enrolled and underwent PVI. Oral anticoagulation consisted of a VKA in 56%, whereas 41% of patients were taking NOACs. Peri-procedural anticoagulation management was left to the investigator`s discretion. Post-procedural DW-MRI examination was performed in n=97 patients. In 9 of them, 11 SCLs were detected by MRI (incidence 9.3%, 95% confidence interval [CI] 4.3%–16.9%). Eight patients showed 1 lesion, whereas one patient showed 3 new lesions. In a per-protocol analysis excluding patients with violation of in- or exclusion criteria or violation of INR criteria, the incidence of SCLs was only 7.1% (CI 2.6–14.7%). Univariate analyses did not detect any significant predictor for new SCLs. Non-significant trends were observed for low ACT values during ablation and INR at ablation out-of-range 2–3. There was no evidence of significant deterioration of neurocognitive function after PVI.

Conclusion: The REDUCE-TE Pilot study showed a low incidence (9.3%) of new SCLs after PVI using the AlCath Flux eXtra Gold catheter without evidence of deterioration in neurocognitive function. Maintenance of effective anticoagulation throughout the procedure seems to be important for preventing new SCLs.