Real-time assessment of pulmonary vein isolation using the novel Achieve mapping catheter during cryoablation

P156 | BEDSIDE
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Purpose: The Achieve inner lumen mapping catheter can be used with the cryoablation system to assess real-time isolation of pulmonary vein (PV) during cryoablation and to act as a guiding wire during balloon positioning. We sought to analyze the feasibility of this novel catheter and to assess real-time PV isolation during cryoablation.

Methods: Patients undergoing 28-mm cryoballoon PVI using the Achieve catheter were included from two centers. Each application lasted 5 min. Real-time PV recording during freezing and time to PV isolation were analyzed. Lastly, the number of applications needed to achieve PV isolation was investigated.

Results: 68 pts (47 male; 61±10 yo) were included. Average procedure duration and fluoroscopy times were 118±24 min and 29±10 min. During the first application, PV potentials could be detected during freezing in 92.2%, 75.0%, 81.5% and 31.2% of the left superior (LSPV), left inferior (LIPV), right superior (RSPV) and right inferior (RIPV) PVs, respectively. When PV potentials were detected, they appeared in 4/2, 4/2, 4/4, and 3/2 pads in the first cryoenergy application was successful in 68.7%, 82.8%, 80.0% and 90.0% of the LSPVs, LIPVs, RSPVs, and RIPVs, respectively. PV deconnection occurred at -38.4±8.9°C for the LSPV, -33.4±34.6°C for the LIPV, -33.0±10.6°C for the RSPV, and -33.3±10.6°C for the RIPV, respectively. PV was isolated at the end of the procedure. 100% of the PVs were isolated after 1.2±0.6 applications (from 1 to 4).

Conclusion: Cryoablation in conjunction with the novel Achieve catheter is feasible, leading to high acute PV isolation rates. Real-time PV recording during freezing can be performed in most of the left PVs and the RIPVs while recording of RIPV potentials is harder due to stability issues.

AF ablation: evaluation of procedural parameters and acute results comparing ablation catheters with traditional and new irrigation design

P157 | BEDSIDE
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Purpose: In order to make atrial fibrillation (AF) ablation procedures safer and easier, new technologies have been developed leading to optimize cooling of the electrode-tissue interface. Recently, two different companies proposed different novel irrigated ablation catheters. The first, a flexible and fully-irrigated tip catheter with an innovative design to better adapt the ablation tip to the surrounding tissue and the second with a greater number of irrigation holes being able to increase the irrigated area. The aim of this study was to evaluate the efficacy and safety of the two irrigation designs providing a more efficient cooling.

Methods and results: One hundred thirty-one patients with paroxysmal atrial fibrillation (PAF) were consecutively enrolled and underwent PVI being divided in four groups: Group 1, patients treated with Thermocool (Th) catheter (Group 1), 34 with Thermocool SF (SF) catheter (Group 2), 32 with Coolpath (CP) catheter (Group 3) and 32 with CoolFlow (CF) catheter (Group 4). All groups were comparable for population characteristics. PVI was obtained in 100% of patients in all groups. Among procedural parameters, procedural time was significantly shorter using SF vs Th, 32 W; p=0.035; CF, 32 W vs CP, 30 W; p=0.046; Th vs CP p=0.017; SF vs CF p<0.001. Concerning saline volume infusion, this was significantly reduced with new irrigated catheters (SF, 871 ml vs Th, 1610 ml; p<0.001; CF, 963 ml vs CP, 1231 ml; p=0.045) but no significant differences were observed between SF and CF (p=0.328). No acute or late complications occurred.

Conclusion: PVI was obtained in all groups with no significant complications. Catheters with new irrigation design have been able to reduce procedure and RF time. Furthermore, a more efficient cooling allowed to increase RF power delivery and to abate saline volume infusion.

Preservation of luminal coronary artery diameter after epicardial irreversible electropropagation ablation

P158 | BENCH
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Introduction: Permanent coronary artery damage is a hazardous complication of epicardial radiofrequency ablation. Irreversible electropropagation (IRE) is a promising non-thermal ablation modality able to create deep myocardial lesions. We investigated the effect of epicardial circular IRE-ablation on luminal coronary artery diameter.

Methods: In a porcine model (5 pigs, 60-75 kg), the pericardium was exposed using surgical subxiphoidal epicardial access. A custom delectable octopolar 12 mm circular catheter with 2 mm ring electrodes was introduced in the pericardial space via a steerable sheath. After coronary angiography (CAG), mid and distal LAD and CX arteries were targeted with IRE-ablation. A single, non-arcing, non-endothelial, cathode 200 J application was delivered. After IRE-ablation and after 3 months follow-up, CAG was repeated. Luminal diameters of the artery proximal and distal to the lesion site were averaged with use of quantitative CAG (Q-CAG) and used as reference. Minimal luminal diameter at the lesion site was calculated with use of Q-CAG. Lesion length and depth were measured at autopsy.

Results: CAG directly post-ablation demonstrated short-lasting luminal narrowing with normalization in the targeted area, suggestive of coronary sparing. After 3 months survival, all IREGs were identical to pre-ablation CAGs: mean reference luminal diameter was 2.3±0.4 mm, mean luminal diameter at the lesion site was 2.3±0.5 mm (p=0.822). Inspection at autopsy demonstrated presence of extensive epicardial lesions. Median lesion width and depth were 25 and 8 mm.

Real-life treatment persistence with newer oral anticoagulants and potential strokes avoided in patients with atrial fibrillation

P159 | BEDSIDE
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Purpose: Discontinuation rates for vitamin K antagonists are high in patients with atrial fibrillation (AF). The aim of the current study was to assess the impact of real-life treatment persistence on the incidence of ischaemic strokes in patients with AF treated with a vitamin K antagonist or one of the newer oral anticoagulants (NOACs: rivaroxaban 20 mg, dabigatran 110 mg or dabigatran 150 mg). A model, accounting for switching patterns, was developed, combining these data with published ischaemic stroke rates for each treatment. The model assumed an annual risk of ischaemic stroke of 1.65% and 4.59% for patients receiving warfarin or no treatment, respectively. To obtain the risk of stroke for patients receiving NOACs, published relative risks were applied to the warfarin risk, giving an annual probability of stroke between 1.29% and 1.78%.

Methods: Real-life data on persistence from a US claims database and a German registry were combined to estimate the persistence rates for warfarin, dabigatran and rivaroxaban over 6 months and to calculate the mean duration on treatment. A model, accounting for switching patterns, was developed, combining these data with published ischaemic stroke rates for each treatment.

Results: In the first 6 months, patients starting on warfarin stayed on treatment for a mean of 131 days before switching to another NOAC or stopping treatment completely. Patients starting on a NOAC had a longer duration on treatment (dabigatran [combined dose]: 149 days; rivaroxaban 20 mg: 168 days), before switching to warfarin or stopping treatment completely. The total ischaemic stroke risk
P520 | BEDSIDE Evaluation of edoxaban in patients with atrial fibrillation and severe renal impairment

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Purpose: Compare safety and pharmacokinetics of edoxaban (EDX) 15 mg, an oral selective FXa inhibitor, in patients with nonvalvular atrial fibrillation (NVAF) and severe renal impairment (SRI; creatinine clearance [CLCR] < 30 mL/min) to that of EDX 60 or 30 mg in NVAF patients with normal renal function or mild renal impairment (NMRI; CLCR ≥ 30 to < 60 mL/min).

Methods: Patients with NVAF and SRI or NMRI were enrolled in a randomized, open-label study in Japan. Patients requiring hemodialysis, at high risk for bleeding, or already receiving an anticoagulant (except warfarin, rivaroxaban, or dabigatran) were excluded. SRI patients received EDX 15 mg. NMRI patients were randomized to either EDX 60 or 30 mg. NMRI patients weighing ≤ 60 kg or receiving concomitant treatment with quinidine or verapamil had a 50% dose reduction. EDX was administered once daily for 12 weeks. Blood samples to assess plasma EDX concentrations and prothrombin time (PT) were taken at week 2 and week 8. Bleeding and adverse events (AEs) were monitored and recorded throughout the study.

Results: Of 93 patients enrolled, 50 had SRI and 43 NMRI (21 EDX 60 mg and 22 EDX 30 mg). In the EDX 15, 60, and 30 mg groups, median CLCR was 26.3, 62.5, and 64.4 mL/min, respectively. Safety outcomes and plasma concentrations at week 8 are provided in the Table. No major bleeding events occurred in any treatment group. No serious AE was considered related to study drug. Median Pt ratios were similar between the SRI and NMRI 30mg groups at all time points.

Bleeding, AEs, and plasma concentrations

<table>
<thead>
<tr>
<th>Severe renal impairment</th>
<th>Normal renal function/mild renal impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Edoxaban-dose (mg)</strong></td>
<td><strong>15 mg (N=50)</strong></td>
</tr>
<tr>
<td>Any bleeding, n (%)</td>
<td>10 (20.0)</td>
</tr>
<tr>
<td>Major bleeding, n (%)</td>
<td>0</td>
</tr>
<tr>
<td>CRPin bleeding, n (%)</td>
<td>0</td>
</tr>
<tr>
<td>Serious AEs, n (%)</td>
<td>5 (10.0)</td>
</tr>
<tr>
<td>Plasma concentration (ng/mL), median (IQR–G3)</td>
<td></td>
</tr>
<tr>
<td>Pre-dose</td>
<td>N=39</td>
</tr>
<tr>
<td>1–3 hours</td>
<td>16.7 (12.4–23.8)</td>
</tr>
<tr>
<td>4–8 hours</td>
<td>107.5 (63.5–121.5)</td>
</tr>
<tr>
<td>11–16 hours</td>
<td>N=19</td>
</tr>
<tr>
<td>16–24 hours</td>
<td>82.3 (70.7–95.6)</td>
</tr>
</tbody>
</table>

*Eight patients had a 50% dose reduction; †No serious AE was related to study drug or led to study drug discontinuation; AE, adverse event.

Conclusions: These results indicate that EDX 15 mg may be an appropriate therapeutic option in SRI patients with AF.

P521 | BEDSIDE Should we recommend oral anticoagulation therapy in patients with atrial fibrillation undergoing coronary artery stenting with a low/moderate CHADS2 score?

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Purpose: Identify 640 consecutive patients with AF (75% male, 73.2 ± 8 years old). From this study cohort, 400 (62.5%) had a CHADS2 score < 2 and 51.7% of them were on OAC (45.4% on OAC plus DAPT, and 6.7% on OAC plus Clodi-dogrel). Baseline characteristics were similar between patients with and without OAC, including HASBLED score = 3 (OR 0.95, 95% CI 0.23, P = 0.92). At follow-up, patients on OAC showed a higher mortality (8.8% vs 4.1%, P = 0.04) due an excess of cardiovascular death (7.4% vs 1.5%, P = 0.004) and more major bleedings (7% vs 4.1%, P = 0.03). However, they showed a lower incidence of thromboembolism (1.4% vs 5.7%, P = 0.01). The incidence of major adverse cardiac events (13.5% versus 13.9%; P = 0.51) and major adverse event (25.6% versus 24.2%; P = 0.41) were similar between both treatment groups. A total of 27 patients (6.8%) died during follow-up, 19 (70.4%) were on OAC, 6 died because of a bleeding event, and 2 of them had CHADS2 score > 2, treatment with OAC was predictor of an increased mortality (OR 2.4% 95% CI 1.01 to 5.7%; P = 0.04), due to an excess of cardiovascular mortality (OR 4.8 95% CI 1.33 to 17.4; P = 0.017). OAC was predictor of major bleeding too (OR 7.8: 1.7 to 35.5, P = 0.008).

Conclusions: In patients with AF and CHADS2 score ≤ 2 submitted to PCI-S, OAC increases mortality and major bleeding despite reducing thromboembolic events.

P522 | BENCH Platelet reactivity monitoring in patients with atrial fibrillation treated with dabigatran

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Purpose: Dabigatran is a new oral anticoagulant that directly inhibits thrombin (Factor IIa). Thrombin demonstrates multiple actions in physiologic (e.g. hemostasis, vasodilatation) and pathophysiological conditions (e.g. atherosclerosis, sepsis, etc.). Thus thrombin may mediate the bidirectional interactions between inflammatory and coagulation pathways. P-selectin, an inflammatory marker expressed on activated platelets surface, mediates platelet adherence to leukocytes (mainly monocytes and neutrophils). Several clinical studies have demonstrated the efficacy of dabigatran in preventing venous thromboembolism (VTE) in patients undergoing elective total hip or knee replacement and in preventing strokes in patients with non valvular atrial fibrillation (AF), and in treating acute VTE. However, to date there are limited data about the effects of dabigatran on inflammation and atherosclerosis. The aim of this study was to assess the effect of dabigatran on platelet aggregation, platelet-integrin receptor (Ib/IIa) activation (PAC-1 binding), as well as on platelet-mediated inflammation (P-selectin) in comparison with patients in warfarin with non valvular AF.

Methods: Patients suffered from AF (non valvular) and receiving warfarin were eligible for the study. 15 Patients switched from warfarin to dabigatran after informed consent. Blood samples were collected while on treatment with warfarin and 3-5 days after treatment with dabigatran. The platelet aggregate response to ADP (20 μM and 5 μM) or TRAP-14 (10 μM) was studied by Light Trans-mission Aggregometry (LTA). The surface expression of P-selectin and the PAC-1 binding either to resting or activated platelets was studied by flow cytometry in whole blood.

Results: No difference between warfarin or dabigatran treatment was observed in platelet aggregation to both agonists as well as in PAC-1 expression in both resting and ADP-activated platelets. Similarly, no difference in P-selectin expres- sion in resting platelets between warfarin or dabigatran treatment was observed (3.3±2.4 vs 2.5±0.9). Importantly, a significant reduction in P-selectin membrane expression was observed when patients were switched from warfarin to dabi- gran after platelet activation with ADP (54.5±25.4 vs 18.4±8.2 respectively, P = 0.005).

Conclusions: We show for the first time that switch from warfarin to dabigatran in patients with AF does not affect platelet aggregation and GPIIb/IIIa activation, but it reduces P-Selectin membrane expression which may represent an impor- tant anti-inflammatory and antiatherogenic activity of this potent direct thrombin inhibitor.

P523 | BENCH Identification of thrombus in left atrial appendage by 320-row ADCT is superior beyond CHADS2 score for initiating anticoagulation treatment in patients with atrial fibrillation

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Background: Atrial fibrillation (AF) is an important risk factor of stroke and left atrial appendage (LAA) is a major site of thrombus formation. CHADS2 score is a standard protocol for the determination of anticoagulation treatment in patients with AF. Thrombus of LAA can be identified by multi-detector contrast-enhanced computed tomography, whereas transient supravalvular echocardiography (TEE) is a traditional and promising method for identifying LAA thrombus.

Aim: In this study, we attempted to investigate whether identifying thrombus in LAA by 320-row area-detector contrast-enhanced computed tomography (ADCT) was superior beyond CHADS2 score for initiating anticoagulation treatment in patients with atrial fibrillation.