

carditis, although performed in a technically appropriate way and in a heart center with sufficient experience, is associated with higher long-term mortality especially in primary polymorbid and fragile patients. Patient preparation, maximally gentle procedure and post-operative patient management are key to reduce the potential complications of lead extraction. Monitoring and periprocedural control by ICE significantly increases safety of endovascular lead extraction and should be standard for all complex procedures.

P3882

Safety of continuous use of Apixaban, Rivaroxaban and Dabigatran in patients undergoing cardiac implantable electronic device implantation in a real-world cohort

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Background: The safety of continuous vitamin-k-antagonists (VKAs) – in comparison with bridging therapy in patients undergoing cardiac implantable electronic devices (CIED) implantation – has been shown previously. So far, data on continuous therapy with apixaban, dabigatran and rivaroxaban appear to be missing.

Methods and results: The aim of this study was to evaluate the safety of continuous NOAC intake compared to VKAs in patients undergoing cardiac rhythm device implantation or a generator change.

529 patients were included. Each patient was treated with one of four different anticoagulation regimes: 223 (42.2%) with VKAs; 148 (27.9%) with apixaban, 93 (17.6%) with rivaroxaban and 65 (12.3%) with dabigatran. The four groups were comparable with regard to age (VKAs 75 years [69; 79]; apixaban 76 years [70; 80]; rivaroxaban 67 years [74; 78] and dabigatran 72 years [64; 79]; $p=0.011$), CHA2DS2VASc Score (VKAs 4 [3; 5]; apixaban 4 [3; 5], rivaroxaban 4 [3; 5], and dabigatran 4 [3; 5]; $p=0.075$), and HAS-BLED score (VKAs 2 [2; 3], apixaban 2 [2; 3], rivaroxaban 2 [2; 3] and dabigatran 2 [2; 3]; $p=0.071$).

20 (0.4%) patients demonstrated major bleeding events. No ischemic complication was documented in this patient cohort. With regard to major bleeding events no significant differences were observed between the different anticoagulation regimes.

Conclusion: This is the largest study evaluating the safety of apixaban, dabigatran and rivaroxaban compared to phenprocoumon in patients undergoing CIED implantation or generator change. Continuous medication with apixaban, rivaroxaban or dabigatran – in comparison with VKAs – appears to yield a comparable risk of bleeding and ischemic complications in this patient group.

P3883

Overall and cardiovascular-related mortality after complications of cardiac implantable electronic devices: preliminary results from the IMPACT registry

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Background: While many evidence are currently available regarding incidence, type and treatment of complications related to cardiac implantable electronic devices (CIED), less is known regarding the impact of these complications on the patients in terms of mortality and morbidity.

Purpose: The present analysis aims to describe how CIED-related complications affect patient survival after hospital discharge.

Methods: The IMPACT study is a national registry promoted by the Italian Association of Arrhythmology and Cardiac Pacing (AIAC). All consecutive patients undergoing a CIED implant in one of the six high-volume, enrolling centres between January 2010 and December 2012 were enrolled in the registry and followed-up for at least three years. During the follow-up, we considered as a complication any event that was related to the CIED and that resulted in any of the following: a) unplanned surgical procedure (re-implant, upgrade, extraction, pocket surgery); b) unplanned hospitalization (device malfunctioning, inappropriate shocks or pacing therapy); c) unplanned out-of-hospital visit with CIED interrogation. Overall survival has been compared between CIED patients experiencing at least one complication and patients who did not. Mortality was further categorized into cardiovascular death, non-cardiovascular death, and sudden cardiac death.

Results: We enrolled 2811 consecutive patients (age 71 ± 14 years, 66.7% males), of which 1413 (50.3%) undergoing a pacemaker (PM) implant, 815 (29%) an implantable cardioverter defibrillator (ICD) implant and 583 (20.7%) a cardiac resynchronization therapy (CRT-D) implant. During follow-up (median 56.9 months) we observed 283 complications in 263 patients: 15.1% pocket hematoma, 11.8% pocket decubitus, 31.5% dislodgment of one or more leads, 14.3% pocket infection, 11.3% lead fracture, 8.0% device malfunctioning, 5.5% pneumothorax, 2.5% cardiac effusion. Annual complication rate was 2.2%/year,

and ICD and CRT-D implants had significantly more complications when compared to PM (3.1% and 2.6% vs 0.9% respectively; $p<0.001$). In patients with CIED complications, Kaplan-Meier curves showed a similar risk of death (Figure 1a, $p=0.462$) and an increased risk of cardiovascular death (Figure 1b, $p=0.003$) when compared to patients without complications over eight years. Rates of non-cardiovascular death and sudden cardiac death were similar between the two groups.

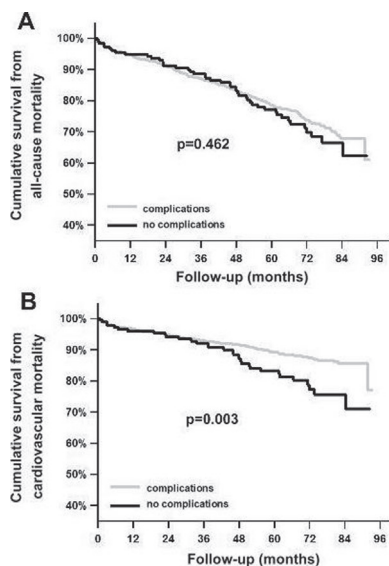


Figure 1

Conclusions: CIED-related complications are associated with an increased risk of cardiovascular mortality. These data underline the importance on adopting specific protocols and preventive measures in order to reduce CIED complications and improve their management.

P3884

Persistence of current of injury is associated with pacing threshold in a canine model of experimental helix electrode implantation

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Background: Time course of current of injury (COI) is correlated with acute stability of active-fixation pacing lead. Little is known about its association with pacing threshold.

Aims: This study was aimed to investigate the relevance between persistency of COI and pacing threshold in active-fixation pacing leads, and to compare characteristics of COI derived by the leads fixated with different depths and angles.

Methods: The helical electrode was attached to the epicardium of canine heart with either half rotation, full rotation, over-torquing or acute-angled manner. Dynamic COI tracing was performed up to 10mins post fixation. COI time persistency was defined as the percentage of COI magnitude recorded at 5min or 10min after fixation relative to its initial measurement. Acute lead stability and pacing threshold were tested by digital force gauge and pacing system analyzer, respectively.

Results: Twelve beagles were studied. There were 123 lead implants in total. COI persistency in over-torqued leads was higher in comparison to that in controlled leads ($80.25 \pm 9.21\%$ vs. $64.54 \pm 15.30\%$ at 5min, and $69.48 \pm 14.19\%$ vs. $45.15 \pm 14.91\%$ at 10min, over-torqued vs. controlled, $P<0.05$), whereas half rotated leads revealed lower COI persistency at 5min ($30.90 \pm 13.00\%$ vs. $64.54 \pm 15.30\%$) and at 10 min ($10.29 \pm 9.43\%$ vs. $45.15 \pm 14.91\%$) than the controlled leads (half rotated vs. controlled, $P<0.05$). Comparable results on COI persistency were found between acute-angled and half rotated leads ($P>0.05$). The value of $<30\%$, $30-60\%$, $60-80\%$ and $>80\%$ represented low, moderate, high and very high COI persistency, respectively. Leads of high COI persis-

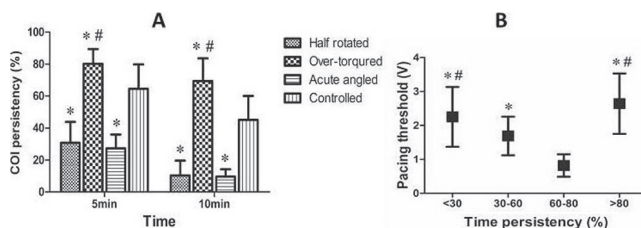


Figure. Comparisons of COI persistency and lead performance. Panel A showed that COI persistency was higher in over-torqued leads, and lower in half rotated and acute-angled leads than that in controlled leads. *: $P<0.05$ (vs. controlled); #: $P<0.05$ (vs. half rotated and acute-angled). Panel B. Pacing threshold was higher in half rotated, over-torqued and acute angled leads than control leads. *: $P<0.05$ (vs. controlled); #: $P<0.05$ (vs. half rotated and acute-angled).

tency showed the lowest pacing threshold (0.82 ± 0.33 V) among groups ($P < 0.05$), whereas those of low (2.25 ± 0.68 V) and very high (2.64 ± 0.89 V) COI persistency had significantly higher pacing threshold than those of moderate COI persistency (1.69 ± 0.57 V) ($P < 0.05$).

Conclusions: COI persistency is associated with pacing threshold of active-fixation leads in canine hearts. Pacing threshold is appears to be satisfactory when leads manifested COI with moderate to high persistency, whereas low or very high COI persistency may indicate unacceptable pacing threshold and predict the risk of lead dislodgement or perforation, respectively.

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P3885

Safety of anticoagulation therapy in patients undergoing pacemaker implantation

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Introduction: The use of anticoagulation, especially new oral anticoagulants (NOACs) in patients requiring cardiac implantable electronic device surgery continues to increase. Periprocedural management of oral anticoagulation remains controversial and requires balancing the risk of bleeding complications with the risk of thromboembolic events.

Purpose: The objective of this study was to assess patterns of anticoagulation management at the time of pacemaker surgery and the associated risk of significant hematomas and other bleeding complications.

Methods: We performed a prospective study in 446 consecutive patients (200 female, age range: 18–91 years) undergoing primary pacemaker implantation. Patients were grouped according to medication taken at the time of device implantation: OAC (137 patients), NOAC (65 patients), bridging therapy with low molecular weight heparin (BD - 10 patients), triple antiplatelet therapy (TAPT - 11 patients) and none anticoagulant group (NA - 223 patients). The periprocedural anticoagulation management was consistent with the EHRA 2015 Position. Bleeding risk was assessed using HAS-BLED score. The incidence of perioperative pocket hematoma or major bleeding events or thromboembolic events were evaluated. The major pocket hematoma was defined as a hematoma requiring surgical evacuation, prolonging hospitalization or major bleeding with blood products transfusion or decrease in hemoglobin concentration more than 1 mmol/l. Hematomas dimensions were measured using an electronic caliper and the volume was calculated according to the formula $V = \text{length} \times \text{width} \times \text{depth}$. The follow-up visit was one and 6-month after surgery.

Results: The occurrence of major pocket hematoma was 4.4% in OAC group, 6% in NOAC group, 10% in BD group, 9% in TAPT group and 0.9% in NA group. Any minor pocket hematoma was observed in 25% in OAC group, 18% in NOAC group, 40% in BD group, 45% in TAPT group and 15% in NA group. The incidence of minor pocket hematoma was significantly higher in OAC and NOAC group in comparison to NA group ($p = 0.002$). Two patients with interrupted NOAC (3.0%) experienced stroke next day after the procedure. The median volume of major pocket hematoma was 343.0 cm^3 (IQR=191.1–222.9 cm^3), while median volume of minor pocket hematoma was 37.8 cm^3 (IQR=22.6–135.3 cm^3). HAS-BLED score significantly correlated with the volume of minor pocket hematoma ($p < 0.0001$, $r = 0.53$). Follow-up did not reveal any major bleedings, thromboembolism or pocket infections.

Conclusions: Clinically significant bleeding and thromboembolic complications in patients undergoing pacemaker implantation on any form of anticoagulation are rare and do not correlate with the use of specific anticoagulant agent during the periprocedural period. Results of the study suggest that HAS-BLED score can be recommended in the overall prediction of minor bleeding complication in patients undergoing pacemaker surgery.

BETA BLOCKERS: REQUIRED IN ALL ACUTE CORONARY SYNDROMES?

4054

Beta-blockers and outcomes in stable coronary artery disease. Insights from the CLARIFY registry

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Background: The role of beta blockers (BB) in the management of stable coronary artery disease (CAD) remains disputed. Data suggesting benefit are largely derived from post myocardial infarction trials antedating the advent of revascular-

ization. Recent studies suggest that BB may have limited benefit in stable CAD patients without heart failure (HF).

Purpose: To describe the use of BB and their association with outcomes in a large contemporary cohort of stable CAD patients.

Methods: CLARIFY is an observational longitudinal cohort of stable CAD patients from 45 countries enrolled in 2009–2010. The inclusion criteria were any of the following (non-mutually exclusive): prior myocardial infarction (MI); angiographic coronary stenosis $> 50\%$; proven symptomatic myocardial ischemia; or prior revascularization procedure. The main exclusion criteria were severe diseases including advanced HF or conditions interfering with life expectancy. Follow-up was by yearly visits up to 5 years. Comparisons were done with multivariable adjusted Cox proportional hazards models.

Results: At baseline among 32 376 patients, 24 372 (75.3%) were treated by BB. The most prevalent BB were bisoprolol (34.3%), metoprolol (28.0%), atenolol (14.8%), carvedilol (11.6%) and nebivolol (5.7%). Patients with BB, compared to those without, were younger, with more symptoms of angina or HF, diabetes, hypertension, hypercholesterolemia and prior MI, coronary revascularization or hospitalization for HF.

At 5 years, after adjustment with a multivariable model (including the CV REACH risk score, blood pressure, left ventricular ejection fraction and histories of revascularisation, peripheral artery disease and asthma/chronic obstructive pulmonary disease), BB use at baseline was not associated with any difference in the occurrence of major events, including all-cause death, CV death, non-CV death, CV death or non-fatal MI or non-fatal stroke (Table).

Results were consistent when accounting for changes in use of BB over time. A sensitivity analysis excluding patients with intolerance or contraindication to BB, focused on attainment of target recommended doses of BB found similar results.

5-year outcomes

(n events/ N patients, %)	Beta-blockers	No beta-blockers	Adjusted HR (95% CI)	p value
All cause death	1345/17135 (7.8%)	407/4871 (8.4%)	0.94 (0.84–1.06)	0.3
CV death	861/17135 (5.0%)	262/4871 (5.4%)	0.91 (0.79–1.05)	0.2
CV death, MI or stroke	1508/17131 (8.8%)	400/4871 (8.2%)	1.04 (0.93–1.16)	0.5

Conclusion: In this large contemporary cohort of stable CAD without chronic HF, BB use whatever the dose was not associated with difference in major outcomes.

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4055

Should we use beta-blockers in all patients after st-segment elevation acute myocardial infarction?

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Background: Beta-blockers (BBs) were initially developed in the 1960s for the treatment of angina pectoris. Nowadays they have a much larger therapeutic spectrum. The benefit of long-term treatment with oral BBs after acute myocardial infarction with ST-segment elevation (STEMI) was established in the pre-reperfusion era, almost 20 years ago and, today, we still read conflicting data regarding the need for beta-blockers as well as treatment duration after patient release.

Purpose: To determine the association between BBs use and mortality after discharge in STEMI patients with preserved, mid-range and reduced left ventricular ejection fraction (LVEF).

Methods: We analyzed data from 2091 patients admitted for STEMI in a Coronary Intensive Care Unit (CICU). Patients with other final diagnoses, missing mortality data, previous STEMI, contra-indications to beta-blockers and known heart failure before admission were excluded. All patients underwent transthoracic echocardiography during hospitalisation. We used propensity score matching to study the impact of BBs on patient mortality and adjusted data for relevant comorbidities. We then compared mortality after hospital discharge between BB group and no-BB group.

Results: Of the 2091 patients admitted for STEMI, 1685 (80.4%) received BBs after discharge. Patients in the BB group showed male prevalence (83.1% vs. 77.1%, $p = 0.002$) and were younger (65.5 ± 13.7 vs. 71 ± 13.5 years, $p < 0.001$). Patients in no-BB group had a higher prevalence of diabetes (61.8% vs. 49.7%, $p < 0.001$), higher mean GRACE score (189 vs. 144, $p < 0.001$), higher maximum Killip class (2.53 vs. 1.32, $p < 0.001$) and more acute kidney injury during hospital stay (38.7% vs. 22.7%). We did not find significant differences regarding number of mean diseased coronary vessels (1.76 vs. 1.75, $p = 0.135$). In this STEMI cohort (5 years follow-up) a total of 604 patients died (29.4%), and non-adjusted 1-month (40.5% vs. 8.5%), 6-month (42.7% vs. 11.8%), 1-year (46.2% vs. 13.5%), 3-year (53.8% vs. 19.1%) and 5-year (56.5% vs. 23.1%) mortality was significantly lower in the BB group. After propensity score matching, we obtained 362 patients for analysis. We then analysed separately groups regarding LVEF (LVEF $< 40\%$, LVEF 40–49% and LVEF $> 50\%$). After adjustment, there was a significant difference in survival of patients on LVEF $< 40\%$ group at 1 month (No BB vs. BB group, HR 3.724, 95% CI 1.2–12.2, $p = 0.03$) and 1 year (No BB vs. BB group, HR 2.192, 95% CI 1.1–4.8, $p = 0.048$) follow-up. There were no significant differences in mortality when comparing groups with mid-term LVEF and preserved LVEF.

Conclusions: Despite having a class IIa indication in the most recent european STEMI guidelines and a class I indication in the american guidelines, the sys-