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# Risk of complications following external cardioversion in cardiovascular implantable electronic devices with and without generator replacement

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Funding Acknowledgements: Type of funding sources: Foundation. Main funding source(s): Karl G. Andersen Foundation Introduction: External cardioversion (ECV) with transthoracic shock is a standard procedure to control atrial fibrillation and flutter in patients regardless of whether cardiovascular implantable electronic devices (CIED) are in situ. Studies have demonstrated infrequent ECV-related CIED malfunction, requiring device re-interventions, but the mechanisms seem heterogeneous. We hypothesized, that replaced CIED generators are more vulnerable to ECV procedures, maybe caused by insulation defects. The aim of this study is to investigate the long-term risk of complications following ECV in CIEDs with or without previous generator replacement.

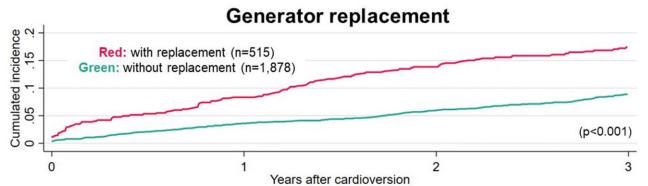
**Methods:** All CIED implants and re-operations in Denmark were identified in the Danish Pacemaker and ICD Register and ECVs were identified in the Danish National Patient Registry from January 2010 to February 2019. We identified CIED patients with and without previous generator replacement. Inclusion was at the time of first ECV. Time to generator replacement with the same type and lead re-intervention with the same lead type after ECV were calculated independently, using Cox regression with death, generator extraction, and system up-/down-grade being competing events. The cause-specific hazard ratios (HR) were calculated using inverse probability of treatment balancing patient age and sex and stratified for the different types of CIED and lead, allowing different baseline hazard functions (1).

Results: We identified 515 CIED patients with previous generator replacement and 1,878 CIED patients without generator replacement. Mean age of patients at inclusion was 68.7±11.7 years with 74% men and the median generator and lead implant times were 1.6 years (0.9 years without replacement) and 3.0 years (0.7 years without replacement) before ECV. The types of CIED included 50% of pacemakers, 30% of Implantable Cardioverter Defibrillators, 6% of Cardiac Resynchronization Therapy-Pacemaker, and 14% of Cardiac Resynchronization Therapy-Defibrillators. During the first 3 years of follow-up, 92 (18%) of the patients with replaced generator had an additional generator replacement compared to 161 (9%) of the patients without generator replacement. The type of leads included 38% atrial leads, 26% right ventricle leads, 13% left ventricle leads, and 23% high voltage leads. During the first 3 years of follow-up, 71 (8%) of the patients with a replaced generator had lead re-intervention compared to 191 (5%) of the patients without a replaced generator. The HR of generator replacement was 2.00 (95%CI:1.51;2.64, p<0.001) and 1.60 (95%CI:1.21;2.12, p=0.001) balancing generator implant time. The HR of lead re-intervention was 1.62 (95%CI:1.21;2.16, p=0.001).

**Conclusion:** Wearing a contemporary cardiovascular implantable electronic device with a prior generator replacement is associated with a two-fold increased risk of additional generator replacement and an increased risk of lead re-intervention following external cardioversion.

Figure 1





## Lead re-intervention

