External cardioversion of atrial fibrillation and flutter in patients with cardiac implantable electrical devices

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Abstract

Background: Atrial fibrillation and flutter are often treated with external electrical cardioversion (ECV) in patients with potentially electrically sensitive cardiovascular implantable electronic devices (CIED). Long-term follow-up data on contemporary CIED undergoing ECV is sparse. The aim is to investigate shock-related complications and impact on CIEDs.

Methods: All ECV procedures from 2010 to 2020 in patients with CIED performed at a tertiary university hospital were identified in the Danish National Patient Registry. Changes in device measurements after ECV were retrospectively studied and procedure-related complications were identified by review of medical records.

Results: We analyzed 763 ECV procedures in 372 patients, median device implant time 1.9 years. The mean age of patients was 69.9 ± 9.9 years of which 73.4% were men. We identified two cases of device programming changes and four cases of premature battery depletion (≤3 years after device implant). Minor changes in device measurements were found for impedances, sensing, and pacing thresholds. No patients died due to ECV-related device dysfunctions within the first 12 months after cardioversions.

Conclusion: External cardioversion in patients with contemporary pacemakers and implantable cardioverter-defibrillators seems safe in the majority of patients. Clinically important changes in device function following cardioversion were rarely observed but may be critical for device function. In an observational study, causality between cardioversion and device dysfunction cannot be established. For patient safety, we suggest that routine device interrogation after cardioversion still should be part of standard care.

KEYWORDS
CIED, defibrillation, device complication, external cardioversion, ICD, interrogation, Pacemaker

Abbreviations: AF, Atrial fibrillation; AFL, Atrial flutter; ECV, external cardioversion; CIED, cardiovascular implantable electronic device; PM, pacemaker; ICD, Implantable Cardioverter Defibrillator; CRT-P, Cardiac Resynchronization Therapy Pacemaker; CRT-D, Cardiac Resynchronization Therapy Defibrillator; RV, Right Ventricle; LV, Left Ventricle; ERI, Elective Replacement Indicator; V, Voltage; mV, milliVolt; SD, standard deviations; CI, confidence interval; IQR, interquartile range.

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The number of patients with a cardiovascular implantable electronic device (CIED) and the prevalence of atrial fibrillation (AF) and atrial flutter (AFL) are increasing, and atrial tachyarrhythmias are very frequent in device patients.1–4 External cardioversion (ECV) with synchronized transthoracic direct current (DC) shock is a recommended part of maintaining a rhythm control strategy in CIED patients, which includes pacemakers (PM) and Implantable Cardioverter Defibrillators (ICD).5 Prior observational studies and case reports have demonstrated rare but serious CIED malfunctions related to the ECV procedure including rise in pacing thresholds ultimately with loss of capture, unintended programming changes, and premature battery depletion.6–9 The present use of biphasic shock for ECV with reduced amount of electrical energy seems to minimize this risk.10–12 Few studies have examined this risk in a contemporary clinical setting. Despite minor changes in lead impedances, pacing thresholds, and sensing measurements they concluded that ECV seems safe in CIED patients and challenging the need for immediate post-shock device interrogations.10,13 Previously, routine post-shock CIED interrogations were recommended in the American (AHA/ACC/HRS) and European (ESC) guidelines, but in the versions routine post-shock device interrogation is not directly mentioned.14,15 This study aims to investigate ECV-related complications and impact on contemporary CIEDs.

2 | METHODS

2.1 | Population

We included all consecutive CIED patients undergoing both elective and acute ECV procedures from January 1, 2010 to December 31, 2020 at Aalborg University Hospital, Denmark. All CIEDs and ECV procedures were identified in the Danish National Patient Registry (DNPR). This registry contains all registered hospital discharge diagnoses since 1977 and outpatient visits since 1995 at Danish hospitals with high validity for procedures and surgeries.16 Cardioversion in patients with cardiac devices in The North Denmark Region is centralized to Aalborg University Hospital only with an uptake area of 590,000 citizens. We included patients with contemporary cardiac devices: PM, ICD, Cardiac Resynchronization Therapy Pacemaker (CRT-P), and Cardiac Resynchronization Therapy Defibrillator (CRT-D), and ECV indication of atrial tachyarrhythmias. Exclusion criteria were cardiac devices implanted before January 1, 2005, leadless PMs (Micra TM), loop recorders, external pacing devices, subcutaneous-ICDs, ECV indication of ventricular tachyarrhythmias, and ECV during cardiac invasive intervention or surgery. The standard procedure was anterior-posterior position of defibrillation pads with recommended 10 centimeters (3.9 inches) distance between the anterior pad and implanted generator device and sedation with Propofol. All cardioversions were performed with ZOLL R or M Series defibrillator systems and biphasic shock therapy only with a maximum programmed output of 200 Joule.

2.2 | Data collection

The study was based on data from medical records and from device interrogations. Baseline characteristics and 12-months follow-up information were retrieved by review of medical records. This included electrocardiograms, numbers of shocks, patch positions, and shock-related device complications. From the Pacemaker Clinic, we retrospectively collected tested device measurements: before ECV, immediately after ECV (typically 1–4 hours after cardioversion), and at the next follow-up visit after ECV (≥4 weeks after cardioversion). Data included values from all implanted active leads in the categories: PACing thresholds in Voltage (Volt/V), sensing impedances in Ohms, sensing values in Voltage (millivolt/mV). The data for battery longevity (in years) were mainly available for ICDs and CRT-Ds. Generator pacing setting was registered at time of cardioversion. Audited data were managed using REDCap electronic data capture tools hosted in the North Denmark Region and we used the embedded functions for accurately data input to consecutively check for input error.17,18 REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and inter operability with external sources.

2.3 | Statistical analysis

For the descriptive analysis, means ± standard deviations (SD) were calculated for normally distributed variables and medians for non-normally distributed variables. Number and percentages (%) were used for categorical variables. p-values < .05 were considered statistically significant. Linear regressions were used to estimate changes in device parameters with one-way clustering of standard errors. This analysis allowed correlation for repeated ECV procedures for devices and independence between patients. Immediate changes (before ECV vs. immediately after ECV) and delayed changes (before ECV vs. next follow-up visit after ECV) were determined. Premature battery depletions were defined as replacement indicator appearing ≤3.0 years after device implant.19 All statistical analyses were performed using Stata software package (Stata version 17.0, StataCorp LP, College Station, TX, USA).

2.4 | Ethics

Data from medical records were acquired with approval from the health authorities in the North Denmark Region (ID 2020–170). Approval from a scientific ethical committee is not required for registry-based studies in Denmark.
3 | RESULTS

We identified 931 ECV procedures in patients with a cardiac device from the DNPR and excluded a total of 168 ECV procedures (32 loop recorders, 17 external PMs, and 41 ECVs with ventricular tachyarrhythmia). We analyzed 763 ECV procedures involving 395 CIED systems. Baseline characteristic of the devices are presented in Table 1. The devices were implanted in 372 patients of which 73.4% were men and the mean age was 69.9 ± 9.9 years at the first ECV-procedure. Primarily anterior-posterior pads position was used. The maximum number of ECVs was 14 in one patient; however, the median was one ECV and the 75% percentile was two ECVs. Thirty-one patients underwent ECV within a month after implantation, and the median device implant time at ECV was 1.9 years with a maximum age of 11.3 years. During follow-up 91 (24.5%) patients underwent generator replacement and subsequently 23 of these patients underwent one or more ECVs.

3.1 | Post-cardioversion changes in device measurements

Following 763 ECV procedures we found two cases (2/395: 0.5%) of changed major programming, resulting in a new pacing setting (see below). Premature battery depletions were found in four cases (4/395: 1.0%). Sinus rhythm or atrial pace rhythm were restored after 688 (90.2%) of the ECV procedures. The post-cardioversion device changes are presented in Table 2. Minor deviations were found of impedances, sensing, and pacing threshold of right ventricle (RV) leads, without clinical significance. No cumulative effect for more ECVs were found. In one patient, increased pacing threshold of the RV lead was introduced after ECV and exit-block was observed 137 days after ECV (see below). No inappropriate pacing episodes resulting in transient tachyarrhythmias was observed following ECV. To our knowledge, no patients died due to ECV-related device dysfunctions within the first 12 months after cardioversion.

3.2 | Cases with adverse events following ECV

The two cases of major programming change are described in case 1 and case 2 (see below). The four cases of premature battery depletion (replacement < 3.0 years after implant) included two CRT-Ps and two PMs and the ECVs were performed: 15 days, 57 days, 135 days, and 2.4 years before generator replacement, respectively. In one case, the battery depletion was accompanied by a battery alert (ERI), described in case 2 (see below). Finally, two cases of major increases in RV pacing thresholds are described in case 3 and case 4 (see below).

Case 1: Pacing programming setting changed after ECV

In a 54-years-old woman with AF and AFL, sick sinus syndrome, and previously implanted dual-chamber PM (Advisa DR, Medtronic) a pacing mode failure was observed after the second ECV procedure.
The PM generator had been implanted for 4.8 years in left pectoral region. Prior to cardioversion, the CIED interrogation was performed with pacing mode of atrial-based pacing with ventricular backup (AAIR-DDDR). Immediately after cardioversion with one external shock, the generator could only perform ventricle-based pacing mode. No other changes were found at device interrogation or x-ray. The manufacturer was consulted, the root cause analysis was inconclusive regarding ECV-related association, but the generator was replaced the next day.

**Case 2: False battery alert after ECV**

In a 76-years-old man with persistent AF, Type 2 atrioventricular block (Mobitz II), and previously implanted dual-chamber PM (Accent RF DR, St. Jude Medical) a battery depletion and later battery alert were observed after the first ECV procedure. The PM generator had been implanted for 11 months in left pectoral region. Before cardioversion, pacing mode was set to VVI-pacing because of poor atrial sensing of 0.1 mV and AF. After successful cardioversion with three shocks, an unexpected battery depletion was reached. No changes in lead measurements were observed and pacing mode was changed to dual-chamber-based pacing. At next follow-up 2 months later, the atrial pacing threshold was increased from 0.75 V/0.4 milliseconds (ms) before cardioversion to 1.75 V/1.0 ms, unchanged poor atrial sensing, and x-ray confirmed dislodgement of the atrial lead. The patient was admitted for atrial lead replacement due to a combination of 96% of atrial pacing and poor atrial threshold. During the procedure, now 3 months after the ECV procedure, the Elective Replacement Indicator (ERI) was observed. The manufactory was later consulted, and the root cause analysis excluded high atrial output, but phenomenon called False ERI. In this case, firmware reset within a 3-month period after battery depletion might have restored normal device function. During this procedure both the atrial lead and generator were replaced.

**Table 2** Post-cardioversion device changes following 763 ECV procedures

<table>
<thead>
<tr>
<th>Interrogation parameters</th>
<th>Immediate changes, mean (95%CI)</th>
<th>Delayed changes, mean (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial impedance (Ohm)</td>
<td>−20 (−26; −14)*</td>
<td>−6 (−12; −1)*</td>
</tr>
<tr>
<td>RV impedance (Ohm)</td>
<td>−10 (−15; −5)*</td>
<td>−10 (−18; −2)*</td>
</tr>
<tr>
<td>LV impedance (Ohm)</td>
<td>−3 (−24; 18)</td>
<td>39 (15; 63)*</td>
</tr>
<tr>
<td>Atrial sensing (mV)</td>
<td>0.4 (0.2; 0.6)*</td>
<td>0.2 (−0.1; 0.4)</td>
</tr>
<tr>
<td>RV sensing (mV)</td>
<td>−0.2 (−0.5; 0.1)</td>
<td>−0.4 (−0.8; −0.1)*</td>
</tr>
<tr>
<td>Atrial threshold (V)</td>
<td>0.0 (0.0; 0.0)</td>
<td>0.0 (0.0; 0.1)</td>
</tr>
<tr>
<td>RV threshold (V)</td>
<td>0.0 (0.0; 0.0)</td>
<td>0.1 (0.0; 0.1)*</td>
</tr>
<tr>
<td>LV threshold (V)</td>
<td>0.0 (−1.0; 1.0)</td>
<td>0.1 (0.0; 0.2)</td>
</tr>
</tbody>
</table>

Changes in device specific parameters including mean and 95% of confidence interval (CI). Immediate changes were present 1–4 hours after cardioversion, and delayed changes were present ≥4 weeks after cardioversion, with median follow-up time of 96 days (interquartile range: 42–185 days). RV (right ventricle), LV (left ventricle), mV (millivolt), V (Volt). *p < .05.

In an 78-years-old man with persistent AF, tachy-brady syndrome, moderate heart failure, and previously implanted dual-chamber PM (Adapta DR, Medtronic) rise in RV threshold was observed after the second ECV procedure. The PM generator had been implanted for 7.2 years in left pectoral region. Immediately after successful cardioversion with one shock, the RV threshold was unchanged 1.0 V/0.5 ms (bipolar). At next follow-up 5 weeks later, the RV threshold was increased to 1.75 V/1.0 ms. Three months after ECV the RV threshold was 3.0 V/1.0 ms (uni- and bipolar) and decreasing remaining battery time of 1 month. RV lead and generator were replaced within a week. The root cause analysis from the hospital could not confirm relation to ECV, however, the high voltage shock from the ECV may have influenced the observed rise in RV threshold.

**Case 3: Rise in RV threshold within months after ECV**

In a 78-years-old man with persistent AF, tachy-brady syndrome, moderate heart failure, and previously implanted dual-chamber PM (Adapta DR, Medtronic) rise in RV threshold was observed after the first ECV procedure. The PM generator had been implanted for 3.8 years in left pectoral region. Before ECV, the RV pacing threshold had been constant between 1.0–1.5 V/1.0 ms (bipolar) for two years. Immediately after successful ECV with two shocks, the RV threshold was 1.5 V/1.0 ms (bipolar). At next follow-up 5 weeks after ECV, the RV threshold had risen to 5.0 V/1.0 ms (bipolar) or 1.75 V/0.64 ms (unipolar). Two months after ECV, the RV threshold was 2.5 V/0.64 ms (unipolar), however, x-ray confirmed correct placed RV lead. Three months after ECV the RV threshold was 6.0/1.5 ms (unipolar) and the patient was referred to RV lead replacement. Meanwhile, the patient was admitted for respiratory tract infections and cardiac decompensation with delayed lead procedure. During recovery, RV exit-block was induced within the next month and in total 137 days after ECV. The root cause analysis from the hospital could not confirm relation to ECV, however, the high voltage shock from the ECV may have influenced the observed rise in RV threshold.

**Case 4: Rise in RV threshold and exit-block after ECV**

In an 84-years-old man with AF and AFL, transitory Type 3 atrioventricular block, episodes of cardiac syncope, and previously implanted dual-chamber PM (Adapta L, Medtronic) rise in RV threshold was observed after the first ECV procedure. The PM generator had been implanted for 2 years in left pectoral region. Prior to cardioversion, the RV pacing threshold had been constant between 1.0–1.5 V/1.0 ms (bipolar) for two years. Immediately after successful ECV with two shocks, the RV threshold was 1.5 V/1.0 ms (bipolar). At next follow-up 5 weeks after ECV, the RV threshold had risen to 5.0 V/1.0 ms (bipolar) or 1.75 V/0.64 ms (unipolar). Two months after ECV, the RV threshold was 2.5 V/0.64 ms (unipolar), however, x-ray confirmed correct placed RV lead. Three months after ECV the RV threshold was 6.0/1.5 ms (unipolar) and the patient was referred to RV lead replacement. Meanwhile, the patient was admitted for respiratory tract infections and cardiac decompensation with delayed lead procedure. During recovery, RV exit-block was induced within the next month and in total 137 days after ECV. The root cause analysis from the hospital could not confirm relation to ECV, however, the high voltage shock from the ECV may have influenced the observed rise in RV threshold.

**Discussion**

Understanding the hazards for contemporary device function following external cardioversion as well as the need for routine post-cardioversion device interrogations are of clinical importance. We investigated the long-term impact of ECV on CIED functions in a standardized clinical setup in a single center cohort. A main finding of the study was, that minor device changes in impedances, sensing, and ventricular pacing thresholds were found after ECV, however, these changes were predominantly clinically non-significant. Another main finding of the study was, that programming changes and premature battery depletions were observed rarely following ECVs.
4.1 | Safety of ECV in patients with PMs and ICDs

All shock-related procedures might involve a risk of device complications and previous studies have identified a spectrum of changes in PMs and ICDs from clinically non-significant changes to critically device dysfunctions, which can be life-threatening for pace-dependent patients. A smaller comparable retrospective study was done by Pluumakers N. et al. in 2018 with 203 CIED-patients including 229 cardioversions. They studied tested device measurements before and after ECVs and found minor increases in impedances for atrial and RV leads. No clinically important CIED changes or complications were reported, and the authors concluded ECV was safe and immediate device interrogation was considered unnecessary. Few device complications after ECVs were found in another large multi-centre survey study by Lücke J. et al. in 2018 including 1809 CIED-patients. They observed cardioversions from 2014 without data from device measurements. They reported 11 cases (0.6%) of shock-related complications. The cases included temporarily increased pacing threshold (n = 9) and exit-block (n = 2), without life-threatening conditions. The types and incidence of device changes after ECVs were comparable to our findings. In the prospective study by Manegold et al. from 2007 with 44 PM-/ICD-patients CIED changes after ECV were studied. Minor changes in tested impedances were observed after ECV without clinical significance. Consequently, they concluded that ECV was safe for device patients. In contrast, more notable results were observed by Altamura G. et al. in a small prospective study from 1995 including 36 PM-patients with repeated device interrogations after ECV. The generators were all implanted in right pectoral region with unipolar leads and shocks were delivered with anterior-lateral paddle position with maximum energy of 360 Joule. Half of the patients (18/36) having exit block in the first minutes after cardioversion, which decreased over the next 24 h and correlated with cumulated shock energy. They found statistically significant abrupt increases in pacing threshold (after 3 min p < .004 and after 60 min p < .05), undersensing (7/36), and three cases of programming changes after ECV.

The incidence of device dysfunctions differs from more recent studies, but many types of changes in device function were observed in our findings despite using of biphasic shock therapy and contemporary CIED systems with primary bipolar leads. The standard (rectilinear) biphasic shock therapy is more efficient for cardioversions compared to monophasic shock and less shock-energy is generally required. A possible mechanism for delayed rises in pacing threshold could be shock-induced energy in implanted leads with conductor coils from capacitive coupling. This induced energy in the implanted leads is delivered direct to the lead tip and causing local myocardial trauma and depends on the shock pads orienteering and delivered shock energy. Routine post-shock device interrogation seems important for patient safety to detect critical device changes. However, this safety measure does influence the clinical workflow of ECVs with increased complexity, time consumption, and costs. Finally, the applied standard procedure in the present study with 10 centimeters (3.9 inches) distance between the anterior shock pad and generator might have contributed to relatively rare observed device changes following ECVs. This practice is in accordance with American (AHA/ACC/HRS) and European (ESC) guidelines on performing ECV in patients with CIEDs.

4.2 | Limitations

This study was based on a retrospective collection of device measurements and review of medical records. Hence, the observed device changes including the rises in pacing threshold and the premature battery depletions may also be seen sporadically over time independently of ECV. However, the observed timing to ECVs in the present study was striking. By the exclusion criteria for generators implanted before 2005, we might have excluded some cardioversions in patients with older devices, mainly in the first years of the study period. However, compared to earlier studies, we assume that these older generators are equivalent or more electrically sensitive, needing routine post-shock device interrogations. After audit, seventy-two interrogation reports were missing, foremostly from the first years of our study period. We have generally limited battery data for PMs and CRT-Ps including post-shock battery measurements in the four cases with premature battery depletions. We found that device measurements seemed stationary during the study period and no medical records were missing for review. Pulse durations for pacing threshold were not included in our analyses and only specified for extraordinary values. These findings might only be representative to hospitals with comparable clinical ECV setup and CIED systems.

5 | CONCLUSION

External cardioversion in patients with contemporary pacemakers and implantable cardioverter-defibrillators seems safe in the majority of patients. Clinically important changes in device function following cardioversion were rarely observed but may be critical for device function. In an observational study, causality between cardioversion and device dysfunction cannot be established. For patient safety, we suggest that routine device interrogation after cardioversion still should be part of standard care.

AUTHOR CONTRIBUTIONS
All Authors have contributed to the concept and design of the study, in the data analysis and interpretation, as well as in drafting, critical revision, and approval of the article. The data audit is completed by Elgaard AF.

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CONFLICT OF INTEREST
The authors have no conflicts to disclose.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

REFERENCES