



Retained cardiac implantable electronic device fragments are not associated with magnetic resonance imaging safety issues, morbidity, or mortality after orthotopic heart transplant

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Background Cardiac implantable electronic device therapy (CIED) has revolutionized treatment for advanced heart failure. Most patients considered for orthotopic heart transplantation (OHT) are treated with implantable cardioverter defibrillators, cardiac resynchronization therapy, or both. These CIEDs are surgically extracted at the time of transplant. Occasionally, CIEDs are incompletely removed. Little is known about the outcomes of post-OHT patients with retained CIED fragments.

Methods We identified 200 consecutive patients that underwent OHT at our institution between April 2006 and December 2014 and performed a retrospective analysis of available radiographic images and clinical records. Chest radiographs prior to and following OHT were reviewed for the presence of CIED or retained CIED fragments. The outcomes of patients with retained CIED fragments that had subsequent magnetic resonance imaging (MRI) studies performed were further investigated.

Results One hundred eighty of 200 patients were identified as having CIED prior to OHT, of which 29 had retained CIED fragments after OHT. Most retained CIED fragments originated from superior vena cava defibrillator coils. There were no adverse events in the retained CIED fragment cohort, and survival was unaffected. Ten patients with retained CIED fragments safely underwent a total of 28 MRIs after OHT, all of diagnostic quality.

Conclusion Retained CIED fragments are not associated with adverse events or increased mortality after OHT. Diagnostic MRI has been safely performed in patients with retained CIED fragments after incomplete device extraction. Retrieval of these fragments prior to MRI does not appear warranted given the demonstrated safety and preserved image quality in this population. (*Am Heart J* 2017;190:46-53.)

Cardiac implantable electronic devices (CIEDs), specifically implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT), are frequently used for the treatment of end-stage heart failure and prevention of sudden death in patients awaiting orthotopic heart transplantation (OHT).¹⁻⁴ Patients undergoing OHT generally have transvenous CIED such as an ICD or a CRT device with defibrillator (CRT-D) extracted at the time of surgery. Despite the best efforts of the surgical team, removal of CIED at the time of OHT is often incomplete because endothelialization of the device is an

expected and time-dependent occurrence. Extraction of ICD leads containing dual shocking coils has proven to be particularly challenging. Fibrous tissue in-growth may form in the proximal coil which is located in the superior vena cava (SVC) and positioned in a high-risk region associated with vascular trauma, greatly increasing the risk of transvenous lead extraction.⁵ Adherence of the proximal shocking coil to the SVC combined with diminished lead integrity following transection at the level of the distal SVC during OHT makes en bloc removal challenging, occasionally resulting in retained CIED fragments in situ.

The presence of CIED has dramatically increased over the last decade, and device extraction at the time of OHT has become a routine part of the procedure. Little is known about long-term outcomes in the post-OHT cohort with retained CIED fragments. In particular, magnetic resonance imaging (MRI) safety and image quality in the presence of retained CIED have not been described. We present the outcomes of a retrospective cohort of patients that underwent CIED extraction at the time of

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OHT including morbidity, mortality, and MRI safety in patients with retained CIED fragments.

Methods

Patient population

This retrospective cohort included 200 patients that underwent OHT at Mayo Clinic Florida, a major OHT center for northern Florida and southern Georgia, between April 2006 and December 2014. All patients had longitudinal care provided both pre- and postoperatively in the Mayo Heart Transplant clinic. All patients received transplanted organs through the United Network for Organ Sharing/Organ Procurement and Transplantation Network and were provided standard care throughout the transplant process. Patient demographic data were retrospectively collected through the electronic medical record and United Network for Organ Sharing database. CIED information was obtained via electronic medical record through multiple modalities including device interrogation reports, chest radiographs (CXRs), and surgical pathology.

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Surgical CIED extraction during OHT

CIED extraction was performed by 1 of 3 transplant surgeons at the time of OHT using a standardized approach. For intravascular CIED, the atrial (if present) and ventricular leads were cut at the distal SVC, and the distal portions of the leads were removed with the excision of the recipient's heart. The device generator pocket was surgically opened, and the generator and proximal portion of the leads were removed using manual traction following separation from cardiopulmonary bypass. Specialized transvenous extraction tools were not used. CIEDs in the pericardial space such as epicardial ICD patches were removed in a similar manner by cutting the leads and removing the distal portion of the leads and epicardial patch with the recipient's heart. The tunneled portion of these leads was left in situ. Portions of CIEDs that were adherent to surrounding tissues and more technically difficult to remove were left in situ in an effort to simplify the surgical procedure and to minimize ischemia time of the donor organ. Fluoroscopic guidance was not used during the procedure, and therefore, the completeness of CIED extraction was unknown at the time of OHT.

Determination of retained CIED

Pre-OHT CXRs were reviewed for the presence of CIED. Immediate post-OHT, CXRs of the subgroup with CIED were reviewed for retained fragments pertaining to the previous CIED. Retained CIED fragments were described as having either an intravascular or an extravascular location.

Fragments were further classified as lead associated (including active fixation), ICD coil, or both.

Determination of MRI safety and efficacy

Patients with retained CIED that underwent MRI were further analyzed. All MRIs for this cohort were performed at Mayo Clinic Florida. There were no modifications to the standard MRI protocol for patients with retained CIED. Pre- and post-MRI CXRs were reviewed for changes in CIED location following MRI. When appropriate, serial CXRs were reviewed to mitigate changes in technique. Safe performance of MRI was determined by review of the electronic medical record. In particular, procedural reporting at the time of MRI was reviewed. Clinic documentation was also analyzed for incident reports of vascular complications associated with retained CIED fragments in the post-MRI setting. MRI efficacy was determined through review of MRI reports for mention of artifact and suggestion for alternative imaging modality. MRI images were personally reviewed for artifact in the area of interest per the MR order indication.

Survival analysis

Vital status and date of death were obtained from the electronic medical record or Social Security Death Index as of August 1, 2016. The duration of follow-up was calculated as the total number of days between OHT and death or most recent patient contact including follow-up visits, hospitalizations, diagnostic testing, and phone correspondence.

Statistical analysis

Continuous data are presented as median and interquartile range (IQR), whereas categorical variables are presented as frequency and percentage of the total population. Student *t* tests were performed to compare continuous variables across groups. Nominal variables were compared using a χ^2 test or Fisher exact test when appropriate. Odds ratios (ORs) were calculated to determine the association of pre-OHT patient characteristics and post-OHT retained CIED fragments. Cumulative probability of survival was calculated through Kaplan-Meier analysis, and survival curves were compared using the log-rank test. A value of $P < .05$ was considered statistically significant. All statistical analyses were performed using JMP 10 software (SAS Institute Inc, Cary, NC).

Results

Clinical characteristics

Pertinent demographics of the 200 consecutive patients that underwent OHT at Mayo Clinic Florida between April 2006 and December 2014 are described in detail in Table I. The median age was 54 ± 13 years, 147 (74%) were male, and 139 (70%) were white. One hundred and eighty of the 200 patients (90%) that

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