

Complication Rates Associated with Pacemaker and Implantable Defibrillator Generator Replacement: Results from the REPLACE Registry

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Introduction: Limited data on true complication rates from cardiac rhythm management (CRM) device replacements is available. Outcomes benchmarks are needed to accurately weigh risk versus benefit when considering elective replacements for device recalls and lifetime risk of primary prevention device implantation. The REPLACE study is a prospective multicenter registry undertaken to estimate the procedure related complication rates for patients undergoing generator replacement without (Cohort 1) and with planned lead addition or revision (Cohort 2). This study reports the results from Cohort 1.

Methods: Patients undergoing elective CRM generator replacement from 68 US centers were enrolled, prospectively followed for 6 months and data collected to determine pre-defined major and minor complication rates. Major complications included infection requiring IV antibiotics or hospitalization, device or lead malfunction requiring reopening of the pocket, re-hospitalization directly related to the generator replacement procedure, hematoma requiring evacuation, drainage or transfusion, and death within 30 days where the death was clearly procedure related. Minor complications included visible swelling, blistering, and superficial cellulitis. All events were adjudicated by an independent blinded clinical events committee. Infectious events were classified based on the Center for Disease Control surgical site infection definitions. Descriptive statistics included frequency distribution and cross tabulations for discrete variables, with means, standard deviation and ranges for continuous variables.

Results: REPLACE enrolled 1,031 patients between July 23, 2007 and March 18, 2008. An ICD was present in 49% and a pacemaker in 51%. The mean age (\pm SD) was 71.1 ± 14.1 years, 62% were male, 29% had diabetes mellitus, and 37% were on warfarin. Preoperative antibiotics were given in 100%. Sixteen patients had an unplanned new lead addition. Six deaths occurred within 30 days, none adjudicated to be a direct result of the procedure.

Complications:

Type of Complication	Number of Complications	Number of Patients with Complications	% of Total Patients (n = 1031) with at least one Complication (95% CI)
Total	136	112	10.9 (9.0, 12.9)
Major	53	43	4.2 (3.0, 5.6)
Minor	83	75	7.3 (5.8, 9.0)
Infections	13	13	1.3 (0.7, 2.2)

Conclusion: In this first prospective multicenter registry, patients undergoing a CRM generator replacement had at least 1 major complication in 4.2% and at least 1 minor complication in 7.3% of patients.