**The impact of Charlson Comorbidity Index on *de novo* CIED procedural outcomes in the United States**

Short Title: Impact of comorbidity on CIED procedural outcomes

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Word count (inc. title page, abstract and references): 4633

# Abbreviations

CCI Charlson Comorbidity Index

CIED Cardiac Implantable Electronic Device(s)

CRT Cardiac resynchronization therapy

ICD Implantable cardioverter defibrillator

MACCE Major Adverse Cerebrovascular and Cardiovascular Events

PPM Permanent pacemaker

OR Odds Ratio

**Abstract**

**Objective:** To investigate the utility of Charlson comorbidity index (CCI) as a measure of comorbidity burden to predict procedural outcomes after de novo cardiac implantable electronic device (CIED) implantation.

**Methods:** All de novo CIED implantations in the United States National Inpatient Sample between 2015 and 2018 were retrospectively analysed, stratified by CCI score (0=no comorbidity burden, 1=mild, 2=moderate, ≥3=severe). Multivariable logistic regression models were performed to examine the association between unit CCI score (scale) and in-hospital outcomes (MACCE: composite of all-cause mortality, acute ischemic stroke, thoracic and cardiac complications, and device-related complications; and MACCE individual components).

**Results:** Of 474,475 CIED procedures, the distribution of CCI score was as follows: CCI-0 (17.7%), CCI-1 (21.8%), CCI-2 (18.7%), CCI-3+ (41.8%). CCI score was associated with increased odds ratios (OR) of MACCE (1.10; 95%CI 1.09, 1.11), all-cause mortality (1.23; 95%CI 1.21, 1.25) and acute stroke (1.45; 95%CI 1.44, 1.46). This finding was consistent across all CIED groups except the cardiac resynchronisation therapy (CRT) groups in which CCI was not associated with increased risk of mortality. A higher CCI score was not associated with increased odds of procedural (thoracic and cardiac) and device-related complications.

**Conclusion:** In a nationwide cohort of CIED procedures, higher comorbidity burden as measured by CCI score was associated with an increased risk of in-hospital mortality and acute ischemic stroke, but not procedure-related (thoracic and cardiac) or device-related complications. Objective assessment of comorbidity burden is important to risk-stratify patients undergoing CIED implantation for better prognostication of their in-hospital survival.

# Key Words: pacemaker, defibrillator, cardiac devices, outcomes, Charlson comorbidity index

# Introduction

The volume of cardiac implantable electronic device (CIED) implantation procedures in the United States (US) has increased in the last two decades, primarily due to an ageing population in which cardiac conduction disease is more prevalent. 1-6 Furthermore, mounting evidence on the efficacy of implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices in patients with heart failure has contributed to the growing number of implantations of these devices.7-9 With advanced age, patients are more likely to be multi-morbid, with isolated comorbid conditions shown to correlate with worse outcomes in patients undergoing CIED implantation. However, comorbidities rarely occur in isolation and the total burden of comorbidity is an important consideration in the assessment of many cardiovascular procedures. 10-15

 The Charlson Comorbidity Index (CCI) measures co-morbidity burden and prognostic impact of 17 comorbid conditions by means of a score based on their number as well as the individual impact of each condition, which is assigned a certain weight. 16, 17 CCI has been shown to predict mortality, long-term morbidity, repeat hospitalizations and length of stay in many cardiovascular cohorts. 12, 14, 17 While previous studies have examined the impact of comorbidity burden on procedural outcomes in the context of CIED implantation, they have been largely limited by factors such as the analysis of single device types, small samples drawn from single-centre or regional databases, the inclusion of *de novo* and upgrade/revision CIED procedures, or the focus on composite endpoints with no stratification according to type of complication, with conflicting results reported.1, 18-23

This leaves a gap in evidence on the prevalence of comorbidity burden amongst those undergoing *de novo* CIED implantation as well as the prognostic impact (or lack thereof) of comorbidity burden on procedural outcomes, particularly according to the type of device implanted.

In the present study we evaluated the association between CCI score and post-procedural outcomes in a national cohort of *de novo* CIED procedures in the US between October 2015 and December 2018, stratified by type of CIED (permanent pacemaker (PPM), CRT with pacemaker (CRT-P) or defibrillator (CRT-D), and ICD).

# Methods

*Data Source*

The National Inpatient Sample (NIS) is the largest publicly available all-payer database of hospitalized patients in the United States and is sponsored by the Agency for Healthcare Research (AHRQ) and Quality as a part of the Healthcare Cost and Utilization Project (HCUP). NIS includes anonymized data on discharge diagnoses and procedures from more than 7 million hospitalizations annually.24 The NIS dataset constitutes a 20% stratified sample of US community hospitals and provides sampling weights to calculate national estimates that represent more than 95% of the US population. It contains up to 40 diagnosis field (DX) and 25 procedure fields (PR) for each hospitalization record, which are coded using the ICD-10 manual, in addition to sociodemographic data for each hospitalization including age, sex, race, primary expected payer, median household income (quartile), hospital bed size, teaching status and location, as well as information on length of stay and total charges for the admission.

*Study Design and Population*

All hospitalizations during which *de novo* CIED implantations were performed were retrospectively analysed. CIED procedures (Single and Dual Chamber PPM, CRT-P, CRT-D, and ICD), patient characteristics, comorbidities other than those in the CCI score as well as data for other procedures, diagnoses and clinical outcomes were extracted from NIS using the International Classification of Diseases, tenth revision (ICD-10) procedure and diagnosis codes provided in the supplements (**Supplemental Table 1**). Missing records (n=328, 0.3% of dataset) for age, sex, procedure urgency (elective vs. urgent), length of stay and mortality were excluded from the analysis, as were any cases of device upgrades or generator replacements and patients undergoing multiple CIED procedures or PCI or CABG during the same admission. A flow diagram illustrating the selection process and missing variable in the present study is presented in the supplements (**Supplemental Figure 1**).

Variables in the CCI score are presented along with their individually assigned scores in **Supplemental Table 2** and were extracted using the Charlson package in STATA based on ICD-10 codes as per the algorithm previously described by the package authors.16

*Outcomes*

The primary outcome measures were in-hospital rates of all-cause mortality and major acute cardiovascular and cerebrovascular events (MACCE), and procedural complications (thoracic, cardiac and device-related complications). In-hospital MACCE was defined as a composite of all-cause mortality, thoracic, cardiac and device-related complications. Thoracic complications were defined as a composite of pneumothorax, pleural drainage and thoracic vascular laceration while cardiac complications were a composite of hemopericardium, pericardial effusion or pericardiocentesis, cardiac tamponade, and cardiac laceration. Cardiac complications were defined as a composite of cardiac tamponade, hemopericardium, pericardiocentesis. Device-related complications were defined as a composite of wound disruption, device infection, lead revision and mechanical device complications.

*Statistical Analysis*

Data extraction and cleaning was performed using STATA 16 MP (College Station, TX, USA) while statistical analysis was performed using SPSS version 26 (IBM Corp, Armonk, NY). Continuous variables are presented as medians with interquartile range (IQR) and were compared using the Kruskal-Wallis test. Categorical variables are presented as percentages and were analysed using the chi squared (X2) test.

For exploratory analysis, the CCI groups were stratified into the following categories: CCI 0 (no comorbidity burden), CCI 1 (mild), CCI 2 (moderate) and CCI ≥3 (severe).

Multivariable logistic regression models were fitted using maximum likelihood estimation to examine the association between CCI (as a continuous scale) and in-hospital outcomes (MACCE, all-cause mortality and individual complications), expressed as odds ratios (OR) with corresponding 95% confidence intervals (CI), adjusting for all patient-related, procedural and sociodemographic variables that could influence in-hospital outcomes and that were not part of CCI to avoid collinearity. Survey estimation commands were employed to account for the sampling structure of NIS. The following variables were adjusted for: type of device, age, sex, elective admission, weekend admission, primary expected payer, median household income, hospital bed size, location and teaching status, pre-procedure cardiogenic shock, ventricular tachycardia and fibrillation, atrial fibrillation, dyslipidaemia, smoking status, thrombocytopenia, history of percutaneous coronary intervention and/or coronary artery bypass surgery, anaemias and coagulopathies (including hereditary and acquired factor deficiencies and thrombophilia as well as disseminated intravascular coagulation), hypertension, and valvular heart disease. The model fits were assessed using the Hosmer-Lemeshow statistic.25

# Results

#  A total of 474,475 *de novo* CIED implantation procedures were included our analysis. The most frequently implanted device type was dual chamber PPM (n=305,705, 64.4%), followed by ICD (n=75,055, 15.8%), single chamber PPM (n=40,575, 8.6%), CRT-D (n=35,990, 7.6%) and CRT-P (n=17,150, 3.6%). The distribution of CCI score in the overall cohort was as follows: CCI 0 (no comorbidity burden: 17.7%), CCI 1 (mild: 21.8%), CCI 2 (moderate: 18.7%), CCI ≥3 (severe: 41.8%). Patients with higher CCI class were more likely to undergo ICD and CRT-D implantation instead of a dual chamber PPM. (Table 1)

#  Overall, the most common CCI comorbidities in the total CIED cohort were congestive heart failure (48.8%), followed by renal failure (28.5%), diabetes without complications (24.4%) chronic obstructive pulmonary disease (22.8%) and previous myocardial infarction (17.3%). (Supplemental Table 2, Figure 1) This pattern was observed across CIED types.

*Patient characteristics*

#  In the total cohort, patients with a higher CCI class were older, more likely to be male, Black, admitted urgently (vs. elective), and admitted to urban teaching hospitals. As CCI class increased, there was an increase in the prevalence of in-hospital cardiac arrest and pre-procedure cardiogenic shock; a greater prevalence of ventricular tachycardia, atrial fibrillation, dyslipidaemia, previous PCI, anaemias (deficiency and chronic disease), and valvular heart disease (Table 1). These differences in patient characteristics were largely similar within individual CIED subgroups (Supplemental Tables 3-4).

*In-hospital outcomes*

 The crude rates of MACCE, primarily driven by all-cause mortality and acute ischemic stroke, as well as thoracic and cardiac complications, length of stay and total hospitalization costs in the total cohort increased in line with higher CCI class. (**Table 2, Figure 2** p<0.001 for all) Whilst there was no difference in the total rate of device-related complications between CCI classes, the rates of device-related infection and wound disruption were marginally higher in those with CCI ≥3 (0.2% for both) compared with all other classes (0.1% for CCI 0, 1 and 2 of both outcomes).

 The crude rates of adverse outcomes according to CIED type are presented in **Supplemental** **Table 5** and further illustrated in **Figure 3**. The rates of MACCE, all-cause mortality and acute ischemic stroke were higher with more advanced CCI class in all CIED types, except for MACCE in the CRT-P group which was similar across CCI classes. Although the rates of other adverse outcomes (thoracic, cardiac and device-related complications) were generally higher in patients with CCI class>0 for most device types, this was dependent on the endpoint studied. (**Figure 3**)

 In multivariable analysis, each unit of CCI score was associated with an increase in odds of MACCE (OR 1.10; 95% CI 1.09, 1.11), all-cause mortality (OR 1.23; 95% CI 1.21, 1.25) and acute stroke (OR 1.45; 95% CI 1.44, 1.46). (**Table 3, Figure 3,** *p*<.001 for all) Although these findings were consistent across CIED subtypes, there was no difference in odds of mortality with increasing CCI score in the CRT-P and CRT-D groups. Increasing CCI score was associated with decreased odds of thoracic (OR 0.95 95% CI 0.94, 0.96), cardiac (OR 0.95 95% CI 0.94, 0.96) and device-related (OR 0.96 95% CI 0.95, 0.97) complications in the overall cohort. This pattern was consistent in the majority of the device subgroups. (**Table 3, Figure 3)** Similar findings were demonstrated when CCI was analysed as a categorical variable using CCI 0 as the reference category. **(Supplemental Table 6)**

# Discussion

The present study, drawn from a national cohort of more than 470,000 procedures, is the first and largest to examine the role of comorbidity burden, as measured by the CCI score, in predicting procedural outcomes across all CIED types. Several important findings can be concluded. First, we find that between 4 and 6 out of every 10 patients undergoing CIED implantation had severe comorbidity burden as defined by CCI score ≥3, depending on the type of device, with CRT-D and ICD being the most utilized devices in this high-risk group. Second, we show that comorbidity burden is associated with critical illness during admission as evidenced by the rates of pre-procedure cardiogenic shock, cardiac arrest during admission, and ventricular tachycardia in patients with higher CCI class. Finally, despite adjustment for baseline differences, CCI score was associated with increased odds of MACCE, driven by higher all-cause mortality and acute stroke, without an increased risk of thoracic, cardiac or device-related complications after CIED implantation.

There is ample evidence from real-world studies on the relationship between individual patient comorbidities (e.g., diabetes, heart failure, chronic kidney disease, cancer) and CIED procedural outcomes. 26-31 However, these comorbidities often co-exist, making their overall burden an equally important consideration for procedural risk assessment in patients undergoing CIED implantation. This is particularly relevant for operators performing cardiac procedures whose procedural outcomes, including mortality, are often perceived as a measure of the quality of care they provide.32-34

Very few studies have looked at the impact of overall comorbidity burden as part of their secondary outcomes and these have been largely limited for a number of reasons.1, 18-23 Prior studies have looked at the number of comorbidities subjectively as opposed to using an established, validated scoring system such as CCI, that takes into account the differing prognostic impact of each type of comorbidity.1, 22 Other studies have focused on specific types of devices (e.g. ICD), despite well-recognized differences in the complexity of procedures between CIED types, or certain outcomes (e.g. composite in-hospital complications or 1-year mortality), which does not inform operators about the impact of CCI score on specific postprocedural outcomes.18-21, 23 Furthermore, many studies have included *de novo* and upgrade CIED procedures despite the different procedural risks of each procedure type. 20, 21, 23

In our analysis, a significant number of patients undergoing CIED implantation are classed as having severe comorbidity burden as measured by the CCI score (CCI≥3), with the lowest (36%) and highest prevalence (60.8%) being amongst those undergoing dual chamber PPM and CRT-D, respectively. Comorbidity burden was associated with increased odds of all-cause mortality (16-27% increase per unit CCI score) and acute stroke (36-54% increase in odds per unit score) but not procedure-related complications, a finding that was consistent across device groups. No previous study has previously assessed the impact of comorbidity burden (as measured by CCI) on *de novo* CIED procedures specifically for a number of outcomes, including all-cause mortality and complications (thoracic, cardiac and device-related). However, a number of previous studies have looked at the relationship of comorbidity burden and mortality at different time points. For example, a study by Swindle et al. that examined 26,887 adults with a diagnosis of heart failure undergoing ICD and CRT implantation from a commercial database showed that severe comorbidity (CCI≥3) was associated with a significant increase in odds of in-hospital mortality (OR ICD: 2.44 (1.47-4.05); CRT-P: 3.01 (1.17-7.77); CRT-D: 2.74 (1.62-4.65)).23 This is in keeping with our findings, although their cohort included both *de novo* and upgrade/revision procedures. Similarly, a single-centre analysis of 1,062 ICD/CRT-D procedures by Bhavnani et al. concluded that each unit CCI score was associated with 40% increased hazard of 1-year mortality (HR 1.40 (1.20-1.60)), although this was based on a single-centre experience for specific device types and also included both upgrade and CIED procedures.18

 In the absence of evidence on the relationship between CCI score and procedural outcomes such as thoracic, cardiac and device-related complications, it is difficult to place our findings in the context of those from other studies. A study by Zhan et al. showed that severe comorbidity burden (≥3 comorbidities), measured by simply counting the number of comorbidities, was not associated with any increase in odds of ‘any in-hospital complication’ in those undergoing CIED implantation in the US except in the CRT-D group. 1 However, their definition of their composite endpoint was very expansive (≥7 individual outcomes), and their comorbidity burden assessment was subjective, based on the number of comorbidities without consideration of the prognostic impact of each comorbidity.

The lack of difference in procedure-related complications with advancing CCI score in our analysis suggests that severity of comorbidity burden does confer an operative risk for complications in patients undergoing CIED implantation, or that there may be an element of selection bias, particularly for more complex devices where such devices are only implanted in healthier patients.

*Limitations*

There are several limitations to the present study. First, the NIS database is an administrative dataset which is subject to potential coding inaccuracies. However, the use of ICD-10 codes from administrative databases has been previously validated for the purpose of cardiovascular research. 35-38 Second, since the NIS dataset does not provide information on pharmacotherapy, indication for each CIED device (e.g., type of arrhythmia, primary vs. secondary prevention in CRT-D and ICD procedures), operator experience and procedure time, we were unable to adjust for these covariates between the study groups. However, differences in these factors between CCI groups are not expected to be significant. Furthermore, there is no specific look-back period for comorbidities in NIS, so it is possible that some comorbidities are under-represented. However, we would expect major comorbidities that are part of the CCI, and that have significant implications in subsequent admissions (e.g., AIDS, previous CVA or MI), to have been captured even after a considerable time period. Finally, the NIS only reports in-hospital outcomes and so the present findings may not reflect longer-term adverse outcomes, which may be even worse in patients with a higher comorbidity burden. However, the majority of procedure-related (thoracic, cardiac and device-related) complications have been shown to occur in the peri-procedural and early post procedural phase and, therefore, are unlikely to be differ significantly on longer follow-up.39

# Conclusion

 In a nationwide cohort of CIED implantations we find that at least 4 out of 10 patients are classed as having severe comorbidity burden as measured by the CCI score. While CCI score was associated with the risk of in-hospital all-cause mortality and acute ischemic stroke, a higher CCI score did not confer worse thoracic, cardiac or device-related complications. We conclude that CCI score is an important tool for the risk stratification in those undergoing CIED implantation, irrespective of the type of device.

# Conflicts

Dr Morillo reports financial support from Abbott, Medtronic, Novartis and Servier. Dr Wilton reports research support from Medtronic Canada, Boston Scientific and Abbott. All co-authors have no disclosures and no relationships with the pharmaceutical industry.

# Funding

# M.O.M. receives PhD funding from Medtronic Ltd. Medtronic Ltd was not involved in the conceptualization, design, conduct, analysis, or interpretation of the current study.

# Statement

The manuscript has neither been published nor is currently under consideration for publication by any other journal. All authors have approved the final version of the manuscript.

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**Figure titles and legends**

**Figure 1.** Prevalence of individual CCI comorbidities

**Legend:**

**AMI:** acute myocardial infarction; **CHF: congestive heart failure, CRT:** cardiac resynchronization therapy with defibrillator (CRT-D) or pacemaker (CRT-P); **CVA:** cerebrovascular accident (stroke or transient ischemic attack); **ICD:** implantable cardioverter defibrillator; **PPM:** permanent pacemaker; PVD: peripheral vascular disease.

**Figure 2.** Unadjusted rates of in-hospital adverse outcomes

**Legend:**

**MACCE:** major adverse cardiovascular and cerebrovascular events; composite of all-cause mortality, acute ischemic stroke, thoracic and cardiac complications; **Thoracic complications:** composite of pneumothorax, pleural drainage and thoracic vascular laceration; **CRT:** cardiac resynchronization therapy with defibrillator (CRT-D) or pacemaker (CRT-P), **ICD:** implantable cardioverter defibrillator; **PPM:** permanent pacemaker.

**Figure 3.** Forest plot illustrating adjusted odds of adverse events per unit CCI score

**Legend:**

**Cardiac complications:** composite of hemopericardium, pericardial effusion or pericardiocentesis, cardiac tamponade, and cardiac laceration**; CCI:** Charlson Comorbidity Index; **MACCE:** major adverse cardiovascular and cerebrovascular events; composite of all-cause mortality, acute ischemic stroke, thoracic and cardiac complications; **Thoracic complications:** composite of pneumothorax, pleural drainage and thoracic vascular laceration. **CIED:** cardiac implantable electronic device; **CRT:** cardiac resynchronization therapy with defibrillator (CRT-D) or pacemaker (CRT-P), **ICD:** implantable cardioverter defibrillator; **PPM:** permanent pacemaker.

a reference is CCI 0 in each class

b \*Adjusted for the following: type of device, age, sex, elective admission, weekend admission, primary expected payer, median household income, hospital bed size, location and teaching status, pre-procedure cardiogenic shock, ventricular tachycardia and fibrillation, atrial fibrillation, dyslipidaemia, smoking status, thrombocytopenia, history of percutaneous coronary intervention and coronary artery bypass surgery, anaemias coagulopathies, hypertension and valvular heart disease