# Outcomes of cardiac implantable electronic device transvenous lead extractions performed in centers without onsite cardiac surgery

Short Title: CIED lead extractions in centers without cardiac surgery

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# Disclosures Statement

AG is a consultant to Medtronic and has received grant support from them for 2 projects in the past year. AG also previously received limited honoraria from Medtronic, St Jude (Abbott), and Boston Scientific for lectures (less than $2500). DB is paid by Medtronic for educational sessions. Other co-authors have no disclosures and no relationships with the industry.

# Funding

MOM receives PhD studentship funding from Medtronic Ltd.

# Abstract

**Background:** While major complications associated with CIED lead extractions are uncommon, they carry a significant risk of morbidity and mortality in the absence of surgical intervention. However, there is limited data on the differences in outcomes of these procedures between centers with and without on-site CS support. The present study examined outcomes of transvenous cardiac implantable electronic device (CIED) lead extractions according to admitting hospitals’ cardiac surgery (CS) facilities.

**Methods:** We analyzed the National Inpatient Sample for CIED lead extraction procedures, stratified by hospitals’ CS facilities into two groups; on-site and off-site CS. Logistic regression analyses were performed to estimate the adjusted odds (aOR) of procedure-related complications in off-site CS centers.

**Results:** In 221,606 procedures over an 11-year-period, CIED lead extractions were increasingly undertaken in on-site as opposed to off-site CS centers (Onsite CS 2004 vs. 2014: 78.2% vs. 90.4%, p<0.001) during the study period. In comparison to on-site CS group, patients admitted to off-site CS group were older, less comorbid, and experienced lower adjusted odds of major adverse cardiovascular events (0.72[0.67, 0.77]), mortality (0.60[0.52,0.69]), procedure-related bleeding (0.48[0.44,0.54]) and complications (thoracic:0.81[0.75,0.88]; cardiac:0.45[0.38,0.54]) (p<0.001 for all).

**Conclusion:** Our national analysis demonstrates that transvenous CIED lead extractions are being increasingly undertaken in centers with on-site CS surgery, in compliance with international guideline recommendations. Patients managed with lead extractions in on-site CS centers are more comorbid and critically ill compared to those admitted to off-site CS centers, and remain at a higher risk of procedure-related complications.

**Key Words:** Cardiac devices, pacemakers, defibrillators, removal, extraction, cardiac surgery, outcomes, treatment

# Introduction

 The rate of cardiac implantable electronic device (CIED) implantations continues to grow both in the United States and Europe [[1](#_ENREF_1), [2](#_ENREF_2)] Commensurate with the increased rate of implantation in the older patients with significant comorbidities, there has been an associated higher risk of complications such as CIED-related infection. This has led to an increasing need for CIED lead extractions.[[3](#_ENREF_3), [4](#_ENREF_4)]

Despite advances in CIED lead extraction tools and techniques, safety measures (such as the bridge occlusion balloon) and operator proficiency over the years, there remains a risk of procedure-associated complications. The most feared complication is vascular and myocardial injury, which is rare but requires immediate sternotomy and has poor outcomes despite rapid surgical intervention. As such, the 2017 updated Heart Rhythm Society guidelines emphasize the need for cardiothoracic team back up with ‘access to equipment to perform emergent sternotomy or thoracotomy within 5 to 10 minutes’ for all CIED lead extraction procedures due to the risks associated with the procedure [[5](#_ENREF_5), [6](#_ENREF_6)] However, many patients continue to undergo extractions at facilities without on-site cardiac surgery.

The majority of data pertaining to outcomes of lead extractions is generated from specialized centers with on-site cardiac surgery (CS) facilities and centers with high operator volume, which has shown an overall low rate of complications.[[7-10](#_ENREF_7)] Consequently, little is known about the differences in clinical characteristics and outcomes of patients undergoing CIED lead extractions between centers with and without cardiac surgery (CS) on a national level, and whether there has been a change in practice and subsequently outcomes over time. This gap in evidence drives the need for outcomes data on the safety of CIED lead extraction procedures in centers without cardiac surgery support that represent a notable proportion of centers that undertake such procedures.

 The present study utilized a national contemporary cohort drawn from the National Inpatient Sample from 2004 to 2014 to compare the rates, patient characteristics and in-hospital clinical outcomes of transvenous CIED lead extractions in the United States between centers with and without on-site cardiac surgery facilities.

# 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 and Quality as a part of the Healthcare Cost and Utilization Project.[[11](#_ENREF_11)] It includes anonymized data on primary and secondary discharge diagnoses and procedures from more than 7 million hospitalizations annually. The NIS dataset was designed to approximate 20% stratified sample of United States community hospitals and provides sampling weights to calculate national estimates that represent more than 95% of the US population.

***Study Design and Population***

All hospitalizations during which adults (≥18 years) underwent transvenous CIED lead extraction or replacement were retrospectively analyzed. The cohort was stratified according to the CS facilities of the hospital in to 2 groups; ‘off-site CS’ and ‘on-site CS.’ Unique identifiers of hospitals that performed any CS procedures throughout the study period were used to identify facilities with on-site CS backup. Missing records (n=52,658) for age, gender, admission or discharge date, length of stay and mortality were excluded from the analysis, as were cases of surgical lead extraction. A flow diagram illustrating the selection process and missing variables in the present study is presented in Supplementary Figure 1.

Hospital volume was identified classified as high or low, based on the mean annual volume of each participating center during the years of their participation in the survey, in to ‘low-volume’ (<30 cases per annum) and ‘high-volume’ (≥30 cases per annum) categories, guided by the European Heart Rhythm Association (EHRA) criteria for ‘high-volume’ centers. [[12](#_ENREF_12)]

CIED lead extraction procedures, patient characteristics, comorbidities, and clinical outcomes were extracted using the International Classification of Diseases, ninth revision (ICD-9) and Clinical Classification Software (CCS) procedure and diagnosis codes provided in the supplements (Supplementary Table 1); procedure-related bleeding, cardiac complications (composite of cardiac tamponade, hemopericardium, pericardiocentesis or coronary dissection) and thoracic complications (composite of acute pneumothorax or hemothorax, with or without drainage, or thoracic vascular injury).

***Outcomes***

The primary outcome measures were in-hospital rates of mortality, major acute cardiovascular events (MACE), mortality, and procedure-related bleeding. In-hospital MACE was defined as a composite of mortality, cardiac complications and thoracic complications.

The secondary outcome was to examine the predictors of admission to a hospital with on-site cardiac surgery facilities.

***Statistical Analysis***

Statistical analysis was performed using SPSS version 24 (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 analyzed using the chi-squared (X2) test.

Multiple logistic regression was used to identify the adjusted odds ratios (aOR) of 1) adverse outcomes of procedures performed in off-site CS facilities compared to those performed in on-site CS facilities 2) predictors of these outcomes 3) predictors of admission to a hospital with on-site CS facilities. The variables adjusted for in regression analyses are provided in Appendix A of the supplementary material. All adjusted odds ratios are presented with their corresponding 95% confidence intervals between square brackets (aOR [95 % CI]).

Sensitivity analyses were performed to exclude any confoundment by the inclusion of ‘pacemaker lead revision’ ICD-9 CM procedure code 37.75. Furthermore, we generated a propensity-score matched cohort, using nearest neighbor match, that was analyzed for the same crude and adjusted in-hospital outcomes (MACE, mortality, thoracic and cardiac complications, and bleeding).

# Results

A total of 221,606 hospitalizations during which patients underwent transvenous CIED lead extractions, with or without lead replacement, were recorded in the United States between 2004 and 2014. The proportion of procedures performed in hospitals with off-site CS and on-site CS were 12.7% (29,134) and 87.3% (n=192,472), respectively. A summary of patient demographics for each of the study groups is presented in Table 1a. While the total number of CIED lead extractions increased over the study period (14,370 in 2004 vs. 18,280 in 2014, p<0.001), the proportion of extractions undertaken in centers with off-site CS has significantly declined over the same period (21.8% in 2004 vs. 9.6% in 2014, p<0.001). (Figure 1a)

Several key differences are seen between the study groups. Patients admitted to hospitals with off-site CS facilities were older (median age 78 vs. 72 years), less likely to be male (51.1% vs. 60.4%) and to be admitted for an elective procedure (32.8% vs. 39.3%) than those admitted to on-site CS hospitals. Overall, patients whose procedures were undertaken in hospitals with on-site cardiac surgery facilities were higher risk, with a greater burden of comorbidities such as history of ventricular tachycardia (13.3% vs. 5.9%) and ventricular fibrillation (2.2% vs. 0.9%), all-cause infection (26.6% vs. 12.2%), heart failure (45.2% vs. 31.7%), renal failure(17.7% vs. 14.1%) and previous acute myocardial infarction (13.2% vs. 8.7%) (p<0.001 for all). The overall mean Charlson Comorbidity Index (CCI) score was also higher in the on-site CS group (1.43±1.59 vs. 1.23±1.53; p<0.001). The disparity in baseline comorbidities and patient complexity between off-site CS and on-site CS groups have increased over the study years, with incremental rise in the comorbidity burden, overall CCI score and rates of all-cause infection, shock and heart failure in patients admitted to on-site CS hospitals. (Supplementary Table 2; Figure 1b).

In multivariate analysis, several factors were associated with increased odds of admission to a center with on-site CS facilities, including a history of coagulopathy, ventricular tachycardia or fibrillation, heart failure, and patients with an ICD-device in situ (Table 2). In contrast, females and patients admitted during a weekend were less likely to be admitted to an on-site CS facility.

***In-hospital adverse outcomes***

The overall rates of MACE, mortality, thoracic and cardiac complications, and procedure-related bleeding in the entire cohort were 6.8%, 1.8%, 4.3% and 1.2%, and 5.4% respectively (Table 1b, Figure 2a). Higher crude rates of adverse events were observed in the on-site cardiac surgery group (MACE: 7.1% vs. 4.7%; mortality: 1.9% vs. 1.1%, procedure-related bleeding: 5.9% vs. 1.6%, and complications; thoracic: 4.4% vs. 3.4% and cardiac: 1.3% vs. 0.5; Figure 2a) representing outcomes in a higher risk cohort.

The disparity in clinical outcomes between the study groups were more pronounced as the years progressed, with insignificant differences in the majority of clinical outcomes in earlier years (2004-2006) and the greatest differences seen in the latter years (2010-2012 and 2013-2014). (Figure 2b, Supplementary Table 3)

In multivariate analysis, procedures in the off-site CS group were associated with reduced odds of adverse outcomes including MACE (aOR 0.72 [0.67,0.77], p<0.001), mortality (aOR 0.60 [0.52,0.69], p<0.001), thoracic and cardiac complications (aOR 0.81 [0.75,0.88] and 0.45 [0.38,0.54], p<0.001 for both), and bleeding (aOR 0.48 [0.44,0.54], p<0.001). (Figure 2c).

The strongest predictors of MACE, mortality and cardiac complications included cardiac arrest during admission, previous history of coagulopathy, fluid and electrolyte disorders, pulmonary circulation disorders, and heart failure (only increased odds of MACE and mortality) (Supplementary Table 7). Furthermore, all-cause infection was associated with five-fold increased odds of mortality, while hospitals with an annual extraction volume of less than 30 cases were at 30% increased odds of mortality but no increased risk of other adverse outcomes. (Supplementary table 7) Women were at 20% and 16% increased odds of MACE and cardiac complications, respectively, while gender had no effect on mortality (aOR 0.97 [0.91,1.05], p=0.491).

Amongst the baseline comorbidities, the strongest correlates with procedure-related bleeding and thoracic complications included a history of coagulopathy, chronic blood loss anemia, lymphoma, fluid and electrolyte disorders and pulmonary circulation disorders. (Supplementary table 7). Females were at 30% increased odds of thoracic complications (OR 1.30 [1.24, 1.36]) and 12% increased odds of procedure-related bleeding (aOR 1.30 [1.24, 1.36]) compared to males (p<0.001 for both).

Notably, each point of CCI score was associated with 10% and 15% increased odds of MACE and mortality, respectively, and 13% increased odds of procedure-related bleeding.

***Sensitivity analysis and Propensity-score matching***

 The patient demographics of the propensity-score matched cohort are presented in the supplements (Supplementary Table 4). Furthermore, a distribution of the propensity scores and absolute standardized difference in means of the original and matched cohort are illustrated in Supplementary Figures 2 and 3, respectively.

 The crude rates of adverse events were higher in the on-Site CS group compared to the off-site CS group in the propensity-matched cohorts, similar to those observed in the full cohort (MACE: 6.8% vs. 4.3%; mortality: 1.8% vs. 0.8%, thoracic and cardiac complications: 4.1% vs. 3.2% and 1.5% vs. 0.5%, and bleeding: 5.0% vs. 1.6%). (Table 1b) Furthermore, multivariate analysis of the propensity matched cohort demonstrated a highly comparable adjusted odds of adverse outcomes in the propensity matched cohort to that of the full cohort with reduced odds of all outcomes in the off-site CS group. (Supplementary table 5)

 In another sensitivity analysis that excluded pacemaker revision procedures, the crude rates of adverse events were still higher in the on-site CS group (MACE: 7.4% vs. 4.7%; mortality: 2.4% vs. 1.4%; thoracic and cardiac complications: 4.5% vs. 3.2% and 1.2% vs. 0.4%; bleeding: 7.0% vs. 1.7%). (Supplementary Table 6). Multivariate analysis did not materially change the results and produced similar adjusted odds for all outcomes compared to those derived from the full cohort (Supplementary table 5).

# Discussion

 Our national analysis of 221,606 hospitalizations for transvenous CIED lead removals is the first and largest descriptive study to provide insight into the characteristics and outcomes of patients undergoing these procedures according to cardiac surgery facilities in hospitals. We have observed a change in practice over the study decade with a shift towards more procedures taking place in hospitals with on-site CS in compliance with guideline recommendations.[[5](#_ENREF_5)] Our analysis highlights significant differences in the risk profile and clinical characteristics of patients undergoing CIED lead extractions depending on the admitting hospital CS facilities, with hospitals that have on-site CS support often managing more complex and comorbid patients at higher odds of adverse cardiovascular events compared to centers without CS support. We observe that CIED lead extraction procedures, with or without lead replacement, in centers without on-site CS are not associated with increased odds of adverse outcomes, including mortality, bleeding, thoracic and cardiac complications, compared to procedures in centers with on-site CS facilities, albeit in lower risk and less comorbid patients.

 CIED lead extraction are associated with risks of major complications including vascular laceration, cardiac avulsion, cerebrovascular accidents and even death. [[5](#_ENREF_5)] The reported frequency of these complications is as high as 4.1% in previous studies. [[5](#_ENREF_5), [7](#_ENREF_7), [13](#_ENREF_13)] Almost all contemporary studies that looked at outcomes of CIED lead extractions reported major complications.[[7](#_ENREF_7), [14-16](#_ENREF_14)] However, the majority of outcomes data is generated from tertiary centers with higher operator skill and volume, and greater likelihood of on-site cardiac support, which is a recommendation in current HRS guidelines.[[5-8](#_ENREF_5), [17](#_ENREF_17), [18](#_ENREF_18)]This leaves a gap in evidence on the differences in clinical characteristics and outcomes of patients undergoing CIED lead extractions between centers with and without on-site cardiac surgery facilities.

Our study is the first to provide a real-world perspective on the differences in complications and mortality associated with CIED lead extractions, depending to the presence of cardiac surgery support, in an unselected national cohort of US hospitalizations. We find that patients admitted to centers without on-site cardiac surgery are generally older and yet less comorbid, with a lower prevalence of cardiovascular risk factors, compared to those admitted to centers with on-site cardiac surgery, and that these differences became more pronounced throughout the study years. The rates of overall in-hospital mortality, procedure-related bleeding, thoracic and cardiac complications were 1.8%, 5.4%, 4.3% and 1.2%, respectively, in CIED lead extraction procedures in the US, which is higher than previous figures reported from single center studies. [[8](#_ENREF_8), [10](#_ENREF_10), [18](#_ENREF_18), [19](#_ENREF_19)] These complication rates were higher in patients admitted to centers with on-site CS support, although they were more comorbid and critically ill, as evidenced by their higher prevalence of cardiovascular risk factors, all-cause infection, shock and mean CCI score. The disparity in outcomes between centers with and without CS facilities has increased over the years due to the increased complexity of patients admitted to centers with on-site CS facilities who are increasingly comorbid and complex compared to patients admitted to centers without on-site CS facilities. Although these differences persisted after adjustment for baseline comorbidities, it is likely that there is an element of underlying residual confounding, as procedural complexity, lead dwell time, lead type (atrial vs ventricular, ICD versus pacemaker lead, single versus dual coil lead, leads with increased complexity of extraction such as Riata, Fineline) are not fully captured by administrative databases such as the NIS, and factors such as frailty, LV function, eGFR that are known to impact on outcomes are not recorded.

 Several predictors of mortality and complications have been described in previous studies, including the age at the time of explant, female gender, the presence of local or systemic infection, diabetes mellitus and operator experience. [[8](#_ENREF_8), [9](#_ENREF_9), [18](#_ENREF_18), [20](#_ENREF_20), [21](#_ENREF_21)] In the LEXICON study, patients with pocket-device infections undergoing CIED lead extractions were at a 10-fold increased odds of in-hospital mortality compared to those undergoing CIED lead extractions for other indications.[[18](#_ENREF_18)] Similarly, in a study of 1079 patients undergoing implantable cardioverter-defibrillator lead extractions by Brunner et al., severe LV dysfunction was associated with a 2-fold increased odds of major complications while end-stage renal disease increased the odds of mortality by 5 folds. [[8](#_ENREF_8)] In our analysis, the strongest correlates with in-hospital mortality and major (thoracic and cardiac) complications were cardiac arrest and shock during admission. All-cause infection was also associated with a 5-fold increased odds of mortality, in line with previous reports.[[18](#_ENREF_18), [22](#_ENREF_22)] Our analysis reveals other risk factors that equally signify increased odds of mortality and complications in addition to those previously described, such as previous history of coagulopathy, pulmonary circulation disorders, and valvular heart disease. Furthermore, we show that the overall burden of comorbidities, as measured by CCI score, correlated with mortality and thoracic complication regardless of the type of comorbidity. Each additional point in CCI score was associated with 10% increased odds of MACE and 15% increased odds of mortality. The latter finding supports the objective evaluation of comorbidity burden in patients undergoing CIED lead extraction.

While gender had no effect on mortality in our analysis, women were associated with increased odds of procedure-related bleeding (12%) and major complications (30% and 16% increase in thoracic and cardiac complications, respectively). However, these rates were significantly less than findings from a previous study by Byrd et al. that reported a 4-fold increase in major complications in women undergoing pacemaker lead extractions between 1989 and 1993. [[21](#_ENREF_21)] A possible explanation to the higher odds of CIED procedure-related complications in females was their lower body weight and anatomical differences, such as smaller vessel diameter. [[23](#_ENREF_23)] It is possible that the lower odds of complications in women in our contemporary cohort are explained by the advancements in lead extraction devices and removal techniques, although gender outcomes in this area remain under-researched.

An inverse relationship exists between hospital volume and CIED lead extraction complication rates.[[7](#_ENREF_7), [24](#_ENREF_24)] A recent meta-analysis of 18,493 patients from 66 observational studies shows higher rates of minor complications and 30-day mortality, but no difference in procedure-related mortality, after CIED lead extractions in high-volume centers (≥30 patients/year or 130 cases globally) compared to low-volume centers (<15 patients/year).[[7](#_ENREF_7)] In contrast, findings from the prospective ELECTRa registry showed a higher rate of both in-hospital major complications and in-hospital mortality in low volume centers (<30 cases/year) compared to high volume centers (≥30 cases/year) (2.4% [95% CI 1.9–3.0%] vs. 4.1% [95% CI 2.7–6.0%], P = 0.0146; and 1.2% [95% CI 0.8–1.6%] vs. 2.5% [95% CI 1.5–4.1%] P = 0.0088, respectively). However, the effect of low center volume on major complications including death did not persist in their multivariate analysis. This could be explained by their small sample size (3510 patients), which has underpowered their study in detecting rare events. In our multivariate analysis of predictors of adverse events, low-volume centers were only associated with 30% increased odds of in-hospital mortality without increased odds of any other in-hospital complication.

The present study also demonstrates that a subset of low-risk patients appears to have safely undergone CIED lead extractions in centers without cardiac surgery facilities, especially those with a high procedural volume, without an increased risk of adverse cardiac outcomes. However, the descriptive nature of our study can only provide insight to cardiologists in to the outcomes of CIED lead extractions according to the admitting centers’ cardiac surgery facilities, and does not advocate safety of CIED lead extractions in centers without such facilities on site. Nevertheless, our study carries important clinical implications and emphasizes the need for a risk-based and multidisciplinary approach to managing patients undergoing CIED lead extractions. While the risk of significant complications requiring surgical intervention were shown to be uncommon in previous studies as well as ours, they would almost certainly result in death if such facilities were not available. [[25](#_ENREF_25)] The present study identifies risk factors associated with major complications from a real-world and national perspective, supporting the idea of a risk-based approach to choosing the venue of extraction.[[26](#_ENREF_26)] Patients at low risk can likely undergo extraction in the electrophysiology laboratory, where cardiac surgery back-up is not promptly available, instead of the operating room.

**Limitations**

There are several limitations to our study. First, the NIS is an administrative dataset that is susceptible to coding inaccuracies. However, ICD-9 codes have been previously validated for the purpose of cardiovascular research.[[27](#_ENREF_27)] The NIS was also found to have comparable capture of patient demographics and a more superior geographic capture of hospitalizations in more than 25 diagnosis groups in comparison to a large multistate electronic health record database.[[28](#_ENREF_28)] Furthermore, owing to the observational nature of the study, the results reported should be not be interpreted as causal in nature, but rather associations that prompt further research. Second, since the NIS dataset does not provide information on pharmacotherapy, dwell time, specific type and position of the extracted lead (atrial vs. ventricular), indication for extraction, and use of laser-assisted/mechanical or snaring techniques, operator experience and hospital staffing levels, we were unable to adjust for the differences in these covariates between the study groups, and therefore, these factors remain as potential residual confounders. We were also unable to identify the rate of failed CIED lead extraction procedures or abandoned procedures as these were not coded. Third, the analysis does not provide data around cause of death so it is unclear whether the deaths reported in our analysis were due to a procedural complication or due to non-related causes, which may confound analysis as patients at surgical centers were more complex and are more likely to sustain non-procedural mortality on the basis of their greater comorbid burden. Furthermore, we report trends in lead extraction procedures up to 2014 and, although we expect the trend of increasing lead extractions in on-site CS to continue, we do not have the data to demonstrate this in later years. Finally, the NIS only reports in-hospital outcomes and, therefore, our findings should be interpreted with caution with regards to long term outcomes, although major complications of CIED lead removals are more likely to occur in the peri-procedural and early post-procedural phase.[[7](#_ENREF_7), [13](#_ENREF_13)] It is possible that the disparity in outcomes would become more pronounced in the post hospitalization phase as the more comorbid patients, who were more prevalent in the on-site CS group, could experience worse outcomes. We believe that our findings provide insight into the ‘real world’ in-hospital clinical outcomes of a national and unselected cohort undergoing CIED lead extractions and drive the need for further research in to differences in long term outcomes between patients undergoing CIED lead extractions in centers with and without cardiac surgery backup.

# Conclusion

 In a temporal analysis of a national cohort of transvenous CIED lead extractions according to hospital cardiac surgery facilities, we demonstrate a shift towards more procedures being undertaken in on-site cardiac surgery centers in compliance with contemporary guidelines. Patients admitted to centers with on-site CS facilities are becoming increasingly comorbid and more critically ill, and remain at a higher risk of adverse outcomes compared to those admitted to centers without such facilities.

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**Figure Titles and Legends**

**Figure 1a. Percentage of extractions at centers with off-site cardiac surgery (CS) facilities**

**Figure 1b. Mean Charlson Comorbidity Index according to admitting centers’ cardiac surgery (CS) status (2004-2014)**

**Figure 2a. In hospital adverse events of study groups**

Legend: \***MACE:** Composite of mortality, thoracic complications and cardiac complications; CS: cardiac surgery

**Figure 2b. Trends in in-hospital adverse events form 2004-2014**

Legend: \*non-significant (p≥0.05); † p<0.05; †† p<0.001

**Figure 2c. Adjusted odds ratios (aOR) of adverse outcomes according to admitting hospital cardiac surgery (CS) facility**

Legend: \***MACE:** Composite of mortality, thoracic complications and cardiac complications