# Rates of and Indications for Subcutaneous ICD Extraction: A Multihospital Healthcare System Analysis

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**Abstract**

**Introduction**: The subcutaneous implantable cardioverter defibrillator (S-ICD) is an alternative to a transvenous ICD in patients who meet criteria for ICD implantation without concurrent need for cardiac pacing. The objective of this study is to examine the rates of and indications for S-ICD removal and extraction. **Methods**: A retrospective analysis of all patients who underwent S-ICD implantation between 2010 and 2022 at a single multihospital healthcare system was performed. The primary endpoint was S-ICD removal or extraction. Patient and device characteristics were abstracted from the electronic medical record. Univariate and multivariate analyses were completed to determine factors associated with S-ICD extraction. **Results**: A total of 372 patients (69.5% male; 48.6 ± 14.4 years old) underwent S-ICD implantation during the study period. There were 22 (5.9%) patients (81.8% male; 52.1 ± 13.2 years old) who underwent S-ICD extraction over a median follow up period of 4.4 [2.0-6.5] years. The median length of time between implantation and extraction was 39.6 [8.3-64.6] months. The most common indications for S-ICD extraction were need for bradycardia pacing (incidence, 1.08%), infection (1.34%), and inappropriate shocks due to oversensing (1.34%). A smoking history and higher body mass index were independently associated with S-ICD extraction. **Conclusions**: The overall rate of S-ICD extraction over 4.4 [2.0-6.5] years was 5.9%, with the most common indications for extraction being need for bradycardia pacing, infection, and inappropriate shocks due to oversensing. A smoking history and high body mass index are associated with increased rates of S-ICD extraction. With appropriate patient selection for the S-ICD, the need to remove the device after implantation is low.

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**Methods** : A retrospective analysis of all patients who underwent S-ICD implantation between 2010 and 2022 at a single multihospital healthcare system was performed. The primary endpoint was S-ICD removal or extraction. Patient and device characteristics were abstracted from the electronic medical record. Univariate and multivariate analyses were completed to determine factors associated with S-ICD extraction.

**Results** : A total of 372 patients (69.5% male; 48.6 ± 14.4 years old) underwent S-ICD implantation during the study period. There were 22 (5.9%) patients (81.8% male; 52.1 ± 13.2 years old) who underwent S-ICD extraction over a median follow up period of 4.4 [2.0-6.5] years. The median length of time between implantation and extraction was 39.6 [8.3-64.6] months. The most common indications for S-ICD extraction were need for bradycardia pacing (incidence, 1.08%), infection (1.34%), and inappropriate shocks due to oversensing (1.34%). A smoking history and higher body mass index were independently associated with S-ICD extraction.

**Conclusions** : The overall rate of S-ICD extraction over 4.4 [2.0-6.5] years was 5.9%, with the most common indications for extraction being need for bradycardia pacing, infection, and inappropriate shocks due to oversensing. A smoking history and high body mass index are associated with increased rates of S-ICD extraction. With appropriate patient selection for the S-ICD, the need to remove the device after implantation is low.

**Key Words:** subcutaneous, ICD, extraction, rate, indications

**Introduction:**

The subcutaneous implantable cardioverter defibrillator (S-ICD) is an alternative to a transvenous ICD (TV-ICD) in patients who necessitate prevention from sudden cardiac death without a concurrent need for cardiac pacing.[1, 2] Current factors considered by clinicians when determining the appropriate type of ICD to implant include ECG characteristics, body habitus, comorbidities, and patient preference.[3-6] In addition, the 2017 American Heart Association/American College of Cardiology/Heart Rhythm Society (AHA/ACC/HRS) guidelines give a class I recommendation to S-ICDs over TV-ICDs in patients with high infectious risk, tricuspid regurgitation, and challenging venous access.[7-12] One of the most common indications for extraction or removal of any ICD is device infection. However, other S-ICD patients are later determined to need bradycardia pacing, cardiac resynchronization pacing, or antitachycardia pacing (ATP) for recurrent monomorphic ventricular tachycardia and require device removal and transvenous device

implantation. To date, there are limited data on the how often a patient who undergoes implantation of the S-ICD eventually needs to have the system removed and for which reasons. Only two real-world studies have been published on rates of S-ICD extraction with discordant extraction rates from 2.85% to 12.9%.[13-14] Better characterizing rates of system extraction may provide insight into the overall risk of the S-ICD in specific patient populations, and indications for S-ICD extraction may further inform device selection. Accordingly, the goal of the present study is to assess incidence of and indications for S-ICD extraction in a large, multihospital healthcare system.

**Methods:**

*Study Design and Population*

This is a retrospective study of all patients [?] 18 years old who underwent S-ICD implantation between 2010 and 2022 in a single multihospital healthcare system (Northwestern Medicine, Chicago, IL). Northwestern Medicine is comprised of four tertiary or quaternary care hospitals within a single metropolitan area. All hospitals share a single electronic medical record. Patients who were referred for S-ICD extraction but underwent S-ICD implantation at another institution were excluded from the analysis to ensure that the study population underwent implantation according to a standardized protocol and were followed internally for electrophysiologic care. Patient demographics, clinical characteristics and procedural information were retrospectively abstracted from the electronic medical record for all S-ICD implantation procedures. The primary endpoint of this study was S-ICD removal or extraction, collectively referred to as extraction. If a patient underwent extraction, further clinical information was collected in a retrospective manner from the time of extraction. This study was approved by the Northwestern University Institutional Review Board.

*S-ICD Implant Procedure and Follow Up*

S-ICD implantation followed a standard protocol that has been previously published.[15] After implantation, all patients were seen in clinic for a 1-week device and wound check. Their devices were then followed remotely every three months, and patients were seen in clinic at least yearly. Patients were encouraged to return to clinic immediately with any new cardiovascular symptoms.

*S-ICD Extraction Procedure*

All S-ICD extraction procedures were performed in an electrophysiology lab under general anesthesia, monitored anesthesia care, or conscious sedation. The patient was positioned in the same fashion as for S-ICD implantation. The generator was accessed by making an incision over the existing scar, and sharp or blunt dissection was performed until the generator was visualized. After the generator was disconnected from the lead, another incision was made over the subxiphoid scar to release the suture sleeve. If a three-incision technique was used for S-ICD implantation, a third incision was made over the superior sternum to release the distal lead suture. After all lead tie-down sutures were cut, the S-ICD was removed with manual traction. No transvenous lead extraction tools were required for successful removal. All incisions were closed in three layers following system extraction.

*Definition of Variables*

A patient's sex was categorized as male or female at the time of birth. Body mass index (BMI) was calculated as mass divided by the square of the height ($kg/m^2$). A patient's race was categorized as White, African American or Black, or other based on self-reported race within the electronic medical record. Duration of follow up was defined as the time elapsed between date of implantation to the last date of chart entry in a patient's electronic medical record.

*Statistical Analysis.*

The primary indications for S-ICD implantation across all study participants were analyzed. Study participants were then categorized into two groups based on whether they underwent S-ICD extraction. Univariate analyses were completed using chi-square or Fisher exact tests for categorical variables, and Student's T Tests or Mann-Whitney U Tests for continuous variables as appropriate. Preprocedural variables with a

p value of <0.05 on univariate analysis and those with an a priori association with device extraction were included in a multivariate model. Subgroup analyses were performed within cohorts based on indication for extraction. All statistical analyses were conducted using SPSS Version 26 (IBM, Armonk, NY).

**Results:**

A total of 372 patients (69.5% male; 48.6 +- 14.4 years old) underwent S-ICD implantation during the study period. The most common indications for S-ICD implantation included primary prevention in patients with heart failure with reduced ejection fraction (39.3%), secondary prevention of ventricular tachyarrhythmias (31.1%), and primary prevention in patients with hypertrophic cardiomyopathy with high-risk features (17.2%). There were 22 (5.9%) patients (81.8% male; 52.1 +-13.2 years old) who underwent S-ICD extraction during a median follow-up period of 4.4 [2.0-6.5] years. The baseline characteristics of the study population are listed in Table 1. For all patients, no extraction tools were required to extract the S-ICD, highlighting that S-ICD extraction, when indicated, is uncomplicated.

The median length of time between implantation and extraction was 39.6 [8.3-64.6] months. The most common indications for S-ICD extraction were need for bradycardia pacing (frequency among extractions, 18.2%), infection (22.7%), and inappropriate shocks due to oversensing (22.7%) (Figure 1). Other common indications for S-ICD extraction included need for cardiac resynchronization pacing (9.1%), failure to shock (4.6%), heart transplantation (9.1%), and patient preference (13.6%). No patients required S-ICD extraction for ATP. Programming changes were unsuccessful in two of the five patients who presented with inappropriate shocks due to oversensing. For the other three patients, oversensing could not be overcome with changes in programming. One patient had lead coiling and significant retraction of the lead body, raising concern for Twiddler's syndrome. For the second patient, the S-ICD electrode causing excessive noise was under the Boston Scientific advisory for premature electrode fracture; thus, the device was extracted. The third patient had already undergone revision of her S-ICD parasternal lead in years prior, but re-presented with inappropriate shocks due to oversensing of noise that was reproducible with isometric exercises in all three vectors. Univariate analysis demonstrated that a history of smoking (P=0.01), lower left ventricular ejection fraction (P=<0.001), and history of atrial fibrillation (P=0.02) were associated with S-ICD extraction (Table 1).

A multivariate analysis was conducted of all factors with P<0.05 on univariate analysis as well as BMI, given its established increased risk of shock failure in obese patients.[16,17] This analysis revealed that both a history of smoking (p=0.02) and BMI (p=0.03) were independently associated with S-ICD extraction (Table 2). Specifically, patients whose devices were extracted smoked, on average, 13.9 pack years more than those patients who did not undergo device extraction ($t$ (370)=3.99, P=0.0001). Patients whose devices were extracted had BMIs, on average, 3.91 kg/m$^2$ higher than those patients who did not undergo device extraction ($t$ (370)=2.31, P=0.02).

Subgroup analyses by indication for extraction were performed. Only variables with *a priori* clinical association with extraction for a particular indication were assessed to avoid multiple testing. In comparing those whose devices were extracted for all pacing needs (N=6) with those whose devices were not extracted, no significant differences in baseline PR interval (P=0.78) or QRS duration (P=0.39) were found on univariate analysis. Patients who underwent S-ICD extraction for inappropriate shocks (N=5) had higher BMIs than patients who did not undergo extraction (P=0.01). Finally, compared to patients who did not undergo device extraction, patients whose devices were extracted due to infection (N=5) were more likely to have a history of smoking (P=0.03), have a history of prior pocket infection (0.01), and have elevated BMIs (P<0.001) (Table 3). The bacteria found to be responsible for these new pocket infections included Stenotrophomonas maltophilia, Streptococcus agalactiae, Streptococcus mitis, Staphylococcus aureus, and Enterococcus.

**Discussion:**

In this retrospective cohort study, an S-ICD extraction rate of 5.9% was identified over a median follow-up period of 4.4 [2.0-6.5] years with a median length of implantation of 39.6 [8.3-4.6] months. The most common indications for S-ICD extraction or removal were need for bradycardia pacing, infection, and inappropriate

shocks due to oversensing. Both a history of smoking and a higher BMI were independently associated with S-ICD extraction.

Prior studies have investigated common complications leading to S-ICD extraction. A pooled analysis of patients from the S-ICD IDE study and EFFORTLESS registry cited an incidence of S-ICD extraction for pacing needs of 0.4% and an incidence of infection requiring extraction or revision of 1.7%.[18] A secondary analysis on the PRAETORIAN trial showed that though S-ICDs caused lower rates of lead-related complications (1.4% in S-ICDs vs. 6.6% in TV-ICDs, p<0.001) and systemic infection (0% in S-ICDs vs. 1.2% in TV-ICDs, p=0.03), they were still shown to cause greater rates of pocket bleeding (22.2% in S-ICDs vs. 4.1% in TV-ICDs).[18,19]A large tertiary center study at the University Hospital Munster cited several complications of S-ICDs including oversensing with inappropriate shock delivery, need for pacing, hematoma, infection, hypermobility and ineffective shocks; however, those requiring S-ICD extraction were only in patients who had a need due to oversensing (incidence, 0.85%), new pacing requirements (0.57%), ineffective shock (0.28%), and infection (0.57%) with a total extraction rate of 2.85%. Other complications, such as pocket hematomas, device position change, and re-programming to correct oversensing, were corrected via revisions only.[13] In April 2022, the University of Pennsylvania published a study which cited an incidence rate of S-ICD extraction rate of 12.9% with a mean dwell time of 20 months. Indications for extraction cited in this study included infection (incidence rate, 5.12%), improper device sensing (3.90%), pacing need (2.93%), heart transplantation (1.71%), patient discomfort (0.73%), and other less common device technical issues.[14] These two studies by the University Hospital Munster and the University of Pennsylvania have shown a wide variability in rates of S-ICD extraction, demonstrating that current understanding of the nature of S-ICD extraction is limited.[13,14] The S-ICD extraction rate found in the current study adds to this limited literature, demonstrating a low S-ICD extraction rate of 5.9% with appropriate patient selection. The present study also found that need for bradycardia pacing (1.08%), infection (1.34%), and inappropriate shocks due to oversensing (1.34%) were the most common specified indications for extraction, consistent with findings from prior studies. Other, less common, indications for extraction included chronic resynchronization therapy needs (0.54%), patient preference (0.81%), heart transplantation (0.54%), and failure to shock (0.27%) (Figure 1).

In addition, several studies have also attempted to identify risk factors associated with S-ICD extraction. The S-ICD Post Approval Study identified four risk factors of S-ICD-related infection: patients with previous ICD implantation (extracted for any reason), age [?] 55 years old, left ventricular ejection fraction [?] 30%, and patients with diabetes.[20] Other studies evaluating risk factors for S-ICD extraction have shown that a history of repeat or multiple implantation procedures, perioperative fever, use of temporary pacing, diabetes requiring insulin, end stage renal disease requiring hemodialysis, crowded operating theaters, immunosuppression, corticosteroid use, the presence of central lines, and malignancy all confer a higher risk for infection associated with the new device.[21-25] Results from the current study add to these prior data and suggest that a history of smoking, elevated BMI, and prior pocket infection are also associated with S-ICD extraction due to infection. While elevated BMI is a factor associated with S-ICD extraction for inappropriate shocks in the present study, it is to be noted that S-ICD implantation in obese patients can be safe and feasible if using appropriate technique.[26]

These results suggest that the S-ICD is usually well tolerated in appropriately selected patients, but care should be taken during S-ICD evaluation in patients with a history of smoking or elevated BMI. Further work must be done to determine whether this study's findings regarding rates of, and indications for, S-ICD extraction are transferrable to other health systems.

Limitations:

The results of this study are limited by its retrospective nature and focus on a single healthcare system. The present study occurred in a large metropolitan center and could capture clinical and sociodemographic characteristics that differ from cohort profiles in other studies. Additionally, there is wide variability in provider preferences when it comes to opting for device implantation in patients who are considered borderline in candidacy for S-ICDs and extracting devices in the setting of local pocket infection rather than treating with

antibiotic therapy.[6] Future analyses may compare indications for S-ICD vs TV-ICD extraction to provide results which may shed light on relative benefits of one ICD system in specific patient populations. Furthermore, device technology improved dramatically during 2010-2022 and could have impacted device-related complication rates and provider preferences. Finally, contemporary studies examining patient outcomes and cost effectiveness have sparked an evolution of device guidelines and expansion of indications for S-ICD implantation, changing how S-ICDs have been implemented over the years.[2, 3, 27] Other factors influencing device selection could be further analyzed including patient's socioeconomic status, patient preferences, and cost.

**Conclusions:**

In appropriately selected patients undergoing implantation of the S-ICD, the likelihood of needing the device removed or extracted was 5.9% over 4.4 years. The most common indications for extraction were need for bradycardia pacing, infection, and inappropriate shock due to oversensing. Those with a history of smoking and those of higher body mass indices are more likely to undergo S-ICD extraction. Further work must be done to determine whether these results regarding rates of, and indications for, S-ICD extraction are transferrable to other health systems.

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**Figures:**

**Table 1. Baseline Characteristics of the Study Population.**

| Variable | Total N=372 | Extraction N=22 | No Extraction N=350 | P-Value |
|---|---|---|---|---|
| **Male Gender** | 257 (69.5%) | 18 (81.8%) | 239 (68.7%) | 0.19 |
| **Implant Age** | 48.6 ± 14.4 | 52.1 ± 13.2 | 48.4 ± 14.4 | 0.74 |
| **Clinical Characteristics** | | | | |
| Diabetes | 102 (27.8%) | 5 (22.7%) | 97 (28.1%) | 0.58 |
| Hypertension | 198 (53.8%) | 9 (40.9%) | 189 (54.6%) | 0.21 |
| Prior TIA/CVA | 16 (4.3%) | 1 (4.5%) | 15 (4.3%) | 1.0 |
| COPD | 17 (4.6%) | 2 (9.1%) | 15 (4.3%) | 0.31 |
| OSA | 78 (21.2%) | 6 (27.3%) | 72 (20.8%) | 0.47 |
| CAD | 134 (36.5%) | 10 (45.5%) | 124 (35.9%) | 0.37 |
| LVEF<35% | 185 (50.7%) | 14 (63.6%) | 171 (49.9%) | 0.45 |
| HFpEF | 15 (4.1%) | 2 (9.1%) | 13 (3.8%) | 0.23 |
| LVEF (%) | 41.3 ± 18.8 | 33.2 ± 13.6 | 41.8 ± 19.0 | **<0.001** |
| BMI (kg/m2) | 30.0 ± 7.8 | 33.6 ± 8.4 | 29.7 ± 7.7 | 0.26 |
| ESRD | 27 (7.3%) | 1 (4.5%) | 26 (7.5%) | 0.61 |
| HLD | 253 (68.4%) | 19 (86.4%) | 234 (67.2%) | 0.06 |
| Smoking | 178 (48.1%) | 17 (77.3%) | 161 (46.3%) | **0.01** |
| Prior Pocket Infection | 13 (3.5%) | 2 (9.5%) | 11 (3.2%) | 0.13 |
| Structural Heart Disease | 179 (50%) | 10 (45.5%) | 169 (50.3%) | 0.66 |
| Ischemic Cardiomyopathy | 102 (27.4%) | 8 (36.4%) | 94 (26.9%) | 0.33 |
| History of AF | 116 (31.4%) | 12 (54.5%) | 104 (29.9%) | **0.02** |
| Immunosuppressed Status | 47 (12.7%) | 3 (13.6%) | 44 (12.6%) | 0.89 |
| **Medication Use** | | | | |
| Beta Blocker Use | 315 (84.9%) | 18 (81.8%) | 297 (85.1%) | 0.68 |
| AAD Use | 81 (21.8%) | 7 (31.8%) | 74 (21.2%) | 0.24 |
| OAC Use | 148 (40.0%) | 13 (59.1%) | 135 (38.8%) | 0.06 |
| Steroid Use | 39 (10.5%) | 4 (18.2%) | 35 (10.1%) | 0.23 |
| **Electrophysiologic Characteristics** | | | | |
| Primary Prevention | 289 (78.3%) | 15 (68.2%) | 274 (79%) | 0.23 |
| PR Interval (ms) | 170 ± 29 | 176 ± 27 | 169 ± 29 | 0.91 |
| QRS Interval (ms) | 100 ± 17 | 107 ± 17 | 100 ± 17 | 0.82 |
| DFT Impedance (ohms) | 72.3 ± 24.2 | 76.4 ± 30.2 | 72.2 ± 24.0 | 0.55 |
| DFTs Completed | 282 (82.0%) | 10 (62.5%) | 272 (82.9%) | 0.05 |
| Prior Generator Change | 84 (23.2%) | 1 (5.3%) | 83 (24.2%) | 0.13 |

For normally distributed continuous variables: mean and standard deviation [SD], Student's T Tests or Mann-Whitney U tests; for categorical variables: n and %, chi-square tests or Fisher exact tests. Bolded values indicate statistical significance at alpha = 0.05.

TIA/CVA indicates transient ischemic attack/cerebrovascular accident; COPD: chronic obstructive pul-

monary disease; OSA: obstructive sleep apnea; CAD: coronary artery disease; LVEF: left ventricular ejection fraction; BMI: body mass index; ESRD: end stage renal disease; HLD: hyperlipidemia; AF: atrial fibrillation; AAD: anti-arrhythmic drug; OAC: oral anti-coagulant; DFT: defibrillation threshold testing.

| Variable | B | S.E. | Wald | Significance |
|---|---|---|---|---|
| LVEF | -0.02 | 0.01 | 1.91 | 0.17 |
| BMI | 0.05 | 0.03 | 4.55 | **0.03** |
| History of Smoking | 1.27 | 0.54 | 5.63 | **0.02** |
| History of AF | 0.80 | 0.46 | 3.00 | 0.08 |
| Constant | -4.84 | 1.14 | 18.06 | <0.001 |

**Table 2. Multivariate Analysis of Patient Characteristics that Predict S-ICD Extraction.**

LVEF: left ventricular ejection fraction; BMI: body mass index; AF: atrial fibrillation.

Bolded values indicate statistical significance at alpha = 0.05.

**Table 3. Univariate Analysis of Patient Characteristics that Predict S-ICD Extraction due to Infection.**

| Variable | Extraction N=5 | No Extraction N=367 | P-Value |
|---|---|---|---|
| Diabetes | 2 (40%) | 100 (27.6%) | 0.62 |
| ESRD | 0 (0%) | 27 (7.4%) | 1.0 |
| Smoking | 5 (100%) | 173 (47.4%) | **0.03** |
| History of AF | 3 (60%) | 113 (31.0%) | 0.18 |
| Prior Pocket infection | 2 (40%) | 11 (3.0%) | **0.01** |
| On OAC | 3 (60%) | 145 (39.7%) | 0.36 |
| Steroids | 1 (20%) | 38 (10.4%) | 0.43 |
| Body Mass Index | 41.3 ± 8.8 | 29.8 ± 7.7 | **<0.001** |

ESRD: end stage renal disease; AF: atrial fibrillation; OAC: oral anti-coagulant; BMI: body mass index.

Bolded values indicate statistical significance at alpha = 0.05.

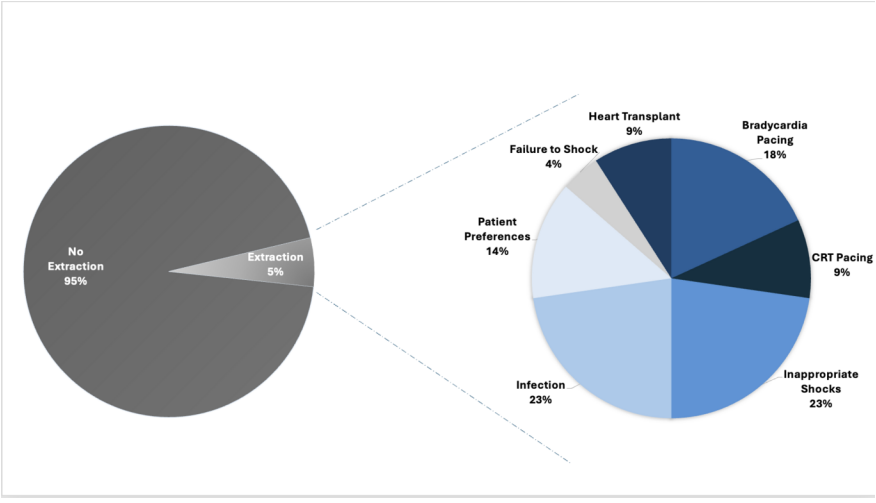

**Figure 1. Indications for S-ICD extraction with respective frequency among extractions** . The most common specified reasons for explantation were need for bradycardia pacing, infection, and inappropriate shocks due to oversensing.