# Navigating complexities in implantable cardioverter-defibrillator therapy: insights, challenges, and patient-centred approaches

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# Part I

Exploring ICD Therapies:
Comparative Clinical Investigations

# Chapter 2

# A Comparison of Long-term Clinical Outcomes of Subcutaneous and Transvenous Implantable Defibrillator Therapy

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## Abstract

**Background**

Transvenous implantable cardioverter-defibrillators (TV-ICD) improve survival in patients at risk for sudden cardiac death, but (lead-related) complications remain an important drawback. The subcutaneous ICD (S-ICD) was developed to overcome lead-related complications. Comparison of clinical outcomes of both device types in previous studies is hampered by dissimilar patient characteristics.

**Objective**

This retrospective study compares long-term clinical outcomes of S-ICD and TV-ICD therapy in a propensity matched cohort.

**Methods**

Analysis of 1160 patients who underwent S-ICD or TV-ICD implantation in two high-volume hospitals in The Netherlands. Propensity matching for 16 baseline characteristics, including diagnosis, yielded 140 matched pairs. Clinical outcomes were device-related complications requiring surgical intervention, appropriate and inappropriate ICD therapy and were reported as five-year Kaplan-Meier rate estimates.

**Results**

All 16 baseline characteristics were balanced in the matched cohort of 140 patients with S-ICDs and 140 patients with TV-ICDs (median age 41 (IQR 30, 52)years and 40% females). The complication rate was 13.7% in the S-ICD group versus 18.0% in the TV-ICD group (p=0.80). The infection rate was 4.1% for S-ICDs versus 3.6% for TV-ICDs (p=0.36). Lead complications were lower in the S-ICD arm as compared to the TV-ICD arm, 0.8% versus 11.5% respectively (p=0.03). S-ICD patients had more non-lead related complications than TV-ICD patients, 9.9% versus 2.2% respectively (p=0.047). Appropriate ICD intervention (ATP and shocks) occurred more often in the TV-ICD group (HR 2.42, p=0.01). Incidence of appropriate shocks (TV-ICD HR 1.46, p=0.36) and inappropriate shocks (TV-ICD HR 0.85, p=0.64) were similar.

**Conclusions**

In this matched cohort of S-ICD and TV-ICD patients the complication rate was similar, but their nature differed. The S-ICD reduced lead-related complications significantly at the cost of non-lead-related complications. Both appropriate and inappropriate shock rates were similar between the two groups. Consideration of these differences in patients eligible for both devices is essential.

# Introduction

Implantable cardioverter-defibrillators (ICD) improve survival of patients at increased risk of sudden cardiac death.[1,2] Advances in ICD programming have reduced the burden of shocks, but device-related complications remain an important drawback of transvenous ICD (TV-ICD) therapy, resulting in significant morbidity.[3] Transvenous sensing and defibrillation leads are associated with both infective and mechanical complications, such as lead endocarditis, pneumothorax, venous occlusion and cardiac perforation.[4,5] Lead failure may cause inappropriate shocks and impede delivery of appropriate therapy for ventricular arrhythmias.[6–8]

The subcutaneous ICD (S-ICD) was designed to eliminate complications related to transvenous leads, but lacks pacing capabilities and can therefore only be used in patients without a need for pacing.[9] Studies of the S-ICD have demonstrated clinical efficacy, but reported also a 13.1% inappropriate shock rate at three-years follow-up, that was significantly reduced with dual zone programming.[10–12] However, direct comparison of clinical outcomes of the available S-ICD cohorts to TV-ICD cohorts is limited by varying patient characteristics, follow-up durations and definition of complications.

The objective of the current retrospective study is to compare long-term clinical outcomes of S-ICD and TV-ICD therapy in a propensity score balanced cohort.

# Methods

## Study Setting

Patients with ICDs implanted in two hospitals in the Netherlands, Academic Medical Center (AMC) and Leiden University Medical Center (LUMC), were included. For this analysis, patients implanted with transvenous single- and dual-chamber ICDs between 2005 and 2014 at the LUMC and S-ICDs between 2009 and 2015 at the AMC were selected. During this period of time, LUMC had not adopted the S-ICD into their clinical practice, and therefore this variation in practice between AMC and LUMC was used to compare the two types of ICD therapy. Patients included in the ongoing PRAETORIAN trial were excluded from this analysis.[13] The need for informed consent was waived in both centers due to the observational nature of the study.

### Study population

At the LUMC 1312 patients received a TV-ICD between 2005 and 2014. In the AMC 148 patients were implanted with an S-ICD between 2009 and 2015. As baseline characteristics were significantly different, we used propensity score matching as the primary analysis. The type of devices used were S-ICDs (Boston Scientific) and TV-ICDs (Biotronik, Boston Scientific, Medtronic and St. Jude Medical). The majority of both S-ICD and TV-ICD patients were implanted under local anesthesia, according to the prevailing local hospital protocol.[14] LUMC is an experienced implantation center for TV-ICDs, as is AMC for S-ICDs and TV-ICDs.

### Data Collection

Data collection in both centers was performed at regular intervals by reviewing medical records for baseline characteristics, implantation data and follow-up data on clinical outcomes, complications and therapy delivery. The survival status of patients was retrieved from municipal civil registries.

### Definition of outcomes

Complications were defined as all device related complications requiring surgical intervention. Lead complications were defined as complications requiring replacement or repositioning of the lead, without elective pulse generator replacement. In addition, lead survival was defined as the time between lead implantation and lead failure, with or without elective pulse generator replacement. Appropriate therapy consists of antitachycardia pacing (ATP) only and shocks (preceded by ATP or not) for ventricular tachycardia (VT) or ventricular fibrillation (VF). Inappropriate therapy consists of ATP and shocks for heart rhythms other than VT or VF. All arrhythmia episodes were adjudicated by the local electrophysiologists.

## Statistical Analysis

### Entire cohort

Categorical variables were presented as numbers and percentages and were compared for the entire cohort with Fisher's exact test. Based on their distributions, continuous variables are presented as mean ± standard deviation or median with interquartile ranges ($25^{th}$, $75^{th}$) and compared with student's t- or Wilcoxon rank-sum test.

### Propensity score matching

Propensity score matching was performed with patients for whom complete baseline variables were available (total n=1154). Analysis of excluded patients due to missing baseline data did not suggest selection bias. We used logistic multivariable regression with device type (S-ICD or TV-ICD) as dependent variable and 16 baseline variables as independent predictors to calculate the propensity score (Table 1). The Harrell's C-statistic for the propensity score logistic regression model was 0.89. Patients were 1-to-1 greedy matched using the nearest-neighbor method. There was sufficient overlap in the propensity scores to individually match each S-ICD case to a TV-ICD control (supplemental figure 1).

### Analysis of the matched cohort

Baseline variables of the matched cohort were compared with paired tests, McNemar and Wilcoxon signed-rank tests and standardized mean differences were calculated. We used the Kaplan-Meier method to correct for difference in follow-up and estimate the cumulative incidence of outcomes at five-year follow-up. P-values and hazard ratios were calculated using conditional proportional hazards (CPH) models with adjustment for ICD programming. CPH assumptions were visually inspected by plotting Schoenfeld residuals.

### Sensitivity analyses

A sensitivity analysis was performed excluding patients exposed to transient external factors: patients implanted with advisory leads, i.e. *Medtronic Sprint Fidelis* and *St. Jude Medical Riata* (n=20) in the TV-ICD group, and an equal number of patients exposed to the operators' learning curve in the S-ICD group. [15,16] Additionally, a sensitivity analysis for patients with a left ventricular ejection fraction ≤35% was performed.

All statistical analyses were conducted in R Studio and R version 3.2.2 and the package MatchIt for propensity matching.[17,18] All reported p-values were 2 tailed, and p-values <0.05 were considered statistically significant.

## Results

### Entire cohort

In the entire cohort, before matching, most baseline variables were significantly different between the two groups (Table 1, left columns). The characteristics of the TV-ICD group represent a typical ICD cohort, with the predominant diagnosis

ischemic cardiomyopathy (64%), significant cardiovascular comorbidity and a median left ventricular ejection fraction of 34%. The S-ICD group is younger with fewer comorbidity, higher left ventricular ejection fraction (50%) and genetic arrhythmia syndromes as the main diagnosis (53%).

### Propensity matched cohort

In the propensity matched cohort S-ICD cases (n=140) were similar to their TV-ICD controls (n=140), with no significant differences in any baseline characteristic (Table 1, right columns). Compared to the entire cohort, the matched cohort was younger with a median age of 41 (30, 52) years and had a higher left ventricular ejection fraction. In the TV-ICD group 124 (88.6%) devices were dual- and 16 (11.4%) were single-chamber. The median follow-up duration was longer in the TV-ICD group than in the S-ICD group: 5 years versus 3 years respectively (p<0.001).

### ICD programming

The conditional zones in S-ICDs and the fast VT zones in TV-ICDs were similar with a median of 190 (180, 200) beats per minute (BPM) and 188 (188, 200) BPM respectively, p=0.77. The unconditional zone in the S-ICD and VF zone in the TV-ICD differed with median 250 (250, 250) BPM and 231 (230, 231) BPM respectively, p<0.001. Defibrillation testing was performed in 92% of S-ICD and 97% of TV-ICD patients. There were 13 (9.3%) patients in the TV-ICD group with >5% bradycardia pacing (atrial or ventricular) in the first year. In the S-ICD group six (4.3%) patients had a concomitant transvenous pacemaker.

## Clinical outcomes

### Complications

The complication rate at five years follow-up was 13.7% (95%CI 6.4-20.3%) in the S-ICD group versus 18.0% (95%CI 10.5-24.8%) in the TV-ICD group, p=0.80 (Figure 1). Table 2 presents the crude number of patients, the type of complications and the Kaplan Meier complication rate, corrected for follow-up duration. Lead complications necessitating surgical intervention that were not performed during elective pulse generator replacement occurred more often in the TV-ICD group (11.5%, 95%CI 5.3-17.2%) compared to the S-ICD group (0.8%, 95%CI 0.0-2.2%), p=0.03 (Figure 2A). Infections occurred in the S-ICD group in 4.1% (95%CI 0.5-7.7%) and in the TV-ICD group in 3.6% (95%CI 0.0-7.1%), p=0.36 (Figure 2B). There were two patients with bacteremia in the TV-ICD group and one in the S-ICD

group, who also had a concomitant transvenous pacemaker. S-ICD patients had more non-lead-related complications (pocket erosion, defibrillation threshold testing failure and device failure) than TV-ICD patients, 9.9% (95%CI 2.0-15.4%) and 2.2% (95%CI 0.0-4.6%) respectively, p=0.047 (Figure 2C). Lead survival was significantly longer in the S-ICD group 99.2% (95%CI 0.0-2.2%) compared to the TV-ICD group 85.9% (95%CI 92.7-78.46%), p=0.02 (Figure 2D).

## Appropriate ICD interventions

Appropriate ICD intervention rates (shocks and ATP) were lower in the S-ICD group 17.0% (95%CI 6.3%-26.4%) versus 31.3% (95%CI 22.6%- 39.7%) (Figure 3A). In the Cox-proportional hazards model adjusted for ICD programming, the HR for appropriate intervention for the TV-ICD group was 2.42, p=0.01. Appropriate shock rates was 17% (95%CI 6.3%-26.4%) in the S-ICD and 21.3%(95%CI 12.6%-27.3%) in the TV-ICD group (Figure 3B). In the Cox-proportional hazards model with adjustment for ICD programming this difference was not significant, TV-ICD HR 1.46, p=0.36.

## Inappropriate ICD interventions

Inappropriate ICD interventions (shocks and ATP) were 20.5% (95%CI 11.5-28.6%) in the S-ICD group versus 29.7% (95%CI 19.7-37.6%) in the TV-ICD group (Figure 3C). The HR for inappropriate therapy, adjusted for ICD programming, in the TV-ICD group was 1.29, p=0.42. The percentage of patients who experienced inappropriate shocks was 20.5% (95%CI 11.5-28.6%) in the S-ICD group and 19.1% (95%CI 11.6-26.0%) in the TV-ICD group (Figure 3D). This difference was not significantly different after adjustment for programming: HR 0.85 for TV-ICD group, p=0.64. In 94%, inappropriate shocks from TV-ICDs were for supraventricular tachycardia (atrial fibrillation, atrial flutter and sinus tachycardia). In 85%, S-ICD inappropriate shocks were for oversensing and in 15% for supraventricular tachycardia.

## Follow-up

Five year patient survival was 96.0% (95%CI 90.1-100.0%) in the S-ICD arm and 94.8% (95%CI 90.7-99.0%) in the TV-ICD arm, p=0.42. Pulse generator replacement due to battery depletion did not differ at five-year follow-up, p=0.18. Of S-ICD patients, 1.3% (95%CI 0.0-3.7%) was upgraded to a TV-ICD or cardiac synchronization therapy device (CRT) versus 4.6% (95%CI 0.5-8.5%) in the TV-ICD group to CRT, p=0.26.

### Sensitivity analyses

The first sensitivity analysis that excluded 20 patients implanted with advisory leads (Medtronic Sprint Fidelis and St. Jude Medical Riata) and the 20 chronologic first S-ICD implants to account for the learning curve, did not show difference in clinical outcomes compared to the primary analysis (supplementary tables and figures). The complication rate at five-year follow-up was 14.0% (95%CI 5.4-21.8%) in the S-ICD group versus 13.8% (95%CI 6.3-20.7%) in the TV-ICD group, p=0.36. Of the 20 TV-ICD patients implanted with advisory leads, 8 (41%, 95%CI 14.6-59.7%) leads failed at 5 years. In the chronologic first 20 S-ICD implants there were 3 (15%, 95%CI 0.0-29.3%) complications at five-year follow-up.

The second sensitivity analysis that included patient with a left ventricular ejection fraction of ≤ 35% yielded 38 S-ICD and 51 TV-ICD patients with a median ejection fraction of 25% and 28%, respectively. None of the comparisons for clinical outcomes demonstrated a significant difference between the S-ICD and TV-ICD patients and trends were similar, except for a non-significant trend towards more inappropriate shocks in the S-ICD arm.

## Discussion

### Main findings

The current study provides the first balanced comparison of S-ICD and TV-ICD therapy for clinical outcomes during long-term follow-up. The main findings of this study are as follows: the complication rate was similar, but the nature of the complications differed significantly. Appropriate and inappropriate shocks were delivered at equal rates in both groups. TV-ICD patients received more appropriate and inappropriate therapy when ATP was also taken into account.

### Complications

The complication rate in both groups was similar, but the nature of complications differed significantly as can be expected by the different design of the devices. The weakest link of the TV-ICD system is the lead, which remained true after exclusion of advisory leads. In the S-ICD group, inappropriate sensing resulted in explanation of the device in one patient and in the need for lead repositioning in another. Improvements of the S-ICD algorithm may avoid sensing issues. The observed complication rate at five year follow-up is similar to the SCD-HeFT trial (9% acute and 5% long-term complications during 3.8 years follow-up) and previous reports on complications in younger patients (22% during 4.5 years follow-up).[2,19]

## Therapy

The difference in appropriate therapy may be explained by the ability of TV-ICDs to deliver ATP instantly after VT detection, whereas the S-ICD has a longer charging time that allows non-sustained VTs to terminate. Although ATP has been demonstrated to successfully terminate approximately 70% of VT episodes, it did not result in fewer appropriate shocks in this cohort.[20–23] This may be explained by the fact that patients with ischemic scars represented a minority in this study. The incidences of inappropriate therapy and inappropriate shocks were high in both groups, but are in line with previous publication on young ICD patients.[19] The reasons for inappropriate shocks differed between the two groups: the majority of inappropriate shocks by TV-ICDs were for supraventricular tachycardia and by S-ICDs for cardiac oversensing.

## Other endpoints

This study did not find a difference in patient survival rate, but may be underpowered to detect such a difference. None of the patients died of sudden cardiac death and all spontaneous ventricular arrhythmia were successfully treated in both groups. The number of patients that required upgrade to a CRT device was low, but similar to what has previously been reported.[24] The shorter battery longevity of the S-ICD as projected by the manufacturer was not detected in this analysis, but is likely to be demonstrated with longer follow-up.

## Sensitivity analyses

The first analysis excluded patients that were implanted with advisory leads in the TV-ICD group and during the S-ICD implanter's learning curve. The second analysis only included patients with a left ventricular ejection fraction ≤35%. Both sensitivity analyses yielded results similar to the primary analysis with the complete matched cohort.

## Clinical implications

This study demonstrates that the S-ICD has a significant benefit over TV-ICDs with respect to lead-related complications. This benefit may be greater with longer follow-up. The rate of non-lead-related complications in the S-ICD group may decrease when the technology is fully matured.

Therefore, in the choice of device type, the risk of lead-related complications versus non-lead-related complications needs to be taken into account as well as specific limitations of the S-ICD including the lack of pacing capabilities and the larger pulse generator size. The consideration also needs to include recommended

defibrillation testing in S-ICD implants, which may be omitted in TV-ICDs.[25,26] It is likely that shorter battery longevity of the S-ICD will require more frequent replacements, which are associated with specific risks.[27]

### Limitations

This study has some limitations. First, patients included in the primary analysis represent a category of young ICD patients with little comorbidity from two centers, which may limit the generalizability to the broader ICD population. Also, approximately 15% of all TV-ICD patients from LUMC were included in the analysis. Second, although there were no differences in baseline characteristics in the matched cohort, we cannot exclude residual confounding of unmeasured variables, such as pacing indication at time of implant, due to the non-randomized character of the study. Third, the match between S-ICD and TV-ICD patients would have been more optimal with a higher rate of single-chamber ICDs, as single-chamber ICDs are associated with an approximately one percent lower rate of major complications compared to dual-chamber ICDs during short-term follow-up.[3,28] The observed rate of dual-chamber ICDs was caused by the implanter's preference as opposed to need for chronic bradycardia pacing, a tendency that has been reported in another large cohort as well.[28] Fourth, there may be hospital bias present, which was explored by comparison of dual-chamber ICD complications in both centers and did not reveal a difference.

## Conclusion

In this matched cohort of S-ICD and mostly dual-chamber TV-ICD patients the complication rate was similar, although their nature differed. The S-ICD effectively reduced lead-related complications at the cost of non-lead-related complications. Both appropriate and inappropriate shock rates were similar. Consideration of these differences in patients eligible for both devices is needed.

## Perspectives

### Clinical competencies

The S-ICD is a new and safe treatment modality that reduces lead-related complications, but does not reduce the total complication rate compared to TV-ICDs. The difference in the nature of complications and inappropriate shocks should be considered when selecting the optimal device for a patient.

## Translational outlook

Future randomized studies with more patients and longer follow-up in a broader ICD population (older and more comorbidities) will lead to better understanding of the comparative benefit of the S-ICD with regards to complications, appropriate and inappropriate therapy.

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# Tables

**Table 1:** baseline characteristics of the unmatched and matched cohort

| Variable | Entire cohort | | | | Complete cases propensity-score matched cohort | | | |
|---|---|---|---|---|---|---|---|---|
| | S-ICD group N=148 | TV-ICD group N=1312 | Standardized mean difference[1] | P Value | S-ICD group N=140 | TV-ICD group N=140 | Standardized mean difference[1] | P Value |
| Age, yrs (IQR) | 41 (26, 52) | 62 (52, 70) | 1.303 | <0.001 | 41 (26, 52) | 42 (32, 50) | 0.119 | 0.33 |
| Female | 60 (41) | 276 (21) | 0.431 | <0.001 | 56 (40) | 53 (38) | 0.044 | 0.71 |
| Height, cm (IQR) | 176 (168, 186) | 176 (170, 182) | 0.072 | 0.52 | 176 (168, 185) | 178 (170, 185) | 0.129 | 0.30 |
| Weight, kg (IQR) | 78 (65, 90) | 80 (72, 90) | 0.235 | 0.01 | 78 (65, 90) | 79 (68, 90) | 0.174 | 0.31 |
| Diagnosis | | | 0.715 | <0.001 | | | 0.061 | 0.66 |
| Ischemic Cardiomyopathy | 27 (18) | 841 (64) | | | 26 (19) | 41 (29) | | |
| Genetic Arrhythmia Syndrome | 79 (53) | 240 (18) | | | 75 (54) | 54 (39) | | |
| Non-ischemic Cardiomyopathy | 30 (20) | 179 (14) | | | 28 (20) | 30 (21) | | |
| Congenital Heart disease | 5 (3) | 49 (4) | | | 5 (4) | 12 (9) | | |
| Fam history of SCD | 7 (5) | 3 (0) | | | 6 (4) | 3 (2) | | |
| QRS duration in ms (IQR) | 98 (90, 108) | 104 (90, 120) | 0.373 | <0.001 | 98 (88, 108) | 100 (90, 113) | 0.135 | 0.22 |
| Hypertension | 30 (20) | 503 (42) | 0.488 | <0.001 | 30 (21) | 34 (24) | 0.069 | 0.56 |
| Primary prevention | 97 (66) | 820 (63) | 0.063 | 0.53 | 93 (66) | 86 (61) | 0.105 | 0.38 |
| Left ventricular ejection fraction | 50% | 34% | 0.381 | <0.001 | 50% | 49% | 0.031 | 0.91 |
| De novo implant | 128 (87) | 1261 (96) | 0.346 | <0.001 | 121 (86) | 125 (89) | 0.083 | 0.47 |
| Coronary Artery Bypass Graft | 3 (2) | 317 (24) | 0.649 | <0.001 | 3 (2) | 3 (2) | 0.000 | 1 |
| Myocardial infarction | 34 (23) | 695 (53) | 0.649 | <0.001 | 33 (24) | 38 (27) | 0.084 | 0.48 |

| Variable | Entire cohort | | | | Complete cases propensity-score matched cohort | | | |
|---|---|---|---|---|---|---|---|---|
| | S-ICD group N=148 | TV-ICD group N=1312 | Standardized mean difference[1] | P Value | S-ICD group N=140 | TV-ICD group N=140 | Standardized mean difference[1] | P Value |
| Diabetes | 8 (5) | 233 (19) | 0.413 | <0.001 | 8 (6) | 5 (4) | 0.092 | 0.62 |
| Atrial Fibrillation | 14 (10) | 320 (24) | 0.407 | <0.001 | 13 (9) | 21 (15) | 0.0196 | 0.14 |
| Renal function | | | 0.280 | 0.002 | | | 0.000 | 1 |
| Good (eGFR >60ml/min) | 134 (91) | 1024 (81) | | | 128 (91) | 129 (92) | | |
| Moderate (eGFR 60-30ml/min) | 11 (8) | 214 (17) | | | 10 (7) | 8 (6) | | |
| Poor (eGFR <30ml/min) | 2 (1) | 31 (2) | | | 2 (1) | 3 (2) | | |
| New York Heart Association Functional Class | | | 0.529 | 0.005 | | | 0.013 | 0.92 |
| NYHA I | 109 (74) | 643 (49) | | | 103 (74) | 102 (73) | | |
| NYHA II | 31 (21) | 489 (38) | | | 30 (21) | 31 (22) | | |
| NYHA III | 7 (5) | 162 (12) | | | 7 (5) | 7 (5) | | |
| NYHA IV | 0 (0) | 11 (1) | | | 0 (0) | 0 (0) | | |

[1]Standardized mean difference is the difference in group means divided by the control standard deviation. Absolute values less than 0.2 suggest balance between propensity matched groups.
NYHA- New York Heart Association Classification, eGFR – Estimated Glomerulofiltration Rate, IQR – Interquartile range, S-ICD – Subcutaneous Implantable Cardioverter-defibrillator, SCD – Sudden Cardiac Death, TV-ICD – Transvenous Implantable Cardioverter-defibrillator.

**Table 2:** Clinical endpoints*

| **Complications** | **S-ICD** | **KM-rate** | **TV-ICD** | **KM-rate** |
|---|---|---|---|---|
| Total | 14 | 13.7% | 21 | 18.0% |
| Lead (total) | 1 | | 17 | |
| *Atrial lead failure* | | | 3 | 2.9% |
| *Defibrillation lead failure* | 0 | 0% | 10 | 8.5% |
| *Atrial and defibrillation lead failure* | | | 3 | 2.9% |
| *Displacement* | 1 | 0.8% | 1 | 0.7% |
| Infection | 5 | 4.1% | 4 | 3.6% |
| Erosion | 3 | 3.0% | 2 | 1.5% |
| DFT failure | 1 | 0.7% | 0 | 0% |
| Inappropriate sensing | 2 | 3.2% | 0 | 0% |
| Twiddler Syndrome | 1 | 1.1% | 1 | 0.8% |
| Device failure | 1 | 1.1% | 0 | 0% |
| Pneumothorax | 0 | 0% | 0 | 0% |
| Appropriate Therapy | 12 | 17.0% | 39 | 31.3% |
| *ATP* | | | 28 | 21.8% |
| *Shock* | 12 | 17.0% | 24 | 21.3% |
| Inappropriate shocks | 20 | | 22 | |
| *Oversensing* | 17 | 17.1% | 1 | 1.2% |
| *Supraventricular tachycardia* | 3 | 4.2% | 21 | 17.6% |
| Deceased | 2 | | 6 | |
| *Non cardiac* | 1 | 2.0% | 3 | 2.6% |
| *Cardiac* | 1 | 2.0% | 2 | 1.7% |
| *Unknown* | 0 | 0% | 1 | 0.9% |

*Crude number of patients in the first five years and the for follow-up duration adjusted Kaplan Meier rate.
ATP – Antitachycardia pacing, DFT- Defibrillation Threshold Testing, S-ICD – Subcutaneous Implantable Cardioverter-defibrillator, TV-ICD – Transvenous Implantable Cardioverter-defibrillator.

# Figures

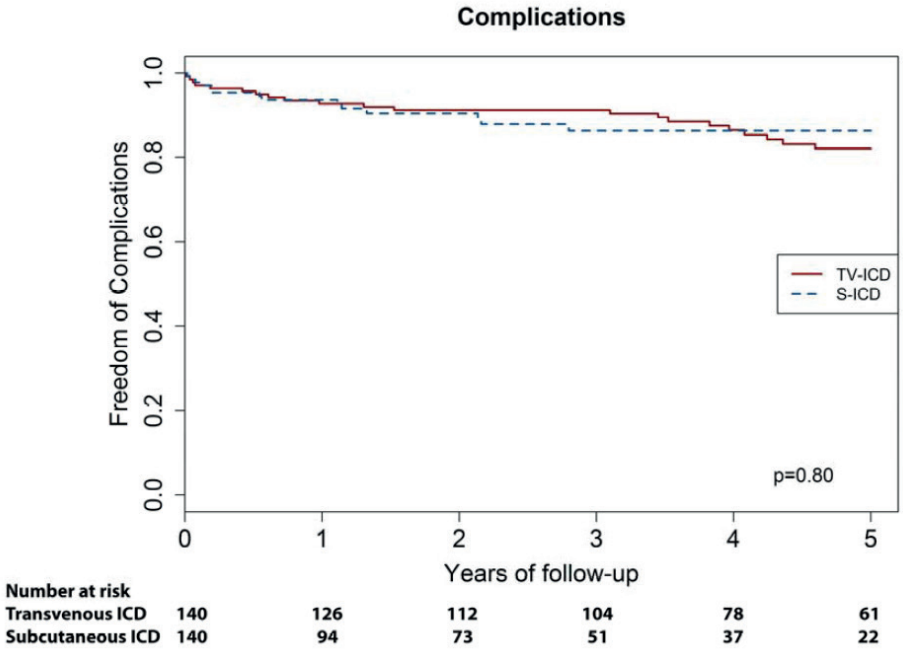


**Figure 1 and Central Illustration:** Kaplan Meier plot of device-related complications in the subcutaneous and transvenous ICD patients in the propensity matched cohort.

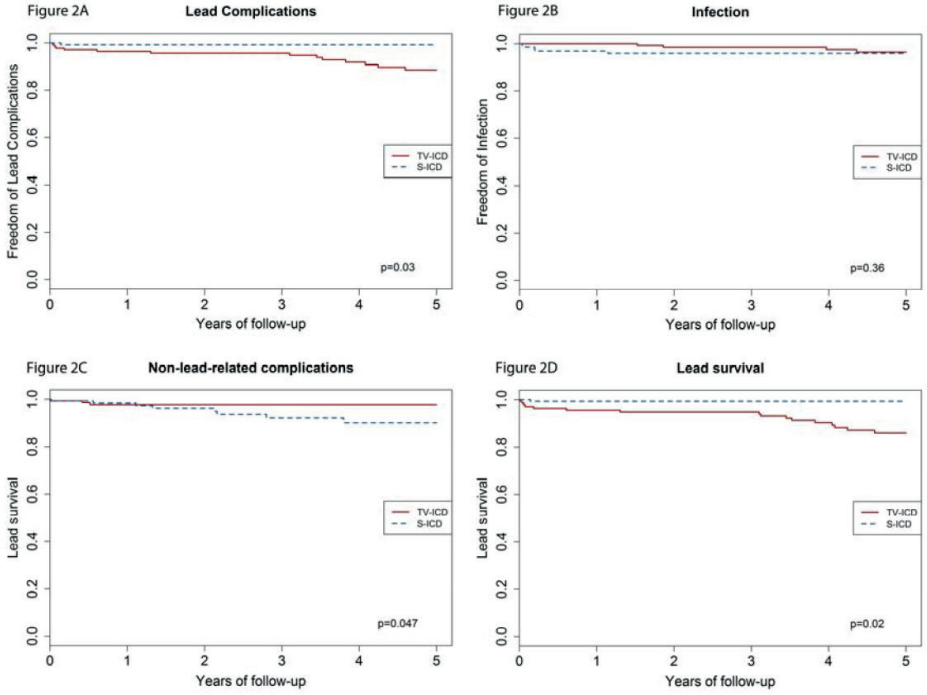


**Figure 2:** Kaplan Meier plot per type of complications: 2A lead related complications, 2B device infections, 2C non-lead-related complications (pocket erosion, defibrillation threshold failure, Twiddler Syndrome, device failure and inappropriate shocks) and 2D lead survival.

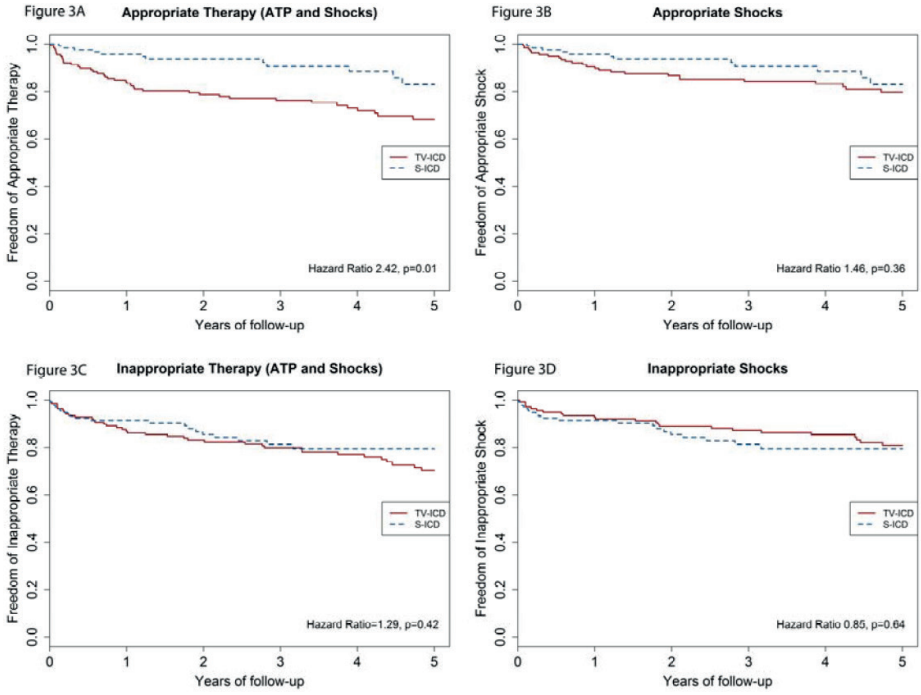


**Figure 3:** Kaplan Meier plot of: 3A appropriate therapy (antitachycardia pacing and shocks), 3B Appropriate shocks, 3C Inappropriate therapy (antitachycardia pacing and shocks) and 3D inappropriate shocks. Hazard Ratio's (HR) are adjusted for ICD programming.