The recent data from the NCDR shows that adoption of S-ICD is increasing, although the AIAC study highlights that some physicians are still reticent to adopt this new therapy. Furthermore, three head-to-head trials have shown multiple benefits of S-ICD over TV ICD, including a significantly lower rate of lead and pacing complications.

A growing body of evidence suggests that S-ICD should be considered in the majority of both primary and secondary ICD recipients. In 448 of 510 cases, a TV-ICD was chosen over an S-ICD. Reasons given included current or expected need for pacing.

The EFFORTLESS registry analysis, which indicated that S-ICD was suitable for the majority of ICD-indicated patients as the system was reprogrammable, and the device size and appearance were patient preference.

Unsuitability of S-ICD: Why not? (n=448)

The low incidence of monomorphic VT and requirement for bradycardia pacing supports previously reported data from the AIAC S-ICD survey, which examined the factors influencing physicians' choice of S-ICD vs TV-ICD.

- In 2012, 3,717 (0.9%) of the 393,734 patients analysed received S-ICDs, making this the largest single analysis of S-ICD therapy adoption in the United States. This retrospective analysis of 383,734 patients reported to the NCDR over 3 years to early 2015, described the adoption of S-ICD in clinical practice in the United States. Implantable outcomes among patients who underwent S-ICD or TV-ICD implantations were compared by Friedman et al.

S-ICDs Implanted, No.  

<table>
<thead>
<tr>
<th>Quarter</th>
<th>2012</th>
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<td>Q4</td>
<td>245</td>
<td>263</td>
<td>246</td>
<td>259</td>
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</table>

Cost of therapy: The cost of S-ICD therapy was not a significant factor in the decision-making process. The majority of physicians were willing to pay for the system.

The ICD therapy adoption increased from 0.4% to 2.0% during the analysis period, and close to 50% of future S-ICD recipients were eligible for an S-ICD based on their risk of infectious complications or on medical indications.
In hospital complication rates for S-ICD recipients were low (3.6%) and were comparable to those with SC-ICD (4.6% and lower) than those with TV-ICD (5.5%).

Furthermore, the S-ICD complication rate was also even lower than the 2% rate found in the IDE study and OFFTREG registry. While the S-ICD cohort had a higher number of complications, including deaths, and higher rates of symptomatic AV block (51 vs. 22) in the TV-ICD group. The S-ICD demonstrated high levels of successful ventricular fibrillation (VF) conversion during defibrillation (thorotest; 95% were defibrillated at 65 J, 89% at 80 J, and 91% at 100 J). While the TV-ICD group may have more overall complications than the TV-ICD group, 19% of patients with TV-ICD, 24% had lead problems. The incidence of implant-related complications in patients with TV-ICD was lower than in patients with S-ICD (6.5% vs. 5.8%).

The risk of device-related complications was reduced in the S-ICD group compared with the TV-ICD group. Overall complication rates were not significantly different between the groups, but the rate of complications differed. Lead-related complications were significantly lower in the S-ICD group than in the TV-ICD group (0.3% vs. 1.7%). The incidence of inappropriate shocks was similar between the two groups (1.2% vs. 1.5%). The incidence of infection was also significantly lower in the S-ICD group than in the TV-ICD group (0.2% vs. 0.6%). The incidence of inappropriate shocks was similar between the two groups (1.2% vs. 1.5%). The incidence of infection was also significantly lower in the S-ICD group than in the TV-ICD group (0.2% vs. 0.6%).

In the TV-ICD group, 3/6 device-related complications were inappropriate shocks due to T-wave oversensing, and were effectively managed by changing the sensing vector. In the S-ICD group, no implant-related complications were observed within 36 days of implantation of the majority of patients, which were appropriately managed by changing the sensing vector.

Inappropriate shocks accounted for only 10 of the 20 complications reported in the TV-ICD group. All but one led to device explantation.

High implant costs and procedural costs, including general anesthesia, were higher for the S-ICD group than for the TV-ICD group. The median total cost of procedures (including hospital stay, procedure-related costs, and the costs of device and/or implantation costs) were significantly lower in the S-ICD group than in the TV-ICD group.

If the rate of device-related complications remains stable over the next 5 years, no cost difference will be apparent between the two groups.

S-ICD had significantly lower complication-related costs than TV-ICD. SICD costs may be mitigated versus TV-ICD costs over a longer period of follow-up.

While the upfront cost of SICD is higher than that of TVICD, SICD demonstrated a higher rate of complications, particularly lead-related complications. SICD costs may be mitigated versus TVICD costs over a longer period of follow-up.

A retrospective study of long-term clinical outcomes of S-ICD vs TV-ICD

A retrospective study by Honarbakhsh et al. analysed 1,150 patients who underwent SICD or TVICD implantation in two high-volume hospitals in The Netherlands between 2005 and 2015, with matching for 16 baseline characteristics yielded 140 matched pairs. A comparative study between S-ICD and TV-ICD showed that SICD costs may be mitigated versus TVICD costs over a longer period of follow-up.

Honarbakhsh et al. conducted a propensity-matched case-control study to compare the safety and efficacy of SICD and TVICD, and performed the first cost-effectiveness analysis of SICD compared with TVICD. All 69 patients, who underwent SICD implantation over a 5-year period in a tertiary centre in London, were included. A total of 626 patients underwent TVICD implantation over the same period, and 496 were matched to the SICD group. Data on device-related complications and mortality were collected during a mean follow-up of 31 months in the SICD group and 36 months in the TVICD group.

The risk of device-related complications was reduced in the S-ICD group compared with the TV-ICD group. Overall complication rates were not significantly different between the groups, but the rate of complications differed. Lead-related complications were significantly lower in the S-ICD group than in the TVICD group (0.3% vs. 1.7%) and lead survival was also significantly higher in the S-ICD group than in the TVICD group (99.2% vs 85.9%). The incidence of infection was also significantly lower in the S-ICD group than in the TVICD group (0.2% vs. 0.6%).

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Inappropriate shocks accounted for only 10 of the 20 complications reported in the TV-ICD group. All but one led to device explantation.

No implant-related complications (occurring within 36 days of implantation) were observed in the SICD group, while two occurred in the TVICD group.

SICD had significantly lower complication-related costs than TVICD. SICD costs may be mitigated versus TVICD costs over a longer period of follow-up.

A retrospective analysis of long-term clinical outcomes of SICD in primary prevention

Boersma et al. analysed 856 patients from the IDE study and the EFFORTLESS Registry. Long-term outcomes were compared for 603 (70.4%) primary prevention (PP) patients, and 253 (29.6%) secondary prevention (SP) patients. Within the PP patients, a secondary analysis compared outcomes for 379 (62.9%) patients with an ejection fraction (EF) ≤ 35% and 149 (24.7%) patients with an EF >35%.

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This study demonstrated that SICD performed well in protecting patients, with either PP or SP implant indications, from SCD, and it supported the consideration of SICD in all primary prevention patients not receiving pacing.

The Italian Heart Rhythm Society (AIAC) survey

Botti et al. surveyed 33 Italian centres between September and December 2015 to analyse the current indications and device choice of SICD. The 2013 procedure performed during the study period, 969 (89%) were de novo implantations. After exclusion of procedures in patients for biventricular pacemaker (2.2%), 853 (86%) were eligible for SICD implantation, but only 426 (50%) actually received an SICD.

SICD: Why?

The most frequent drivers for SICD implantation were young age, long life expectancy and the possibility of avoiding complications. However, a treatment gap still exists between European Society of Cardiology (ESC) guidelines and the practices described in the clinical setting.

SICD survival rate of the preferred treatment option in younger patients with satisfactory indications and for secondary prevention of SCD, consistent with findings from the NORDIC analysis. However, in this study, patients receiving SICD had fewer complications than patients receiving TVICD, whereas the NORDIC study found the opposite.

Suitability of SICD: Why? (n=62)

Device performance was consistent across all indication groups

No significant difference in any outcome was seen between PP and SP patients. Despite the differences in age and comorbidities between groups, there were no differences in inappropriate shock rates or complication rates between the groups.

Complication rates in the PP cohort (8%) were comparable with the PP group (8%). Within the PP group, the mean age of the EF ≤ 35% group was 67 years, which was significantly older than the EF >35% group (mean age 60 years). The patients with EF ≤ 35% had more overall comorbidities than the patients with EF >35%, including higher rates of coronary heart disease, diabetes, hypertension and myocardial infarction. Results were similar between the EF ≥ 35% and the EF >35% groups, with complication-free rates of 82% and 83%, respectively. This consistency in complication rates between the two PP groups is remarkable, considering that long-term complication rates are higher in younger TVICD patients, and TVICD patients with a lower EF.

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