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**EHRA SURVEY**

# Factors influencing the use of subcutaneous or transvenous implantable cardioverter-defibrillators: results of the European Heart Rhythm Association prospective survey

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The purpose of this European Heart Rhythm Association (EHRA) prospective snapshot survey is to provide an overview of the factors influencing patient selection for the implantation of a particular type of device: subcutaneous implantable cardioverter-defibrillator (S-ICD) or transvenous implantable cardioverter-defibrillator (TV-ICD), across a broad range of tertiary European centres. A specially designed electronic questionnaire was sent via the internet to tertiary reference centres routinely implanting both TV-ICDs and S-ICDs. These centres were asked to prospectively include and fill-in this questionnaire for all consecutive patients implanted with an implantable cardioverter-defibrillator (ICD) (both TV-ICD and S-ICD) during an 8-week period of time. Questions concerned standards of care and policies used for patient management, focusing particularly on the reasons for choosing one or the other type of ICD for each patient. In total 20 centres participated at the survey and entered individual data from a total of 429 consecutive patients (men 76.3%). Indication of implantation was primary prevention for 73% of the patients. Implanted devices were distributed between cardiac resynchronisation therapy (CRT) ones with back-up defibrillators (31.6%), single-chamber TV-ICD (29.5%), S-ICD (19.8%), and dual-chamber TV-ICD (19.1%).The rate of S-ICD shows the current penetration of this treatment in everyday practice. Main reasons favouring the use of an S-ICD were young age (66.7%), anticipated (38.9%) or previous (9.3%) lead-related complications, and elevated risk (18.5%) or previous device infection (7.4%). Importantly, the choice for this device was also based on patient preference (16.7%) or active lifestyle (13%). The three most frequent reasons for the use of a transvenous device were the option of antitachycardia pacing (43.2%), and logically, the current or expected need for CRT (40%) or for permanent pacing (39.6%). This snapshot survey with individual patient data provides a contemporary insight into ICD implantation and management in the European electrophysiology tertiary centres. It also helps to better understand the reasons which condition the choice between a S-ICD and a traditional TV-ICD. Finally, it gives a picture of the distribution of various types of ICD, few years after the introduction of the S-ICD in the Europe.

**Keywords** Subcutaneous implantable cardioverter-defbrillator • EHRA survey • Standards of care

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# Introduction

The implantable cardioverter-defibrillator (ICD) is an established treatment for primary or secondary prevention of sudden cardiac death (SCD).[1,2] On the other hand, morbidity associated with these devices has been of great concern,[3,4] and particularly, the presence of a transvenous lead has been one of major weaknesses of these systems.[5,6] The recent development of an entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) represents a major evolution of defibrillator technology,[7–10] and there is consistent clinical evidence regarding its safety and efficacy.[11] Current guidelines state that the S-ICD is a therapeutic option for patients at high-risk of SCD, in whom pacing or cardiac resynchronisation therapy (CRT) is not required.[12] Such indications can explain the growing impact and market share of this device in many European countries, where it is reimbursed. However, this phase of transition is still turbid: current clinical practice of S-ICD use, and particularly the factors that could influence the decision to implant this device, or the traditional transvenous implantable cardioverter-defibrillator (TV-ICD) remain largely unknown among European tertiary centres. The aim of this European Heart Rhythm Association (EHRA) prospective snapshot survey is to provide better insight into ICD utilization across a broad range of European tertiary centres, and to try to identify some important factors that could direct the choice towards the use of an S-ICD or a TV-ICD in a particular patient.

# Methods

A specially designed electronic questionnaire for the collection of individual patient data was sent via the internet to selected tertiary centres that participate in the European Heart Rhythm Association (EHRA) Electrophysiology (EP) Research Network. The local ethics committee approval was obtained where needed, as per local policy. Participating centres were selected according to the following criteria: (i) they needed to be referent centres for the ICD implantation and management in their region; (ii) they had to routinely use both the TV-ICD and the S-ICD; and (iii) the TV-ICD and the S-ICD had to be reimbursed in their country.

In this snapshot survey, a total of 30 questions were focused on standards and policies concerning patients' management, indications and techniques of implantation of the ICDs in the participating EP centres. Many of the questions were directed towards the factors that could influence the choice of the particular type of ICD. The remaining questions were focused on information that allowed for better understanding of utilization of both devices in the current practice.

The participating centres were asked to prospectively include and fill-in the questionnaire for all consecutive patients that were admitted for, and implanted with an ICD (both TV-ICD and S-ICD), during an 8-week period of time, between April and June 2017 (*Figure 1*). All patient data were anonymously collected.

For statistical analyses purposes, continuous variables were presented as mean ± standard deviation (SD), or as median with interquartile range (25th to 75th quartile) if non-normally distributed. Categorical variables were reported as counts with percentages. The Student's *t*-test was used for comparison of continuous variables with normal distribution, and the Mann–Whitney test for those with non-normal distribution. Differences in categorical variables were tested by the $\chi^2$ test. A value of $P < 0.05$ will be considered statistically significant in all analyses.

# Results

## Participating centres

Overall, 20 centres from 6 countries responded, with a wide geographical distribution: 8 centres in France, 6 centres in Poland, 2 centres in Germany, 2 centres in Italy, 1 centre in Switzerland, and 1 centre in Austria. Of these 20 centres, 18 were university hospitals and 2 were private hospitals.

## Patients' characteristics

A total of 429 consecutive patients, mostly men (76.3%), have been implanted with an ICD and included in the survey during the 8-week period. Most of them were older than 55 years: 56–65 (28.5%), 66–75 (25.7%), ≥76 (17.7%). However, a significant proportion were ≤55 years old (28.1%). Interestingly, these data demonstrate a significant prevalence in favour of S-ICD in patients of ≤55 years old, and conversely, of TV-ICD in those older than 65 years ($P < 0.01$) (*Table 1*). Clinical status was mainly New York Heart Association (NYHA) II (53%) and NYHA III (25%), while 21.3% were in NYHA I and only 1% in NYHA IV. Mean ejection fraction (EF) of the cohort was 34 ± 14%.

The majority of included patients (89.3%) had underlying structural heart disease (HD): ischaemic HD (55.4%), dilated HD (29%), hypertrophic HD (6.7%), valvular HD (3%), and other HD (5.9%). Among patients without HD (10.3%), the main reported aetiologies were idiopathic ventricular fibrillation (45%), Brugada syndrome (22.5%), and long QT syndrome (12.5%).

Of note, patients with S-ICD had a higher EF ($P < 0.01$) and were less likely to have HD ($P < 0.01$) than those implanted with TV-ICD (*Table 1*). These two findings are consistent with the need for using cardiac resynchronisation therapy-defibrillator (CRT-D) systems in patients with HD, associated with conduction disturbances and EF < 35%.

Among the comorbidities, the presence of coronary artery disease was very frequent (48%), followed by diabetes (28.2%) and chronic renal failure (14.4%). Interestingly, nearly one-third of the cohort did not report any significant comorbidity (29%). Patients with implanted devices were divided into four groups according to their body mass index: underweight (<18.5 kg/m$^2$: 3.1%), normal weight (18.5–24.9 kg/m$^2$: 47.8%), overweight (25–34.9 kg/m$^2$: 38.6%), and obese (≥35 kg/m$^2$: 10.5%).

## Implantable cardioverter-defibrillator type and indications for implantation

The ICDs distribution was as follows: CRT-D (31.6%), VVI (29.5%), S-ICD (19.8%), and DDD (19.1%).

Patients were in atrial fibrillation in 14.2% of cases. Pacing dependency was found in less than 5% of the patients: 2.9% for sick sinus syndrome and 1.9% for high degree atrioventricular block. In addition, left bundle branch block was reported in 17.2% and right bundle branch block in 5.1% of the patients.

The QRS duration was greater than 150 ms in 29.5% of patients before implantation, which is similar to the rate of CRT-D implantation (31.6%). The incidence of left bundle branch block and wide QRS (>150 ms) was higher in patients with TV-ICD compared to S-ICD group ($P < 0.01$) (*Table 1*).

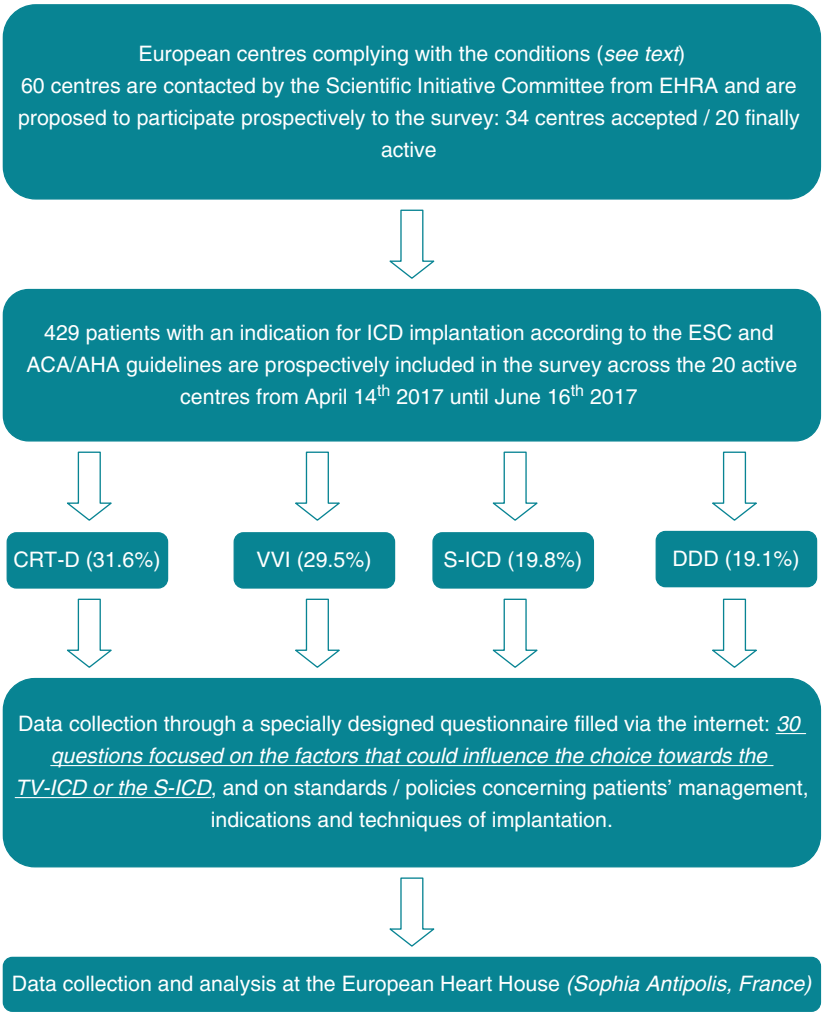


**Figure 1** A flowchart of patients included in the ICD prospective survey from EHRA. CRT-D, cardiac resynchronisation therapy-defibrillator; EHRA, European Heart Rhythm Association; ICD, implantable cardioverter-defibrillator; S-ICD, subcutaneous implantable cardioverter-defibrillator; TV-ICD, transvenous implantable cardioverter-defibrillator.

Devices were implanted for primary prevention, without any documented arrhythmia in 62.2%, and with non-sustained ventricular tachycardia (VT) or syncope in 10.7% of the patients. In patients with secondary prevention ICD (27% of all procedures) indications were as follows: history of cardiac arrest (11.5%), sustained monomorphic VT (11.3%), sustained polymorphic VT (2.1%), or induced VT during EP study (2.1%). The S-ICD devices were reported to be significantly more often implanted in secondary prevention settings ($P < 0.01$) (*Table 1*). This may also be due to CRT-D, which is predominantly used in primary prevention patients.

## Reasons leading to implantation of a subcutaneous or transvenous implantable cardioverter-defibrillator

Main reasons directing towards the use of S-ICD in this survey were young patient's age (66.7%), anticipated (38.9%) or previous (9.3%) lead-related complications, elevated risk (18.5%) or previous device infection (7.4%), desire to preserve vascular system (7.4%), or no adequate venous access (3.7%). Importantly, the choice was also based on patient preference (16.7%) or active lifestyle (13%) (*Figure 2*).

Among factors favouring the use of a transvenous device, besides still significant economic factor (18.5%), the three most important reasons included: the option of antitachycardia pacing (43.2%), and the current or expected need for CRT (40%) or permanent pacing (39.6%). Interestingly, the patient preference (2.9%), size of the device (1.8%), or aesthetical reasons (0.4%), all had negligible impact (*Figure 3*).

# Discussion

This prospective multicentre survey analysing individual patient data from 429 ICD implantations in six European countries provides an insight into contemporary European practice regarding ICD implantation and management. The S-ICD was developed as a simple device to reduce the morbidity associated with ICD therapy (e.g. lead

**Table 1 Baseline characteristics of patients**

| | Total | S-ICD patients (*n* = 76) | TV-ICD patients (*n* = 307) | *P*-value[a] |
|---|---|---|---|---|
| Age[b] | | | | |
| <18 | 4 (1.0) | 2 (2.6) | 2 (0.6) | 0.13 |
| 18–30 | 15 (3.9) | 10 (13.2) | 5 (1.6) | <0.01 |
| 31–45 | 38 (9.8) | 18 (23.7) | 20 (6.5) | <0.01 |
| 46–55 | 52 (13.4) | 18 (23.7) | 33 (10.7) | <0.01 |
| 56–65 | 111 (28.5) | 19 (25.0) | 90 (29.3) | 0.46 |
| 66–75 | 100 (25.7) | 7 (9.2) | 90 (29.3) | <0.01 |
| 76–85 | 67 (17.2) | 2 (2.6) | 65 (21.2) | <0.01 |
| 86 and over | 2 (0.5) | 0 | 2 (0.6) | 0.48 |
| LVEF | 33.8 ± 14 | 43.8 ± 17 | 31.3 ± 12 | <0.01 |
| Structural heart disease | 342 (89.3) | 55 (72.4) | 287 (93.5) | <0.01 |
| Idiopathic VF | 18 (4.7) | 9 (11.8) | 9 (2.9) | <0.01 |
| Brugada syndrome | 9 (2.3) | 8 (10.5) | 1 (0.3) | <0.01 |
| Conduction disturbances at implant | | | | |
| LBBB | 64 (17.2) | 3 (4.0)[c] | 61 (20.4)[d] | <0.01 |
| RBBB | 19 (5.1) | 3 (4.0)[c] | 16 (5.4)[d] | 0.63 |
| QRS duration | | | | |
| <120 ms | 200 (53.6) | 60 (80.0)[c] | 140 (46.9)[d] | <0.01 |
| >120 ms and <150 ms | 63 (16.9) | 14 (18.7)[c] | 49 (16.4)[d] | 0.65 |
| >150 ms | 110 (29.5) | 1 (1.3)[c] | 109 (36.6)[d] | <0.01 |
| Arrhythmia leading to ICD implantation | | | | |
| Primary prevention: no documented VT nor syncope | 232 (62.2) | 42 (56.0)[c] | 190 (63.7)[d] | 0.21 |
| Primary prevention: non-sustained VT or/and syncope | 40 (10.7) | 7 (9.3)[c] | 33 (11.1)[d] | 0.66 |
| Secondary prevention: sustained monomorphic VT | 42 (11.3) | 3 (4.0)[c] | 39 (13.1)[d] | 0.03 |
| Secondary prevention: sustained polymorphic VT | 8 (2.1) | 2 (2.7)[c] | 6 (2.0)[d] | 0.72 |
| Secondary prevention: VF/cardiac arrest survivor | 43 (11.5) | 19 (25.3)[c] | 24 (8.0)[d] | <0.01 |
| Induced VT/VF during EP study | 8 (2.1) | 2 (2.7)[c] | 6 (2.0)[d] | 0.73 |

Figures are in *n* (%) or in mean ± SD unless stated otherwise.
[a]*P*-value for comparisons S-ICD vs. TV-ICD.
[b]Data available for 389 patients in total, but device type specified in 383.
[c]Data available for 75 S-ICD patients.
[d]Data available for 298 TV-ICD patients.
EP, electrophysiologic; ICD, implantable cardioverter-defibrillator; LBBB, left bundle branch block; LVEF, ejection fraction of the left ventricle; RBBB, right bundle branch block; S-ICD, subcutaneous implantable cardioverter-defibrillator; TV-ICD, transvenous implantable cardioverter-defibrillator; VF, ventricular fibrillation; VT, ventricular tachycardia.

dislodgement, infection, etc.), while providing a comparable reduction in the risk of SCD from ventricular fibrillation.[4–6,13,14] We found here some clues to better understand the criteria that govern the choice between the S-ICD and the TV-ICD.

## The picture: current global implantable cardioverter-defibrillator activity in the European tertiary centres

This prospective survey limited by follow-up duration gives a picture of the current ICD activity in European high-reference centres. It confirms some well-known concepts, but also brings new information.

The first and may be the most important novelty is that the rate of S-ICD implantation reported in this survey shows the current penetration of this treatment in everyday clinical practice.

The characteristics of the patients in this survey are broadly concordant with those included in published reports coming from 'real-world' registries.[15–17] We found a much greater proportion of men, a result concordant with data from Spain, showing a five-fold higher implantation rate in men.[15] Similarly, recent analysis of trends in France suggest persisting sex disparities among ICD recipients.[18]

In addition, most patients implanted during our study period were predominantly suffering from ischaemic cardiomyopathy, which is also consistent with other registries.[15–19]

Considering indications, the main reason to implant an ICD in this survey was primary prevention (approximately two-thirds of patients), with only one-third of patients implanted for secondary prevention. This unbalanced distribution has also been observed in many other surveys.[15,16]

Finally, analysing distribution of the device types, our cohort is also in line with other reports, with a stable rate of dual chamber ICD

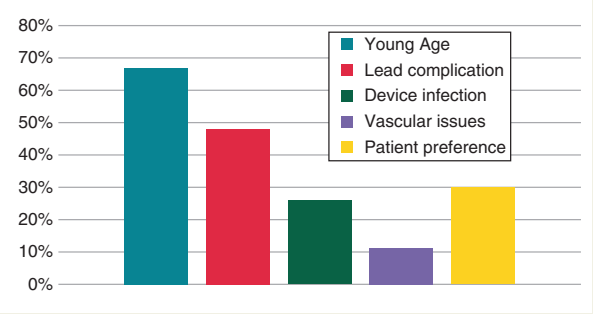


**Figure 2** Factors in favour of S-ICD implantation (multiple answers). Each bar represents one possible answer (proportion of responders to each question). S-ICD, subcutaneous implantable cardioverter-defibrillator.

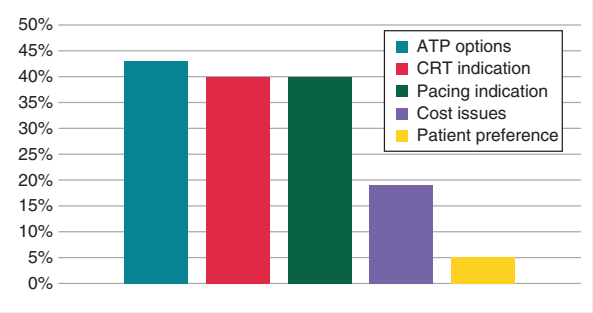


**Figure 3** Factors in favour of a transvenous ICD implantation (multiple answers). Each bar represents one possible answer (proportion of responders to each question). ICD, implantable cardioverter-defibrillator.

implantations (about 20%), with a very significant increase in the number of CRT-Ds during recent years, globally up to about 30% (and even more than 50% in primary prevention patients), and approximately 50% of single chamber ICDs.[15–19] This survey nicely shows that the subgroup of single chamber ICD patients is now comprising a significant proportion of subjects with S-ICD, covering nearly a half of the total number of single chamber ICDs.

## The reasons for selection of an implantable cardioverter-defibrillator type

Reimbursement issues still limit the S-ICD implantation rate across Europe. When this barrier is overcome—for the first time in the real-world practice—our survey clearly reports on the most important reasons favouring one type of ICD over the other.

The first reported reason that directed towards S-ICD implantation was the young age of the patient. The essential issue that immediately arises is: what is the definition of young age? In the setting of an ICD recipient, age can be variously classified. First of all, of course, it can be used an absolute value: subjects <50 or 60 years can be definitely labelled 'young'. However, stratification also depends on the presence of comorbidities, and the perception of family and the patient. In addition, perception of age may significantly vary between countries and economic systems all around the world. Interestingly, previous data have shown that patient survival 10 years after the first ICD device implant is >50% in those subjects younger than 70 years.[20]

Another factor that significantly modifies the perception of age, is the ICD itself. Indeed, this parameter is much more neutral. In addition, it is well known that the risk of lead complications, among others, exponentially increases with time, reaching about 20% after 10 years,[5] whilst risk of infection significantly increases with each generator replacement.[21] Putting together these two aspects, the expected duration of ICD therapy, that is patient's life expectancy, is the most important factor to be considered in order to avoid ICD-related complications. In other words, if the ICD candidate is expected to benefit from the device for a long-time period, considering S-ICD, rather than TV-ICD (if pacing and/or CRT is not needed) does make a sense. These concepts are clearly shown in this survey, which demonstrates a significant prevalence of S-ICD use in subjects <55 years, and, conversely, of TV-ICD in those >65 years.

The second most important reason in favour of S-ICD implantation was the anticipated risk of lead-related complications. This very important point raised by the investigators, is closely linked with the previous one: age of the patient at implantation and their life expectancy. As already discussed, the risk of lead-related complications is directly associated with the duration of the implanted device *in situ* and with the age and activity of the patient: the more active and the younger he is, the higher the risk of lead complications.[5]

A surprising point, emerging from data analysis, is the fact, that in a significant number of cases, the choice to implant S-ICD was taken in agreement with patient's preference, and/or it was driven by his active lifestyle. This is the third most frequent reported reason to choose S-ICD. It seems probable, that the choice of the device is made after discussing the advantages and drawbacks of both TV-ICD and S-ICD. This is also a new finding of this survey. It is reassuring and shows that patients are involved in the management of their disease.

Lastly, and as expected, an elevated risk of device infection or vascular system issues were also applied as criteria of choice favouring an S-ICD implantation.

On the other hand, it is easy to summarize the reasons for choosing TV-ICD systems. Antitachycardia pacing options, the need for CRT, and/or for permanent pacing were the main factors leading to implantation of a TV-ICD system in approximately equal high percentages. Obviously, S-ICD cannot compete in these fields, and it is likely that such reasons will remain valid, until the achievements of technological solutions allowing to replace the transvenous systems.[22] Interestingly, in this survey, patient's preference towards TV-ICD has been only anecdotally reported by the investigators.

## Future perspectives

It seems reasonable to assume that—in the absence of technical issues and if there is no need for pacing or CRT—S-ICD could progressively replace a significant proportion of single and dual chamber ICD implantation procedures. This trend has already been anticipated by the latest ESC Guidelines for the management of patients with ventricular

arrhythmias and the prevention of SCD. The guidelines give a IIa indication for S-ICD implantation, as an alternative to TV-ICD, in patients with an indication for ICD, when pacing therapy for bradycardia support, CRT or antitachycardia pacing is not needed.[12] On the other hand, the same guidelines give a IIb indication for S-ICD, as a useful alternative to the TV-ICD system, when venous access is difficult, after the removal of TV-ICD because of infection or in young patients with a long-term need for ICD therapy.[12] It is to note, that the latter option had a very wide representation in the answers given by the investigators who participated in this survey. The stratification clearly expressed in the guidelines between the two indications (IIa vs. IIb) shows that S-ICD is not considered as a solution in extreme cases, or 'niche', but actually as an alternative to TV-ICD in patients presenting with the standard indications for ICD implantation.

## Limitations

This prospective observational study has some limitations. First, all centres participated on a voluntary basis; the survey is non-exhaustive and it could present some bias in the selection process of the centres. Second, because questions had a limited number of choices, some issues may have not been completely covered. Finally, because purely declarative, without any kind of audit, the survey may not be entirely representative of the whole decisions of the participating investigators.

# Conclusion

This snapshot survey provides a contemporary insight into ICD implantation and management in the European electrophysiology tertiary centres. It also helps to better understand the reasons leading to the choice between S-ICD and traditional TV-ICD. Finally, it gives a picture of the distribution between both devices a few years after the introduction of S-ICD in the Europe.

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