

Implantation of subcutaneous implantable cardioverter defibrillators in Europe: results of the European Heart Rhythm Association survey

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Aims

The purpose of this European Heart Rhythm Association (EHRA) survey is to provide an overview of the current use of subcutaneous cardioverter defibrillators (S-ICDs) across a broad range of European centres.

Methods and results

A questionnaire was sent via the internet to centres participating in the EHRA electrophysiology research network. Questions included standards of care and policies used for patient management, indications, and techniques of implantation of the S-ICDs. In total, 52 centres replied to the questionnaire. More than one-fourth of the responding centres does not implant the S-ICD ($n = 14$, 27%). The majority reported to have implanted <10 (50%) or 10–29 (23%) S-ICDs during the last 12 months. Lack of reimbursement (25%), non-availability (19%), and cost of the device (25%) seem to limit the use of the S-ICD. The most commonly reported indications for S-ICD implantation are a difficult vascular access (82%), a history of previous complicated transvenous ICD (80%), young age (69%), or an anticipated higher risk of infection (63%). Inappropriate therapies were the most frequently reported major problems (38%), but the majority of respondents (51%) never encountered any issue after an S-ICD implantation. Most of the respondents (83%) anticipate significant increase of S-ICD use within the next 2 years.

Conclusion

This survey provides a contemporary insight into S-ICD implantation and management in the European electrophysiology centres, showing different approaches, depending on local policies. Cost issues or lack of reimbursement strongly influence the dissemination of the device. However, most respondents retain that S-ICD use will significantly increase in a very short time.

Keywords

Subcutaneous ICD • EHRA • European survey • Standards of care • S-ICD indications • S-ICD implantation

Introduction

The efficacy of implantable cardiac defibrillators (ICDs) for primary or secondary prevention of sudden cardiac death (SCD) has been well documented.^{1,2} Nevertheless, morbidity and complications of these devices have been of major concern.^{3,4} In particular, the presence of a transvenous lead has been perceived as the Achilles' heel of these systems.^{5,6} The recent release of an entirely subcutaneous implantable cardiac defibrillator (S-ICD)

possibly represents a further step in the evolution of defibrillator technology.^{7–9} The S-ICD may indeed offer a viable therapeutic option in selected patients at high risk of SCD and in whom pacing is not required¹⁰ and there is growing clinical evidence regarding its safety and efficacy.^{10–12} However, current clinical practice of S-ICD use among European countries remains largely unknown. The aim of this European Heart Rhythm Association (EHRA) survey was to provide better insight into S-ICD utilization across a broad range of European centres.

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What's new?

- The most commonly reported indications for S-ICD implantation are a difficult vascular access, a history of previous complicated transvenous ICD, young age, or an anticipated higher risk of infection.
- Lack of reimbursement, non-availability, and cost of the device seem to limit the use of the S-ICD.
- Most of the respondents anticipate significant increase of S-ICD use within the next 2 years.

Methods and results

A questionnaire was sent via the internet to the centres that participate in the EHRA electrophysiology (EP) research network. In this EP wire, 20 questions were focused on standards and policies concerning patients' management, indications and techniques of implantation of the S-ICD in the participating EP centres.

Participating centres

Overall, 52 centres from 21 countries responded, with a wide geographical distribution of responders: 8 centres in Spain, 6 centres in Germany, 5 centres in Italy, 4 centres in France and in the UK, 3 centres in Sweden and Poland, 2 centres in Latvia, Denmark, Belgium, Austria and Norway, and 1 centre in Estonia, Lithuania, Bulgaria, Slovenia, Serbia, Czech Republic, Iceland, the Netherlands, and Switzerland. Of these 52 centres, 75% were university hospitals, 13% were non-university hospital, and 12% were private hospitals.

Of the responding centres, 10% had implanted <50 ICD devices during the last 12 months, 30% of centres had implanted 50–99 ICDs, 30% had implanted 100–199 ICDs, 20% had implanted 200–300 ICDs, and 10% of the centres reported >300 ICD implantations during the last 12 months.

Subcutaneous cardioverter defibrillator use

Subcutaneous cardioverter defibrillator has been implanted in 38 (73%) of the responding centres.

Of all ICD implantations per centre, S-ICDs implantations represented <10% in 57% of the centres, 10–20% in 10% of the centres, 21–50% in 4% of the centres, and 51–70% in 2% of the centres, while 27% of the responding centres ($n = 14$) reported to have never implanted an S-ICDs (Figure 1).

Among the 38 centres implanting S-ICDs, 10% of the centres did not implant a single patient during the last 12 months, 58% reported <10 S-ICD implantations, 29% of centres implanted 10–29 S-ICDs, and only 3% used these devices in 50–100 patients.

Subcutaneous cardioverter defibrillator implantation strategies and techniques

Ventricular detection test before S-ICD implantation was declared to be usually performed at least 1 day before procedure by 73% of responders and much less frequently just before the procedure

(13%) or during the implantation (11%). Only 3% of the responding centres do not routinely perform ventricular detection testing at all.

In the great majority of responding centres (66%), S-ICD implantation procedures are performed during a short hospitalization (<2 days), in 29% of centres peri-procedural hospitalization lasts 3–5 days and rarely >5 days (3% of the centres). Only in 3% of the centres, S-ICD implantations are being performed on an outpatient basis.

In 68% of the centres, S-ICD implantation procedures are performed in an EP laboratory; in 21% of centres, the procedure is done in a surgical theatre. Only in 8% of centres implantations are performed in a hybrid operating room and in 3% of centres both an EP laboratory or a surgical theatre are being used.

In the majority of centres, S-ICD implantations are always performed by an electrophysiologist (63% of centres) or by a cardiologist (18% of centres), while in 11% of centres, they are always performed by a surgeon, and by a miscellaneous of both cardiologists and surgeons in the remaining 8% of centres.

Incision strategy for S-ICD implantation includes two incisions (left latero-thoracic and sub-xiphoidal) in the majority (63%) of the responding centres or three incisions (left latero-thoracic, sub-xiphoidal, and upper-sternal) in the remaining 37% of centres implanting S-ICDs.

Most of the responding centres routinely implant S-ICD under general anaesthesia (55% of centres) or deep sedation (24% of centres). Interestingly, 21% of the centres are performing S-ICD implantation under local anaesthesia.

The reasons why centres do not implant subcutaneous cardioverter defibrillators

As described above, in total, 14 (27%) centres do not implant S-ICD devices. The main reasons reported by these centres for the non-use of S-ICD include non-availability (19%), economic issues, such as lack of reimbursement (25% of not implanting centres), high cost of the device (25% of centres), issues associated with patient selection, such as the lack of pacing function (25% of centres), the absence of eligible patients (25% of centres), or physicians' scepticism towards device efficacy (25% of centres). Less often claimed issues were the lack of training (19% of centres), the complexity of the implantation procedure (6% of centres), or patients' choice (12% of centres) (Figure 2).

Apart from device availability and reimbursement, the obstacles to S-ICD use reported by many centres were mainly linked to patient's habitus (i.e., body size and weight, 55 and 45% of centres, respectively), age <20 years (18% of centres) or >75 years (8% of centres), and female gender (6% of centres). For 29% of the respondents, no particular feature represents a limit to use S-ICD (Figure 3).

The features favouring subcutaneous cardioverter defibrillator over conventional cardioverter defibrillator use

In the 38 centres routinely implanting subcutaneous ICDs, choosing an S-ICD instead of a transvenous system was mainly an anticipated difficult vascular access (82% of the centres), a history of

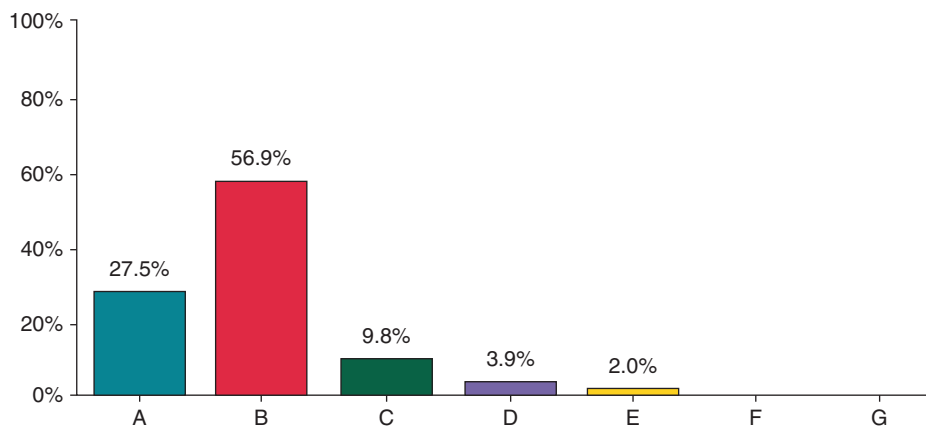


Figure 1 What is approximately the percentage of S-ICDs among all implanted ICDs in your centre? (A) None, (B) <10%, (C) 10–20%, (D) 21–50%, (E) 51–70%, (F) 71–90%, (G) >90%. Each bar represents one possible answer (proportion of responders to each question).

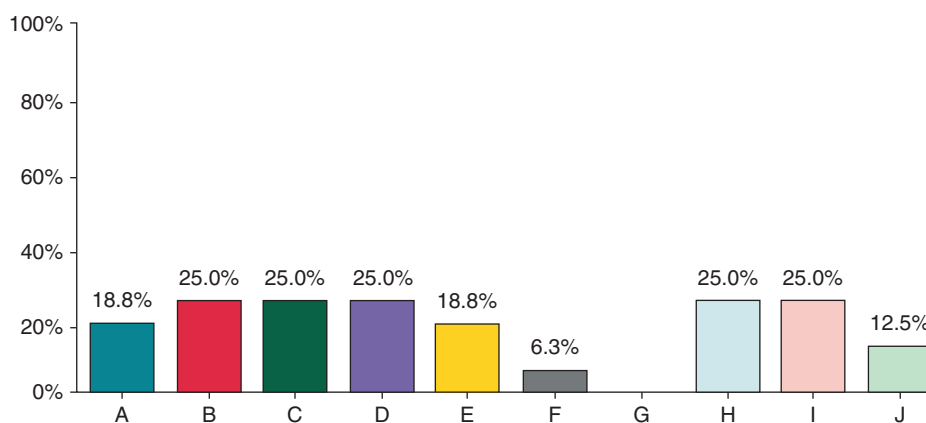


Figure 2 If you do not implant S-ICD in your centre, the reasons are (multiple answers): (A) not available, (B) not reimbursed, (C) price too high, (D) 'I don't believe in this system', (E) 'I've not been trained to this procedure', (F) procedure too complex, (G) need of a surgeon, (H) lack of pacing function, (I) no patients who qualify, (J) patients opt rather for conventional ICDs. Each bar represents one possible answer (proportion of responders to each question).

previous complicated transvenous ICD (80% of the centres), young age (69%), an anticipated higher risk of infection (63%), the availability of the new generation S-ICD (53% of the centres), or a primary prevention indication (45% of the centres). One centre (2%) reported no particular features that would support use of S-ICD (Figure 4).

Current perception of indications

Of the 52 responding centres, 48% undertake implantation of S-ICDs only for very restricted indications, while, in 28% of centres, discussion with the patient and shared decision-making (after both transvenous and subcutaneous alternatives have been proposed) is the ground for device use. When no pacing or cardiac resynchronization therapy (CRT) is needed, some centres (6%) propose S-ICD as a first choice therapy. Finally, 18% of the centres did not adopt any particular policy to decide between a transvenous and an S-ICD implantation.

Outcomes after subcutaneous cardioverter defibrillator implantation

Over half (51%) of the centres never encountered any issue after S-ICD implantation. Among the major problems, inappropriate therapies (38% of centres), post-implant need for bradycardia pacing or for anti-tachycardia pacing requiring device change or up-grade (16% of centres), or local surgical complications like pocket infection, wound dehiscence or prolonged wound healing (11% of centres) were the most commonly reported problems. Less common problems included unsuccessful shocks for VT or VF (5% of centres), and lead or device dislodgment requiring a re-intervention (3% of centres).

Anticipated use of subcutaneous cardioverter defibrillators in the future

The vast majority of respondents anticipate that the number of S-ICD implantations will increase in their centre by >20% (43%

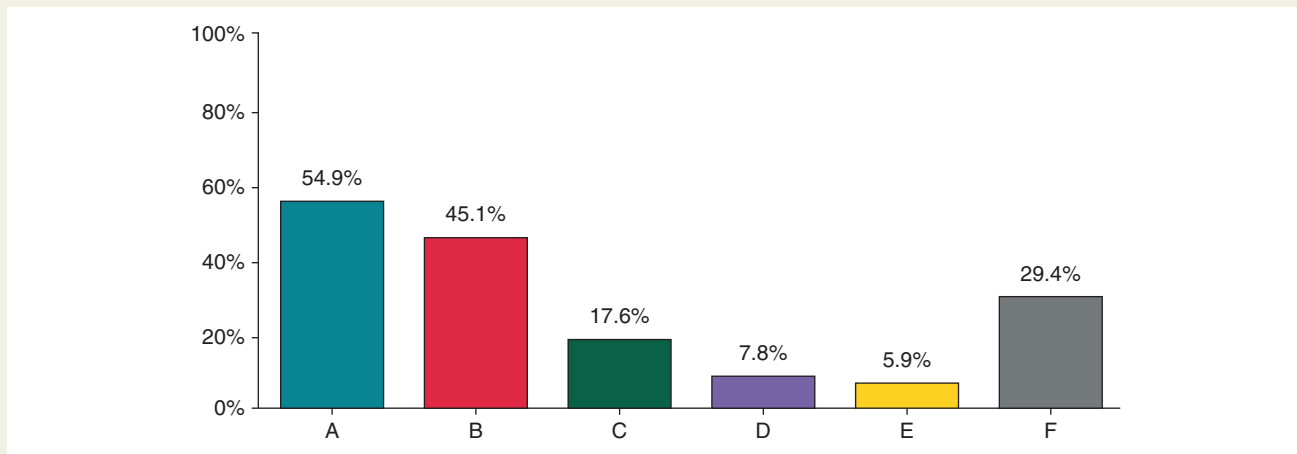


Figure 3 Which features in your opinion could represent an obstacle to S-ICD use (multiple answers)? (A) Body size, (B) weight, (C) age <20 years old, (D) age >75 years old, (E) female gender, (F) no particular feature. Each bar represents one possible answer (proportion of responders to each question).

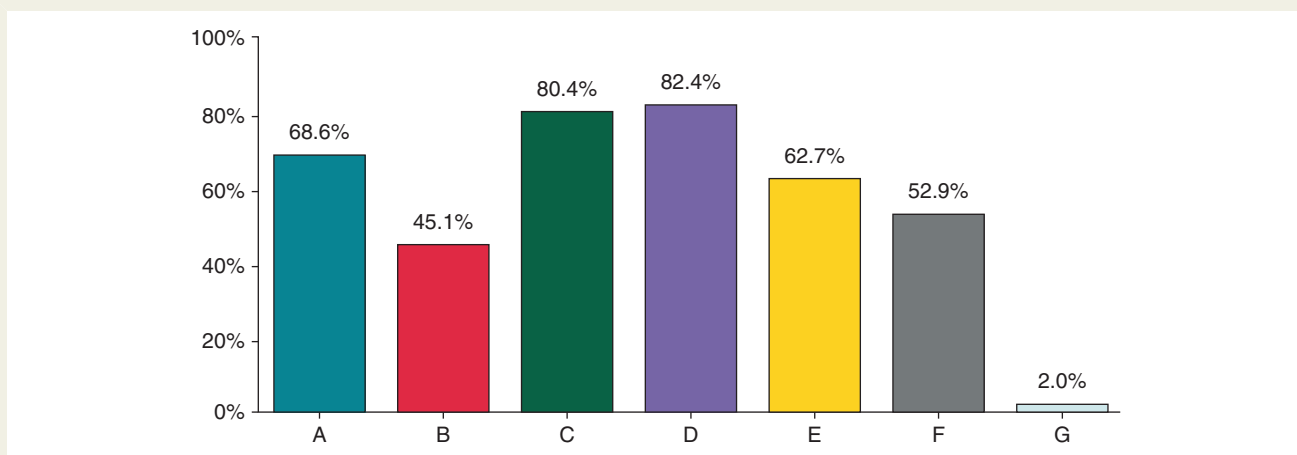


Figure 4 Which features would make you more inclined to use S-ICD, rather than 'conventional' ICD implantation (multiple answers)? (A) Young age, (B) primary prevention, (C) previous complicated 'conventional' ICD, (D) anticipated difficult vascular access, (E) anticipated higher risk of infection, (F) availability of the new generation S-ICD (smaller, MRI compatible, and remote monitoring), (G) no particular feature. Each bar represents one possible answer (proportion of responders to each question).

of centres) or by <20% (40% of centres) in the next 2 years, while 15 and 2% of centres estimate that the volume of S-ICD patients in their centre will remain the same or decrease, respectively (Figure 5).

Discussion

This EP Wire provides an insight into contemporary European practice for S-ICD implantation and management.

The main findings of this survey are: (i) more than one-fourth of the responding centres do not implant the S-ICDs; (ii) the absence of reimbursement, poor availability or device cost seem to be the main factors limiting the use of the S-ICD; (iii) the most reported reasons for preferring an S-ICD over implantation of a transvenous system are an anticipated difficult vascular access, a history of previous complicated transvenous ICD, young age, or an anticipated higher risk of infection;

(iv) the majority of responders did not encounter problems after an S-ICD implantation; the most frequently reported major problems were inappropriate therapies; and (v) most of the respondents to this survey anticipate that S-ICD implantation-rates will increase significantly in their centre within the next 2 years.

The S-ICD was developed as a simple device to reduce the morbidity associated with ICD therapy (e.g. lead dislodgement, infection, etc.), while providing a comparable reduction in the risk of SCD from ventricular fibrillation.^{4-6,13}

Although the S-ICD has now been available for >5 years in most of European countries, the device is not routinely used in many tertiary hospitals. In our survey, more than one-fourth (n = 14, 27%) of the respondents have never implanted an S-ICD. Nonetheless, a number of respondents declared the S-ICD use in a significant proportion of their patients.

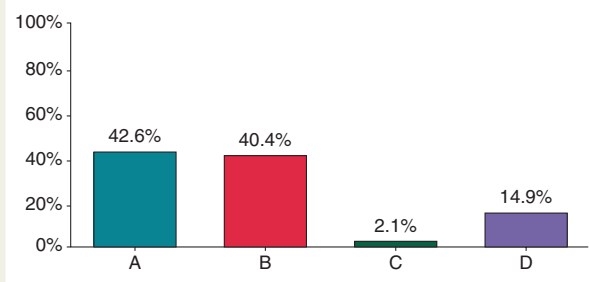


Figure 5 Do you think that the volume of patients equipped with S-ICD in the next 2 years at your centre (single answer)? (A) Will increase by >20%, (B) will increase by <20%, (C) will decrease, (D) will remain the same. Each bar represents one possible answer (proportion of responders to each question).

There are many potential reasons for such discrepancy and slow penetration rate of S-ICD in some countries/hospitals.

First, this is a completely new technique of implantation,^{7,14} which, on the first sight, may seem to require more surgical skills compared with the conventional ICD implantation.

Another potential obstacle may be linked to the logistics rounding the S-ICD implantation: need for a specific ECG screening before implantation, different positioning of the patient on the surgical table, general anaesthesia in most cases, VF induction at the end of the procedure.

Some could see the S-ICD as 'a niche' for rare indications or difficult patients. However, in the latest ESC guidelines for the management of patients with ventricular arrhythmias,¹⁵ the S-ICD is considered as an alternative to transvenous defibrillators in patients with an indication for an ICD in whom pacing is not required (Class IIa recommendation).^{11,16} That recommendation clearly opens the way for a wide range of patients with indications for an ICD implantation both in primary and secondary prevention.

Finally, cost issues may significantly influence the availability of S-ICD and its uptake in the local practices across Europe.

While most centres using S-ICDs in our survey reported no complications or other unfavourable issues after S-ICD implantation, inappropriate shocks were the most frequently reported adverse event in those centres that had experienced S-ICD-related complications. Of note, inappropriate shocks are also the most frequently reported complication with the transvenous ICDs.^{3,4,17} Careful screening, software updates and template selection has reduced the occurrence of inappropriate shocks with the current S-ICDs, compared with the early experience.¹⁸

Many ongoing large studies will continue to gather data on S-ICDs in the near future. The PRAETORIAN trial is a multicentre, randomized, controlled, non-inferiority study comparing the traditional transvenous ICD with the S-ICD.¹⁹ The primary endpoint is a composite of inappropriate shocks and ICD-related complications over 30 months. The EFFORTLESS multicentre international ICD registry has completed enrolment and will follow 1000 patients for 5 years.²⁰

With such improvements and new features, along with the completion and the adhesion of present and future guidelines, it seems highly probable that the S-ICD implantation will notably increase in

the European countries, as anticipated by the participants of this survey.

This survey presents some limitations. First, because fully based on a voluntary participation, it is non-exhaustive. Second, because questions had a limited number of options to be chosen, some situations may have not been completely described. Finally, because purely declarative, it may not be entirely representative of the whole activity or decisions of the answering centres.

Conclusion

This survey provides an insight into the S-ICD implantation and management strategy in European centres. It showed different approaches to S-ICD use, mostly related to local policies. Cost issues and the lack of reimbursement seem to limit the uptake of S-ICD in daily practice. However, most respondents consider likely that S-ICD implantation-rates will significantly increase in the future.

Conflict of interest: S.B. reports consultant fees from Medtronic, Boston Scientific, and Livanova outside of the submitted work. N.D. reports grants from Biotronik, St. Jude Medical, and Boston Scientific outside of the submitted work and personal fees from Boston Scientific outside of the submitted work.

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