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Authors: Maciej Kempa, Szymon Budrejko, Mateusz Tajstra, Paweł Syska, Michał Lewandowski, Tomasz Fabiszak, Marcin Michalak, Adrian Stanek, Krzysztof Nowak, Przemysław Mitkowski, Krzysztof Kaczmarek, Zbigniew Orski, Marcin Janowski, Piotr Szafarz, Artur Filipecki, Adam Sokal, Marek Szołkiewicz, Dariusz Jagielski, Andrzej Przybylski

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Subcutaneous implantable cardioverter-defibrillator therapy in Poland: Results of the Polish S-ICD Registry

Short title: Results of the Polish S-ICD Registry

Maciej Kempa[1], Szymon Budrejko[1], Mateusz Tajstra[2], Paweł Syska[3], Michał Lewandowski[3], Tomasz Fabiszak[4], Marcin Michalak[5], Adrian Stanek[6], Krzysztof Nowak[7], Przemysław Mitkowski[8], Krzysztof Kaczmarek[9], Zbigniew Orski[10], Marcin Janowski[11], Piotr Szafarz[12], Artur Filipecki[13], Adam Sokal[14, 15], Marek Szołkiewicz[16], Dariusz Jagielski[17], Andrzej Przybylski[12, 18]

[1]Department of Cardiology and Electrotherapy, Medical University of Gdansk, Gdańsk, Poland
[2]3rd Department of Cardiology, School of Medical Sciences in Zabrze, Medical University of Silesia, Katowice, Poland
[3]2nd Department of Heart Arrhythmia, National Institute of Cardiology, Warszawa, Poland
[4]Department of Cardiology and Internal Medicine, Collegium Medicum, Nicolaus Copernicus University, Bydgoszcz, Poland
[5]1st Department of Cardiology, Medical University of Warsaw, Warszawa, Poland
[6]Department of Electrocardiology, John Paul II Hospital, Kraków, Poland
[7]Institute of Heart Diseases, Wroclaw Medical University, Wrocław, Poland
[8]1st Department of Cardiology, University of Medical Sciences, Poznań, Poland
[9]Department of Electrocardiology, Medical University of Lodz, Łódź, Poland
[10]Department of Cardiology and Internal Diseases, Military Institute of Medicine — National Research Institute, Warszawa, Poland
[11]Chair and Department of Cardiology Medical University of Lublin, Lublin, Poland
[12]1st Department of Cardiology with the Acute Coronary Syndromes Subdivision, Clinical Provincial Hospital No. 2, Rzeszów, Poland
[13]1st Chair and Department of Cardiology, Medical Sciences in Katowice, Medical University of Silesia, Katowice, Poland
[14]Silesian Center for Heart Diseases 1st Department of Cardiology and Angiology, Zabrze, Poland.
[15]Medical University of Silesia, Faculty of Health Sciences, Department of Dietetics, Bytom, Poland

[16]Department of Cardiology and Interventional Angiology, Kashubian Center for Heart and Vascular Diseases, Pomeranian Hospitals, Wejherowo, Poland
[17]Department of Cardiology, Center for Heart Diseases, 4th Military Hospital, Wrocław, Poland
[18]Medical College of Rzeszow University, Rzeszów, Poland

Correspondence to:
Szymon Budrejko, MD, PhD,
Department of Cardiology and Electrotherapy,
Medical University of Gdansk,
Smoluchowskiego 17, 80–214 Gdańsk, Poland,
phone: +48 58 584 47 60,
e-mail: budrejko@gumed.edu.pl

WHAT'S NEW?

The use of subcutaneous implantable cardioverter-defibrillator (S-ICD) systems has been expanding in Poland since 2014, with a significant rise after introduction of complete reimbursement. The Polish Registry of S-ICD Implantations was held by the Heart Rhythm Section of the Polish Cardiac Society between May 2020 and September 2022 to monitor the implementation of that modern therapy in Poland. We present data regarding 440 procedures reported to the registry, including 411 de novo S-ICD implantations that represent 75% of the total number of implantations in Poland during that period. There were no perioperative surgical complications and the rate of adverse events was low.

ABSTRACT

Background: The use of a subcutaneous implantable cardioverter-defibrillator (S-ICD) has been expanding in Poland since 2014. The Polish Registry of S-ICD Implantations was held by the Heart Rhythm Section of the Polish Cardiac Society between May 2020 and September 2022 to monitor the implementation of that therapy in Poland.

Aims: To investigate and present the state-of-the-art of S-ICD implantation in Poland.

Methods: Implanting centers reported clinical data of patients undergoing S-ICD implantations and replacements, including: age, gender, height, weight, underlying disease, history of pacemaker and defibrillator implantations, indications for S-ICD, electrocardiographical parameters, procedural techniques, and complications.

Results: 440 patients undergoing S-ICD implantation (411) or replacement (29) were reported by 16 centers. Most patients were in New York Heart Association class II (218 patients, 53%) or I (150 patients, 36.5%). Left ventricular ejection fraction was 10-80%, median (IQR) 33% (25%–55%). Primary prevention indications were present in 273 patients (66.4%). Non-ischemic cardiomyopathy was reported in 194 patients (47.2%). The main reason for the choice of S-ICD were: young age (309, 75.2%), risk of infective complications (46, 11.2%), prior infective endocarditis (36, 8.8%), hemodialysis (23, 5.6%), and immunosuppressive therapy (7, 1.7%). Electrocardiographic screening was performed in 90% of patients. The rate of adverse events was low (1.7%). No surgical complications were observed.
Conclusions: Qualification for S-ICD in Poland was slightly different when compared to the rest of Europe. The implantation technique was mostly consistent with the current guidelines. S-ICD implantation was safe, and the complication rate was low.

Key words: implantable cardioverter-defibrillator, subcutaneous implantable cardioverter-defibrillator, sudden cardiac death, ventricular arrhythmia

INTRODUCTION

Implantation of a subcutaneous cardioverter-defibrillator (S-ICD) is commonly used for prevention of sudden cardiac death due to ventricular arrhythmias, which is in line with the European and American guidelines [1, 2]. That method of treatment had been employed in Poland since 2014 [3]. During the early period, the number of implantations was limited by the lack of reimbursement, as it was decided post hoc on a patient-by-patient basis by the National Healthcare Fund, and that fact discouraged the wide application of the new method due to the high cost of the system resulting in the procedure being a high-risk investment of any hospital involved. The complete reimbursement by the National Healthcare Fund was introduced as late as in 2019 (under specific conditions: only for experienced, high-volume cardiology reference centers, performing at least 30 lead extraction procedures annually, and having cardiac or thoracic surgery back-up on-site) [4]. It led to a substantial increase of the number of procedures in the following months. Despite that fact, no national system was established to monitor the growing experience of Polish centers with the new modality of treatment. Therefore the executive board of the Heart Rhythm Section of the Polish Cardiac Society decided to create the Polish S-ICD Registry to monitor the safety, technical issues, complications and clinical results of the implementation of that method in Poland. The registry was launched on May 1, 2020 [5]. Centers implanting S-ICD systems reported add data of

patients undergoing implantation or exchange of the device. Participation was not intended to influence clinical decisions, and data were sent after the implantation-related hospitalization. The initial report comprised the data of 123 patients. Low complication rates were observed, as there were no in-hospital surgical complications, and only 2 adverse events were described (pocket hematoma treated conservatively, and unilateral paresis of the lower limb with no apparent pathology of the central nervous system). The most frequent indication for S-ICD and not a transvenous implantable cardioverter-defibrillator (TV-ICD) was patient's young age, similarly to other reports.

During the first year of data collection, the initial results were also published, comparing Poland to other European countries in terms of characteristics of the population of patients undergoing S-ICD implantation, as well as the reasons for preference of subcutaneous systems over transvenous ones [6]. In that report we concluded, that S-ICD systems in Poland were implanted in patients at a more advanced stage of chronic heart failure, when compared to other European countries. The most frequent reason for choosing S-ICD and not TV-ICD is the young age of a patient, similarly to other countries.

The registry data were also compared with the historical small cohort of S-ICD recipients treated during the initial year after the introduction of the new method of treatment in Poland [7]. In that report we observed a tendency to incorporate new operational techniques (such as intermuscular pocket and 2-incision technique) used in more experienced European centers, with no increase in the perioperative complication rate.

After a significant volume of data was gathered by the participating centers, the decision was made to conclude the registry at the end of September 2022. The aim of our current analysis was to investigate and present the state-of-the-art of S-ICD implantation in Poland based on the data reported to the registry during the whole period of two and a half years of its duration.

METHODS

The analysis was based on patients' records reported between May 2020 and September 2022 to the multicenter registry of S-ICD implantations in Poland. The registry was designed, launched and held by the Heart Rhythm Section of the Polish Cardiac Society, and it was approved by the Bioethical Committee at the Regional Medical Board in Rzeszów (approval no. 35/B/2020). Participation in the registry by the centers was by no means associated with any influence on qualification of patients, procedural technique or further course of the follow-up care. Required data were reported once the index hosptalization of a given patient had finished. The records included information such as: age, gender, height, weight and body mass

index, underlying disease, history of implantation of other implantable cardiac electronic devices (pacemakers and defibrillators) and their extraction, indications for S-ICD implantation, basic electrocardiographical parameters (including any conduction disturbances and QRS widening), procedural techniques (type of anesthesia, the use of 2-incision or 3-incision technique), results of the implantation procedure, and any complications occuring until the end of patient's hospitalization. Data were reported in a digital fashion on a dedicated web-based platform created for that purpose.

Statistical analysis

Continuous variables were presented as mean and standard deviation or median and interquartile range in case of non-normal distribution. Categorical parameters were presented as numbers and percentages. The normality of distribution was tested with the Shapiro-Wilk test. Groups were compared with the Pearson's chi-squared test and post-hoc proportion test with Bonferroni's correction for multiple comparisons. Fisher's exact test was used in case of low sample sizes. A *P*-value of below 0.05 was considered statistically significant. Data management and statistical analysis were performed with Microsoft Excel, Statistica 13.1 software (TIBCO Software, Palo Alto, CA, US) and R version 4.1.2 (1 November 2021, "Bird Hippie", The R Foundation for Statistical Computing, Vienna, Austria) and R-studio software (September 2, 2021 build 382).

RESULTS

Data of 440 patients undergoing S-ICD implantation (411 patients) or device replacement (29 patients) were reported to the registry by 16 centers in Poland. That number represented 75% of all procedures performed in Poland during the period of interest, as we estimated on the basis of unpublished data acquired from the manufacturer of the system. The growth rate of the cumulative number of records was constant during the whole duration of the registry. A quarterly number of new records was between 43 and 49, except for the first (19) and last (25 records) quarters. Among 411 patients undergoing first-time implantation, 297 (72.3%) were male and 114 (27.7%) were female. Patients' age was between 12 and 82 years, with a median (interquartile range [IQR]) value equal to 42 (31–55) years.

Most patients were classified as New York Heart Association (NYHA) class II (218, 53%) or I (150, 36.5%), with all the remaining being in class III. Left ventricular ejection fraction (LVEF) was between 10 and 80%, median (IQR) 33% (25%–55%). In 273 patients (66.4%) S-

ICD was implanted for primary prevention of sudden cardiac death (SCD). Non-ischemic cardiomyopathy was the predominant underlying disease in that cohort, as it was reported in 194 patients (47.2%). Detailed clinical data may be found in Table 1.

Electrocardiography and other cardiac implantable electronic devices (CIED)

Data representing cardiac rhythm, conduction disturbances, and the presence of other CIEDs at the time of S-ICD implantation are presented in Table 2.

Reasons for preference of S-ICD over TV-ICD

The main reason for the choice of S-ICD (instead of a traditional TV-ICD) was young patient's age and long-life expectancy, and it was reported as such in 309 patients (75.2%). The other significant group of reasons declared by the implanting physicians fell into the category of increased risk of infective complications or recurrent infection due to (sorted by decreasing frequency): chronic infective states — in 46 patients (11.2%), prior infective endocarditis — in 36 patients (8.8%), hemodialysis — in 23 patients (5.6%), and immunosuppressive therapy — in 7 patients (1.7%). Lead failure of a previously implanted transvenous lead was reported as a main reason in 27 cases (6.6%), and difficult vascular access in 18 cases (4.4%). In the majority of patients (370 — 90%) the decision to qualify for S-ICD implantation was preceeded by electrocardographic (ECG) screening, as presented in Table 3.

S-ICD implantation procedure

S-ICD systems were implanted mostly by cardiologists. A cardiac surgeon was involved only in 8 cases (1.9%). The procedure was performed most frequently in general anesthesia (302 patients, 73.5%), using a 2-incision technique (323 patients, 78.6%), and creating an intermuscular (over the serratus anterior muscular fascia and beneath the latissimus dorsi muscle) device pocket (367 patients, 89.3%). Defibrillation test was performed in 322 patients out of 411 undergoing first-time implantation (78.3%). The test shock was set to 65J in 309 cases, 70J in 10, 72J in 2, and 80J in one case, respectively. In 89 patients the defibrillation test was waived, and predominant reasons for avoiding the test were: extremely low LVEF (17 patients, 19.1%), thromboembolic material within heart chambers (14 patients, 15.8%) and transvenous lead extraction (possibly increasing the risk of complications) performed just before S-ICD implantation (10 patients, 11.2%).

During data collection we observed an evolution of operational techniques, that is the number of incisions, location of the device pocket and the type of anesthesia used for the implantation

procedure. To trace that evolution, we divided the whole duration of the registry into 4 equal 7-month periods (1st period: May 2020–December 2020, 2nd period: January 2021–July 2021, 3rd period: August 2021–February 2022, 4th period: March 2022–September 2022). During the first period the 3-incision technique was used in 53.2% cases, with predominant intermuscular pocket (96.4%) and the procedure performed in general anesthesia (72.1%). In the last period more procedures were reported to have been performed with 2-incision technique (93.3%, P <0.001) with lower rate of intermuscular pocket (80.9%; P = 0.01). The rates of procedures performed in general anesthesia or fascial plane block were not significantly different (P = 0.83). Detailed data are presented in Figures 1–3.

Periprocedural adverse events and complications related to S-ICD implantation or replacement

S-ICD replacement procedures (29 patients) were not associated with any adverse events. Among 411 patients undergoing first-time implantation, 7 adverse events were observed (1.7%) during the periprocedural period (in-hospital, until discharge from the implantation-related hospitalization). Inappropriate interventions were reported in 4 cases (1%), and they were due to inappropriate sensing resulting most probably from air entrappment in the device pocket or the tunnel around the lead course (4 patients, 1%), as well as to low amplitude of the R wave (in addition) in 1 of those patients (0.2%). Subcutaneous emphysema was reported in one patient (0.2%). Moreover, one patient (0.2%) suffered from transient atrio-ventricular conduction disturbances immediately after the defibrillation test shock. In one patient (0.2%) paresis of the right lower extremity was observed, and in-depth diagnostic investigation did not reveal any neurological reason that could possibly explain that complication. No surgical complications, infections and early system revisions were reported.

DISCUSSION

Data collected in that multicencer registry were used for previously published analyses comparing indications and clinical characteristics of populations of patients undergoing S-ICD implantation in Poland and other European countries [8]. When considering the complete registry duration of 2.5 years, the percentages and trends did not change significantly. Among patients receiving S-ICD systems, the percentage of subjects in NYHA class I is approximately 40%, and in class III — around 11%. Those percentages are different than in the rest of Europe, where more patients are in class I (67.7%) and less in class III (2.9%), as we reported before [8]. In our extended registry cohort the mean LVEF was still below 40%. Hence the tendency

of Polish patients to have more advanced heart failure at the time of S-ICD implantation remained unchanged. That result is concordant with the results of the Heart Failure Pilot Survey [9]. S-ICD was invariably less frequently implanted in patients with no structural heart disease in Poland than in the rest of Europe. That finding is surprising, because in a recently published survey the majority of Polish experts in S-ICD implantation declared, that patients with inherited arrhythmic syndromes should be qualified for S-ICD rather than TV-ICD, unless a history of ventricular tachycardia eligible for antitachycardia pacing was present [10].

Interesting results were found in the analysis of reasons for selection of an S-ICD instead of a TV-ICD. Polish centers reported young patient's age as the predominant reason. The second most important factor was the fear of infective complications. Those results are in conformity with both the European and American guidelines, where the long-life expectancy and the risk of infection or infection recurrence are recommended to be taken into account during qualification, and should favour S-ICD systems [1, 2]. The above observations are also concordant with the results of the survey study, where 92% of Polish experts declared a history of transvenous CIED related infection resulting in the extraction of that system to justify the subsequent choice of S-ICD, and the age below 50 years should favour the choice of S-ICD and not TV-ICD irrespetive of the etiology of heart failure [10]. Importantly, according to legal regulations in Poland, complete reimbursement of the S-ICD system is granted only on declaration of any of the specific reasons predefined by the healthcare fund [4]. Therefore the reasons such as an active lifestyle, cosmetic effect or patient's preference cannot justify the choice of SICD, and then an additional reson should be reported for reimbursement, even if it is not predominant.

In the majority of patients the decision to implant S-ICD was preceded by ECG screening. Three acceptable vectors were recorded in 51.4% of patients, and only one — in 2.4% of cases. According to the S-ICD manual, at least one vector passing in all the tested body positions is considered enough to proceed to S-ICD implantation. Most of authors of that study consider that insufficient and prefer to have at least two vectors positive in supine and standing body positions. Unfortunately, we do not have information on how many of the patients initially considered for S-ICD implantation failed ECG screening, as only S-ICD implantations were reported to the registry, and not preoperative qualifications.

Surgical techniques used during S-ICD implantation were in line with the current EHRA recommendations [11]. Implantation procedures were performed mostly in general anesthesia, using a 2-incision technique and an intermuscular device pocket. The recommended 2-incision technique was used with an increasing rate from the first period of the registry to the last one.

There was no significant difference in the rates of regional anesthesia and fascial plane block between the consecutive periods. We also made a surprising observation, that the rate of subcutaneous (and not intermuscular) pocket increased during the time of data collection. Such a technique is not recommended, as it increases the risk of infective complications. The most propable explanation of this phenomenon is that new centres with less experienced operators joined the registry during ongoing data collection. A conclusion may be drawn, that some form of training requirements for operators, and not only legal requirements for centers, should be considered to promote appropriate operational techniques.

A defibrillation test was performed in 322 of 411 patients undergoing first-time S-ICD implantation. It means that the test is abandoned increasingly more often, despite being a recommended step of the implantation procedure [11]. The main reason for skipping the test was very low LVEF (and thus the fear of worsening heart failure with induced ventricular fibrillation). One of the other reasons was transvenous lead extraction directly preceding S-ICD implantation. Mechanical strain applied to the walls of vessels and heart chambers during the lead extraction may impair their integrity and increase the risk of subsequent rupture and perforation due to increased pressure trauma, which may be related to abrupt chest muscle contraction during the induction and defibrillation of ventricular fibrillation. Although that fear is based on experience of physicians performing lead extractions and has no sound data to support that, it is not limited to the authors of that study. In a recent report of S-ICD implantation up to several days after transvenous lead extraction, defibrillation testing was performed only in 47% of S-ICD recipients, and “physician’s choice” was also among reasons behind skipping the test [12].

In 309 patients a test shock of 65J was effective. The remaining 13 patients were tested with higher energy. Induced arrhytyhmias were successfully terminated in all cases. That result seems to be slightly better than percentages reported in clinical studies [13, 14]. It may be related to a high rate of intermuscular pocket (which is nowadays a preferred device location). In the majority of patients reported to the registry the device pocket was dissected under the border of the latissimus dorsi muscle, as recommended. It forces a more dorsal position of the device can compared to the subcutaneous pocket, and results in a high efficacy of the test shock due to a relatively low impedance of defibrillation pathway [15, 16]. Unfortunately, not all operators declared such a location (i.e. intermuscular and not subcutaneous) as their default choice for the device pocket.

In 10 cases previously implanted ICDs were not removed before S-ICD implantation. The reasons for that decision were not specifically reported in the registry. In general, in such cases

TV-ICDs may be either planned for removal after S-ICD implantation or, alternatively, they may be switched off and abandoned. The last approach is possible only in case of non-infective complications (such as lead failure), but in our opinion it should be avoided if only possible. That issue is still under investigation [17] and conclusive evidence is lacking.

In the group of 411 S-ICD implantations de novo, 7 adverse events were reported. Most of them were inappropriate interventions of the system. The occurrence of those interventions resulted predominantly from a recognized phenomenon of air entrappment in the device pocket and along the lead course after the implantation procedure [18]. That problem is typically self-healing, with air being resorbed within several days. To avoid such events, every operator should carefully evacuate air during implantation, and some authors recommend filling the lead tunnel and the device pocket with sterile saline [19]. A delayed activation of the system, up to 48 hours after implantation, may also be considered. Nonetheless, such an event does not require surgical intervention. According to the results of the UNTOUCHED study, the common use of the 2-incision technique may contribute to a higher rate of air entrappment within the subcutaneous lead tunnel [20]. In 3 of those 4 patients in our group the 2-incision technique was used for implantation. Such a complication may also occur after device replacement when the new can is smaller than the old one, but no such case was reported in our patient population. Subcutaneous emphysema and transient atrio-ventricular conduction disturbances were also incidentally observed in our study, but they did not require any additional intervention. The most serious reported complication was a neurological event in one patient, the mechanism of which remained unclear despite thorough evaluation. Therefore, a complication requiring additional diagnostic and therapeutic measures could be attributed only to that single case. That rate is very low, and lower than reported in the available studies. Surgical complications such as dislocation of system components and inappropriate healing of a postoperative wound have been described in up to 3% of patients durng the first month after implantation [21]. In our group none of the patients had surgical complications after de novo implantation, but the initial observation period was relatively short, as it continued only until patient's discharge from hospital.

Limitations

The main limitation of our analysis is a relatively low number of patients, despite multicenter involvement. The registry covered only 75% of patients undergoing S-ICD implantation or replacement during that specific time in Poland. Participation was voluntary, not all implanting centers joined the registry, new centers were launched as the registry went on and they did not

decide to join. Underreporting from the participating centers cannot be excluded. The registry was launched by the Heart Rhythm Section, it included specified clinical centers, and local coordinators were responsible for data collection and transfer, but we did not verify or confirm the reported data in any way, and therefore a possibly limited data reliability may also be an issue. COVID-19 pandemic might have also influenced the clinical routine, as the availability of S-ICD implantation, device choice and other clinical decisions might have been altered during the pandemic [22]. ECG screening was not performed in 10% of pts.

CONCLUSION

The analysis of data collected in the registry proves that a certain dissimilarity exists in qualification for S-ICD implantation between Poland and other European countries. The course of the procedure and implantation technique are in the majority of cases consistent with the current guidelines. Good outcome and almost complete lack of serious complications during early postoperative period prove that implanting centers were appointed appropriately and the implanting teams were well-trained.

Article information

Conflict of interest: MK received speaker/proctoring fees from Boston Scientific. PS received speaker/proctoring fees from Boston Scientific. ML received lecture honoraria and proctorship agreement from Boston Scientific. PM received speaker's fee from Boston Scientific Poland. KK received proctor and consulting fees from Boston Scientific Poland. AS — consultancy agreement Boston Scientific; AP received advisory board fee from Boston Scientific. Other authors declare no conflict of interest.

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Table 1. Clinical characteristics of patients undergoing first-time implantation of a subcutaneous implantable cardioverter-defibrillator

Clinical feature	**Value**
Age, years, median (IQR)	42 (31–55)
Male gender, n (%)	297 (72.3)
Height, cm, median (IQR)	175 (168–181)
Weight, kg, median (IQR)	80 (70–94)
BMI, kg/m^2, median (IQR)	26 (23–30)
Sinus rhythm, n (%)	386 (93.9)
Prior sternotomy, n (%)	40 (9.7)
LVEF, %, median (IQR)	33 (25–55)
Underlying disease	

NICM, n (%)	194 (47.2)
ICM, n (%)	112 (27.3)
Primary VF, n (%)	46 (11.2)
LQTS, n (%)	11 (2.7)
HCM, n (%)	7 (1.7)
LVNC, n (%)	7 (1.7)
Brugada syndrome, n (%)	6 (1.5)
Myocarditis, n (%)	5 (1.2)
Congenital heart disease, n (%)	5 (1.2)
ARVC, n (%)	2 (0.5)
CPVT, n (%)	2 (0.5)
MAD, n (%)	1 (0.2)

Abbreviations: ARVC, arrhythmogenic right ventricle cardiomyopathy; BMI, body mass index; CPVT, catecholaminergic polymorphic ventricular tachycardia; HCM, hypertrophic cardiomyopathy; ICM, ischemic cardiomyopathy; IQR, interquartile range; LQTS, long QT syndrome; LVEF, left ventricular ejection fraction; LVNC, left ventricle non-compaction; MAD, mitral annular dysjunction; NICM, nonischemic cardiomyopathy

Table 2. Electrocardiography and other cardiac implantable electronic devices

Sinus rhythm, n (%)	386 (93.9)
Atrial fibrillation, n (%)	25 (6.1)
Paced rhythm, n (%)	4 (1)
Bundle branch block, n (%)	20 (4.9)
Right bundle branch block, n (%)	14 (3.4)
Left bundle branch block, n (%)	6 (1.5)
No history of CIED before S-ICD, n (%)	338 (82.2)
Previous ICD-VR, n (%)	53 (12.9)
Previous ICD-DR, n (%)	18 (4.4)
Previous CRT-D, n (%)	5 (1.2)
Previous CRT-P, n (%)	1 (0.2)

Previous TV-ICD not removed, only inactivated, n (%)	10 (2.4)

Abbreviations: CIED, cardiac electronic implantable device; CRT-D, cardiac resynchronization therapy cardioverter-defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; ICD-DR, dual-chamber implantable cardioverter-defibrillator; ICD-VR, single chamber implantable cardioverter-defibrillator; TV-ICD, transvenous implantable cardioverter-defibrillator; S-ICD, subcutaneous implantable cardioverter-defibrillator

Table 3. Results of prepoperative electrocardiography screening, which was performed in 370 of 411 patients undergoing first-time implantation

Number of vectors positive for a given patient	Number of patients (%)
3	190 (51.4)
2	171 (46.2)
1	9 (2.4)
Number and percentage of positive results for a given vector in the whole cohort	Number of patients (%)
Primary	346 (93.5)
Secondary	334 (90.3)
Alternate	241 (65.1)

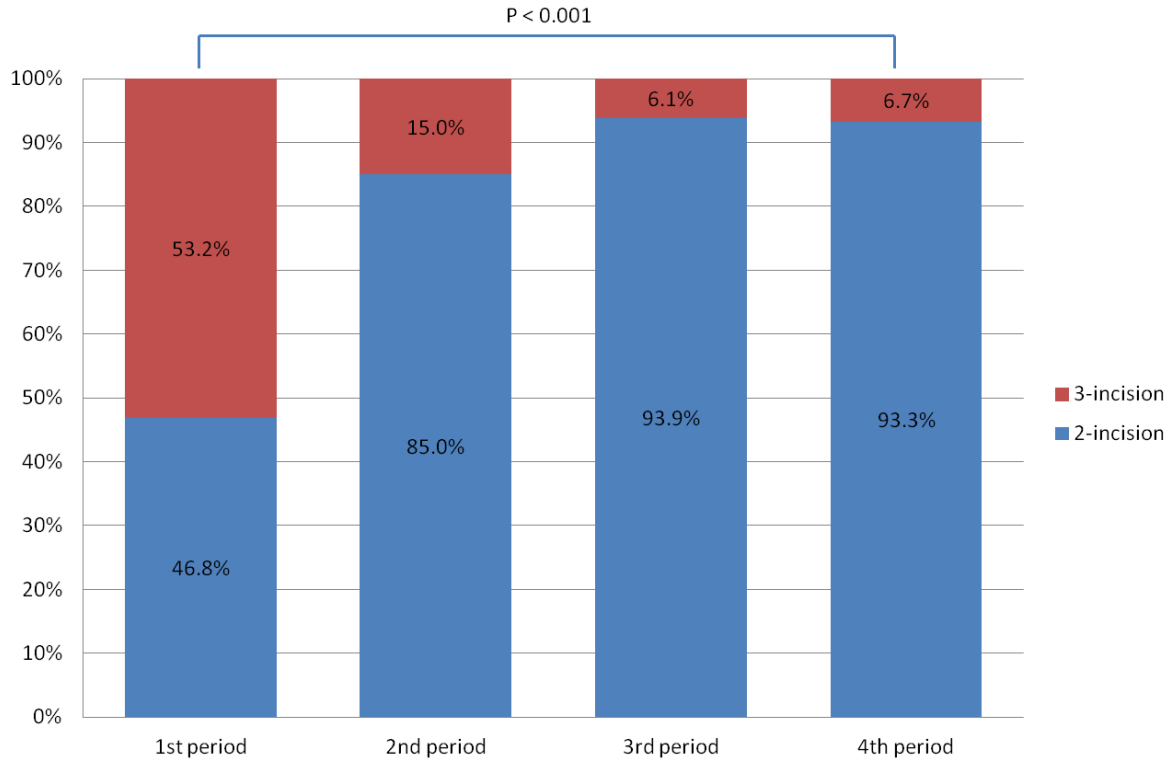

Figure 1. Evolution of the implantation technique — percentages of 2- and 3-incision procedures in 4 consecutive 7-month periods of the registry (1st period: May 2020–December 2020, 2nd period: January 2021–July 2021, 3rd period: August 2021–February 2022, 4th period: March 2022–September 2022). *P* <0.001 for inter-group difference, *P* <0.001 for 1st vs. 4th period comparison

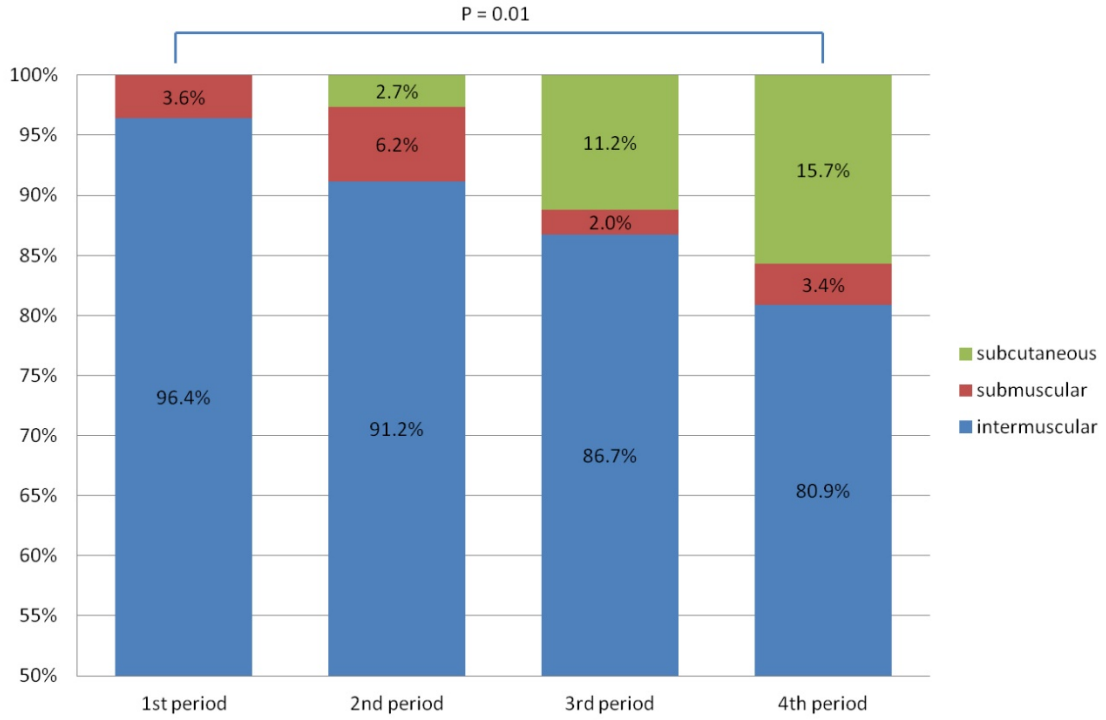

Figure 2. Evolution of the implantation technique — location of the device pocket in 4 consecutive 7-month periods of the registry (1st period: May 2020–December 2020, 2nd period: January 2021–July 2021, 3rd period: August 2021–February 2022, 4th period: March 2022–September 2022). Submuscular pocket is located under the serratus anterior muscle, intermuscular pocket is located between the latissimus dorsi and serratus anterior muscles. *P* <0.01 for inter-group difference, *P* = 0.01 for 1st vs. 4th period comparison

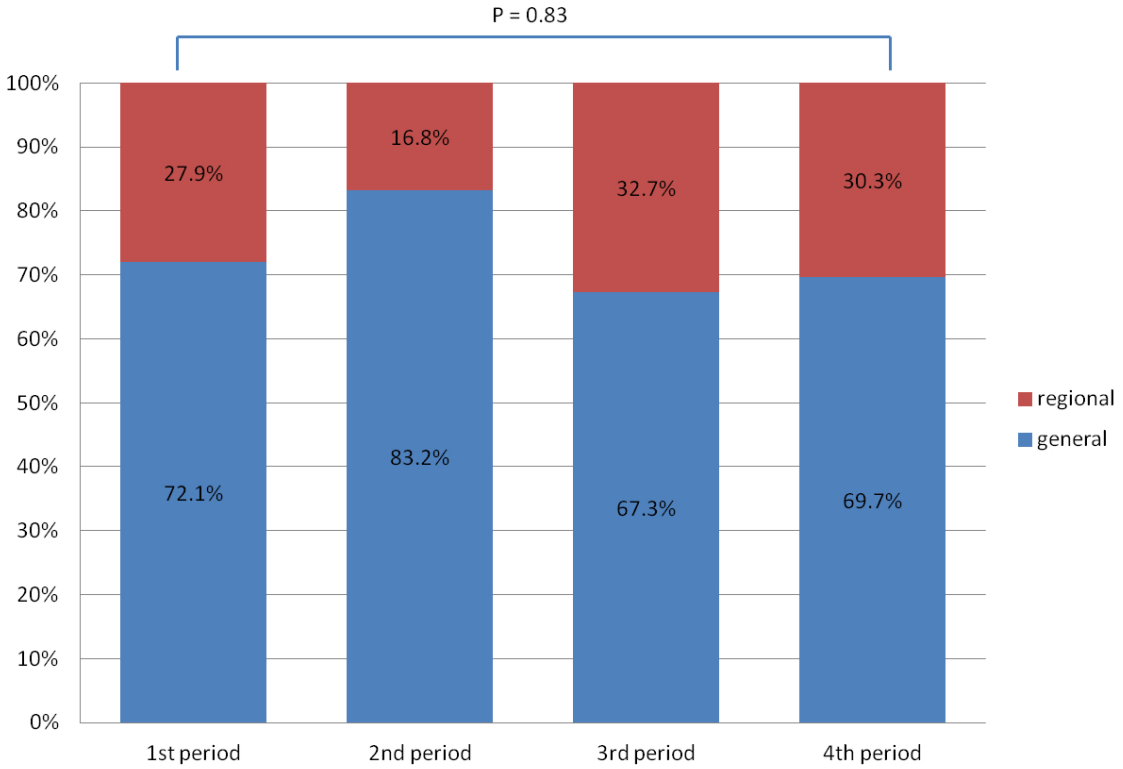

Figure 3. Evolution of the implantation technique — type of anesthesia in 4 consecutive 7-month periods of the registry (1st period: May 2020–December 2020, 2nd period: January 2021–July 2021, 3rd period: August 2021–February 2022, 4th period: March 2022–September 2022). *P* = 0.04 for inter-group difference, *P* = 0.83 for 1st vs. 4th period comparison