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ORIGINAL ARTICLE

Factors determining the choice between subcutaneous or transvenous implantable cardioverter-defibrillators in Poland in comparison with other European countries: a sub-study of the European Heart Rhythm Association prospective survey

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Abstract

Background: Subcutaneous implantable cardioverter-defibrillator (S-ICD) may be an alternative to transvenous ICD (TV-ICD).

Aim: We sought to evaluate factors determining the choice of S-ICD vs. TV-ICD in Polish patients in comparison to other European countries.

Methods: All consecutive patients who underwent TV-ICD or S-ICD implantation in centres participating in the European Heart Rhythm Association prospective snapshot survey were included.

Results: During an eight-week study period, 429 patients were recruited, including 136 (31.7%) ICD patients from Poland (eight with S-ICD). In comparison to other European centres, the proportion of S-ICD implantations in Poland was lower (7% vs. 26%, $p < 0.001$), whereas the ratio of cardiac resynchronisation therapy defibrillator implantations was higher (43% vs. 26%; $p < 0.001$). Subjects receiving S-ICD in Poland were more often over 75 years old (25% vs. 0%, $p < 0.001$), in New York Heart Association class II (87.5% vs. 29.4%, $p = 0.001$), with chronic kidney disease (37.5% vs. 5.9%, $p = 0.003$), and with lower left ventricular ejection fraction (32% [14%–50%] vs. 50% [25%–60%], $p = 0.04$), compared to other European countries. Additionally, in comparison to subjects from other European centres, Polish patients were significantly more often implanted with S-ICD due to prior infection (37.5% vs. 1.5%, $p < 0.001$) and a lack of venous access (25% vs. 0%, $p < 0.001$), whereas the largest subset of patients in other European countries were implanted with S-ICD because of young age (50% vs. 25%, p = NS).

Conclusions: The main reasons leading to S-ICD implantations in Polish patients differ from the indications adopted in other European countries. In Poland, patients referred for TV-ICD or S-ICD implantation had more advanced heart failure and more comorbidities in comparison to subjects from other European countries. S-ICD is still underused in Polish patients.

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

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INTRODUCTION

The role of the implantable cardioverter-defibrillator (ICD) in reducing the rate of sudden cardiac death (SCD) in patients at risk of life-threatening ventricular tachyarrhythmias has been demonstrated in numerous clinical trials [1, 2]. Despite recent developments in technology, device-related complications, especially those connected with transvenous leads, are frequent and are associated with significant morbidity and mortality [3–5]. The purpose of developing an entirely subcutaneous ICD (S-ICD) was to avoid endocardial leads, and thus to eliminate the risk of lead-related complications. This new technology received a Conformité Européene (CE) mark in Europe in 2009 [6]. Subsequent clinical trials have demonstrated that S-ICDs are safe and effective in the treatment of ventricular arrhythmias, with rates of inappropriate shocks comparable to those of transvenous ICDs (TV-ICDs) [7–9]. According to the guidelines, S-ICD may be an alternative to TV-ICD in patients with venous access problems, after removal of a classic ICD due to infections, or in young patients in whom a very long-term need for ICD is anticipated [10]. At the same time, the guidelines state that S-ICD might be an alternative to TV-ICD only in patients in whom pacing (for bradycardia or antitachycardia) or cardiac resynchronisation therapy (CRT) is not needed [10]. The first S-ICD implantation in Poland took place in 2014 [11] and so far this therapy is reimbursed only if the rationale for the implantation of this particular device (rather than the transvenous one) can be provided by the attending physician. The factors that influence the choice to implant S-ICD, rather than TV-ICD in Poland are not fully known. The aim of our study was to evaluate the determinants of this decision among Polish physicians in comparison with other European countries.

METHODS

The data from the European Heart Rhythm Association (EHRA) prospective snapshot survey were used for the analysis. Tertiary cardiac centres, in which both TV-ICDs and S-ICDs are routinely implanted and S-ICD implantations are reimbursed, participated voluntarily in this prospective EHRA survey. The data were collected via an internet-based electronic questionnaire designed by the EHRA Scientific Committee to gather information on ICD patients. All consecutive patients implanted with an ICD in the participating centres during an eight-week survey period were prospectively included in the study. The questionnaire was anonymous and consisted of 30 multiple-choice questions regarding the referral of the patient to a particular type of ICD and to periprocedural proceedings [12].

Statistical analysis

Continuous parameters were expressed as mean ± standard deviation or median and interquartile range if non-normally distributed, whereas categorical variables were expressed as numbers and percentages. The χ^2, Student t test, or Mann-Whitney U test was used to compare the groups, as appropriate. A p-value of < 0.05 was considered statistically significant. All statistical analyses were performed using the Statistica software package (versions 6.0 and 10.0, StatSoft Inc., Tulsa, OK, USA).

RESULTS

Participating centres

A total of 20 centres from six countries participated in this EHRA snapshot survey: eight from France, six from Poland, two from Germany, two from Italy, and one each from Austria and Switzerland. Of those centres, 18 were university hospitals, whereas two were private ones. Where needed, the approval of a Local Ethics Committee was obtained.

Study population

Between April and June 2017, a total of 429 consecutive patients were included into the survey; in 383 of them the device type was specified (307 had TV-ICD and 76 had S-ICD). Most of the participants were aged between 56 and 65 years (28.5%) or between 66 and 75 years (25.7%). Ischaemic aetiology of heart failure (HF) was present in 55.4% of patients, and New York Heart Association (NYHA) functional class II prevailed (53%). The most common comorbidities were coronary artery disease (48%) and diabetes (28%) (Table 1).

Patients in Poland vs. other European countries

In total, 136 (31.7%) patients from Polish centres were included, but the device type was specified for only 125 (91.9%) of them.

The age of Polish patients ranged most commonly between 56 and 75 years (n = 81 [64.8%]), and 22% of them were older than 75 years. The dominant functional NYHA classes were II (50.4%) and III (41.6%). In comparison to other European patients, NYHA class I was less common in Polish ICD recipients (7.2% vs. 28.3%, $p < 0.001$), whereas NYHA class III was more commonly observed (16.7% in the remaining European participants, $p < 0.001$).

The mean left ventricular ejection fraction (LVEF) in Polish subjects was lower than in other European participants (27% [18%–35%] vs. 30% [20%–60%], $p < 0.001$) and the lack of any structural heart disease was observed less often (3.2% vs. 13.9%, $p = 0.001$). In comparison to other European centres, in Poland the devices were implanted more often for primary prevention of SCD (80% vs. 66.7%, $p = 0.007$). Atrial fibrillation at implantation was present in 20.7% of Polish patients referred for ICD — more often than among other Europeans subjects (11.2%, $p = 0.02$). Data on baseline characteristics of patients are shown in Table 1.

ICD type in Poland vs. other European countries

The device that was implanted the most often in Polish patients was a cardiac resynchronisation therapy defibrillator (CRT-D; n = 54 [43%]), followed by a single-chamber ICD

Table 1. Baseline characteristics of patients

	Overall (n = 383)	Poland (n = 125)	Other European countries (n = 258)	p*
Age < 18 years	4 (1.0)	0 (0)	4 (1.6)	0.16
Age > 75 years	69 (17.7)	27 (21.6)	42 (16.3)	0.20
Women	92 (23.6)	33 (26.4)	58 (22.5)	0.39
NYHA I	83 (21.3)	9 (7.2)	73 (28.3)	< 0.001
NYHA II	206 (52.9)	63 (50.4)	139 (53.9)	0.52
NYHA III	96 (24.7)	52 (41.6)	43 (16.7)	< 0.001
NYHA IV	4 (1.0)	1 (8%)	3 (1.2)	0.74
Ischaemic HF aetiology	191 (49.9)	71 (56.8)	120 (46.5)	0.06
No structural heart disease	40 (10.4)	4 (3.2)	36 (13.9)	0.001
Primary prevention of SCD	272 (70)	100 (80)	172 (66.7)	0.007
Diabetes mellitus	108 (28.2)	46 (36.8)	62 (24)	0.009
Chronic renal disease	55 (14.4)	23 (18.4)	32 (12.4)	0.12
COPD	35 (9.1)	16 (12.8)	19 (7.4)	0.08
AF/AFL	54 (14.5)	25 (20.7)	29 (11.2)	0.02
Sick sinus syndrome at implantation	11 (2.9)	7 (5.6)	4 (1.6)	0.03
High-degree AV block at implantation	7 (1.9)	2 (1.6)	5 (1.9)	0.82
LVEF [%]	30 (20–60)	27 (18–35)	30 (20–60)	< 0.001
Left bundle branch block	64 (17.2)	28 (23.1)	36 (13.9)	0.04
QRS 120–150 ms	63 (16.9)	18 (14.9)	45 (17.4)	0.45
QRS > 150 ms	110 (29.5)	54 (44.6)	56 (21.7)	< 0.001

Continuous variables presented as median (interquartile range), categorical variables as numbers (percentages). *p for comparison of Polish patients vs. other European patients. AF — atrial fibrillation; AFL — atrial flutter; AV — atrioventricular; COPD — chronic obstructive pulmonary disease; HF — heart failure; LVEF — left ventricular ejection fraction; NYHA — New York Heart Association; SCD — sudden cardiac death

(ICD-VR; n = 44 [35%]) and a dual-chamber ICD (ICD-DR; n = 19 [15%]). Only eight (7%) Polish subjects had an S-ICD implanted during the eight-week survey period. In comparison to other European centres, the proportion of implanted S-ICDs in Poland was lower (7% vs. 26%, p < 0.001), whereas the ratio of CRT-D implantations was higher (43% vs. 26%; p < 0.001). The types of implanted ICDs are presented in Figure 1.

Polish vs. other European patients with S-ICD

Polish patients with implanted S-ICDs were predominantly male (n = 6 [75%]), with ischaemic aetiology of HF (n = 5 [62.5%]) and there was only one (12.5%) patient without structural heart disease.

In comparison to other European patients, Polish S-ICD recipients were more often at the age above 75 years (25% vs. 0%, p < 0.001), were less often in NYHA class I (12.5% vs. 67.7%, p = 0.002), but more often in NYHA class II (87.5% vs. 29.4%, p = 0.001).

The most common comorbidity in Polish patients was coronary artery disease (50%), followed by chronic kidney disease, which was more prevalent than in other European patients (37.5% vs. 5.9%, p = 0.003). Moreover, Polish S-ICD patients had significantly lower LVEF in comparison to subjects from other European centres (32% [14%–50%] vs. 50% [25%–60%], p = 0.04). The data on Polish and other European patients with implanted S-ICDs are summarised in Table 2.

Factors leading to S-ICD or TV-ICD implantation in Poland vs. other European countries

The main reasons leading to S-ICD implantations in Polish subjects were associated with infections or electrode-related complications (i.e. previous device infection with removal; 37.5%) and anticipated lead-related complications in case of conventional ICD use (37.5%), elevated risk of infection (i.e. diabetes, renal failure; 25%), or no adequate venous access (25%). Conversely, the largest subset of patients in other European countries were implanted with S-ICDs because of young age (50%) and anticipated lead-related complications (26.5%). In comparison to other European subjects, Polish patients were significantly more often implanted with S-ICD due to lack of adequate venous access (25% vs. 0%, p < 0.001) and prior infection with device removal (37.5% vs. 1.5%, p < 0.001). The data on the indications for S-ICD implantation are summarised in Figure 2.

Economic issues and the need for CRT more often determined the use of a conventional defibrillator rather than S-ICD in Polish patients. The need for pacing and the choice

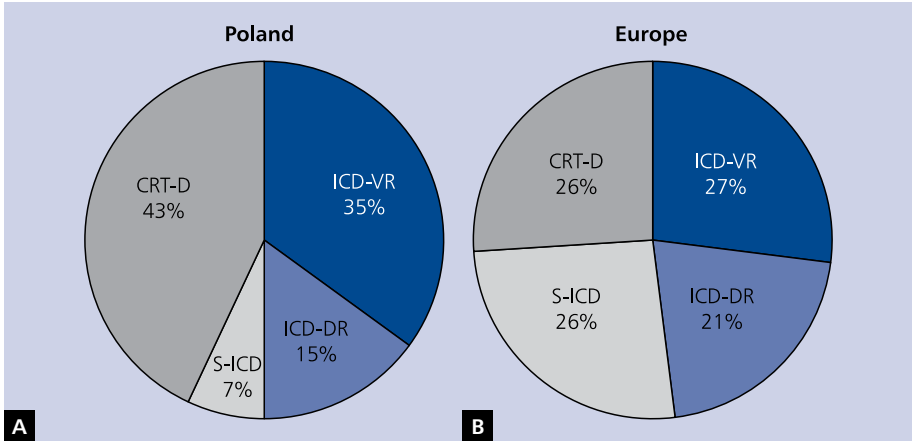

Figure 1. Devices implanted in Poland (**A**) vs. other European (**B**) centres. CRT-D — cardiac resynchronisation therapy defibrillator; ICD-DR — dual-chamber implantable cardioverter-defibrillator; ICD-VR — single-chamber implantable cardioverter-defibrillator, S-ICD — subcutaneous implantable cardioverter-defibrillator

Table 2. Characteristics of patients with subcutaneous cardioverter-defibrillator in Poland vs. other European countries

	Overall (n = 76)	Poland (n = 8)	Other European countries (n = 68)	p*
Age < 18 years	2 (2.6)	0 (0)	2 (2.9)	0.62
Age > 75 years	2 (2.6)	2 (25)	0 (0)	< 0.001
Women	24 (31.6)	2 (25)	22 (32.4)	0.67
NYHA I	47 (61.8)	1 (12.5)	46 (67.7)	0.002
NYHA II	27 (35.5)	7 (87.5)	20 (29.4)	0.001
NYHA III	2 (2.6)	0 (0)	2 (2.9)	0.62
NYHA IV	0 (0)	0 (0)	0 (0)	–
Ischaemic HF aetiology	29 (38.2)	5 (62.5)	24 (35.3)	0.13
No structural heart disease	21 (27.6)	1 (12.5)	20 (29.4)	0.31
Primary prevention of SCD	49 (64.5)	6 (75)	43 (63.2)	0.51
Diabetes mellitus	11 (14.5)	2 (25)	9 (13.2)	0.37
Chronic renal disease	7 (9.2)	3 (37.5)	4 (5.9)	0.003
COPD	3 (3.9)	0 (0)	3 (4.4)	0.54
AF/AFL	6 (7.9)	2 (25)	4 (5.9)	0.06
Sick sinus syndrome at implantation	0 (0)	0 (0)	0 (0)	–
High degree AV block at implantation	0 (0)	0 (0)	0 (0)	–
LVEF [%]	40 (25–60)	32 (14–50)	50 (25–60)	0.04
Left bundle branch block	3 (3.9)	0 (0)	3 (4.4)	0.54
QRS 120–150 ms	14 (18.4)	1 (12.5)	13 (19.1)	0.65
QRS > 150 ms	1 (1.3)	1 (12.5)	0 (0)	0.003

Continuous variables presented as median (interquartile range), categorical variables as numbers (percentages). *p for comparison of Polish patients vs. other European patients. Abbreviations — see Table 1

of an antitachycardia pacing (ATP) option were the other two most frequent reasons influencing the device selection. When compared to Poland, in other European countries the economic factors were significantly less important in the decision-making process (3.9% vs. 32.8%, $p < 0.001$). The choice of an ATP option was the reason for more frequent favouring of conventional defibrillator implantation in other European countries (36.4% vs. 21.6%, $p = 0.003$; Fig. 3A).

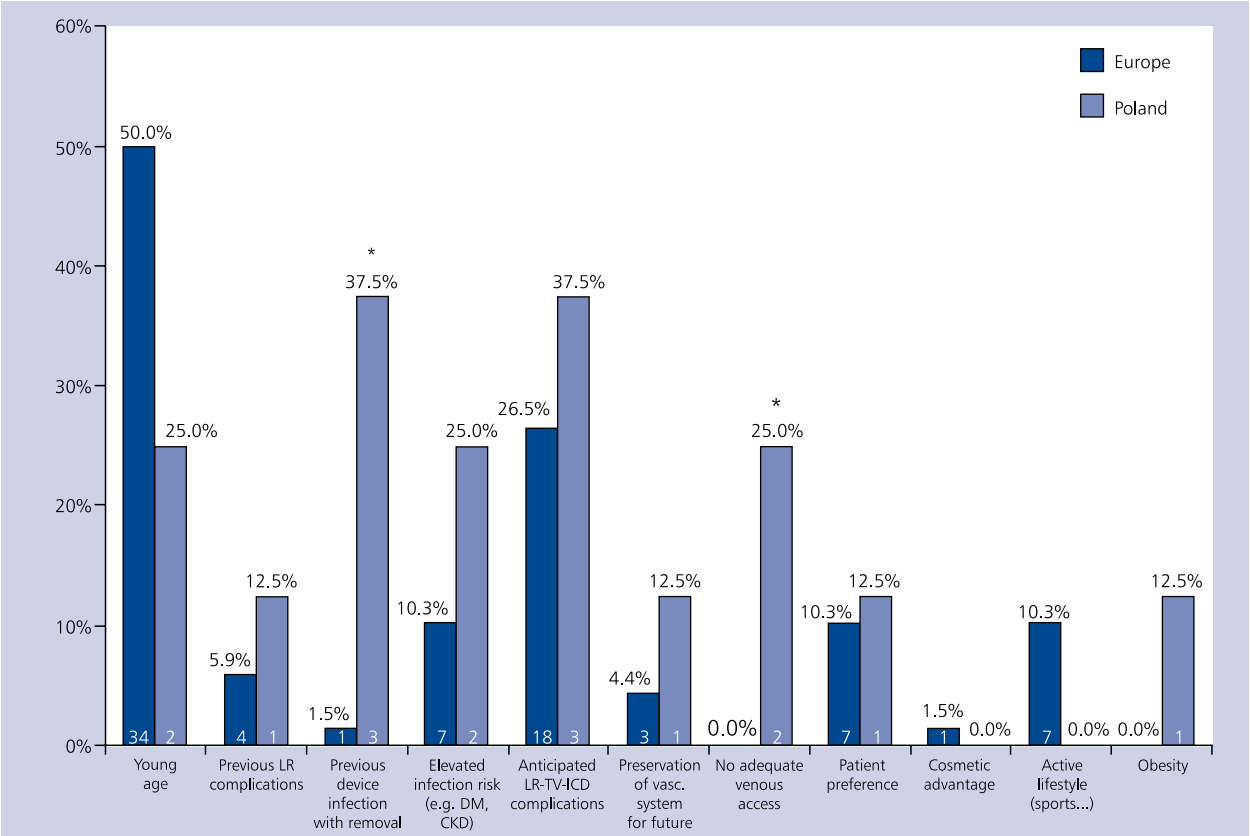

Figure 2. Reasons leading to the implantation of subcutaneous implantable cardioverter-defibrillator (S-ICD) in Polish subjects vs. other European patients (multiple answers). CKD — chronic kidney disease; DM — diabetes mellitus; LR — lead-related; TV-ICD — transvenous implantable cardioverter-defibrillator; *$p < 0.05$

Because there was a significant difference in the percentage of patients with sick sinus syndrome between Poland and other European countries (5.6% vs. 1.6%, $p = 0.03$), a separate analysis of the factors leading to implantation of TV-ICD rather than S-ICD was performed, with the exclusion of these patients (Fig. 3B).

DISCUSSION

The main findings of this sub-analysis are the following: 1) Polish patients referred for ICD implantation had more advanced HF and more comorbidities when compared to subjects from other European countries; 2) S-ICD is still underused in Poland; 3) the main reasons favouring conventional ICD over S-ICD in Polish centres were of economic nature; 4) the main reasons leading to S-ICD implantation in Polish subjects were associated with infections, electrode-related complications or lack of adequate venous access; 5) the distribution of device types was different in Poland as compared to other European countries, with a lower rate of S-ICD implantations and higher rate of CRT-D devices.

This EHRA prospective multicentre snapshot survey was designed to recognise European practices in the management of TV-ICD and S-ICD patients and recently provided an up-to-date overview of indications for ICD, periprocedural routines, and complications in European tertiary centres [12, 13]. Our sub-analysis provides an additional important contemporary view on Polish patients undergoing ICD implantation and examines the criteria that influence the choice between S-ICD and TV-ICD in Poland, in comparison to other European countries.

The baseline characteristics of Polish ICD recipients were different from those of patients from other European countries. The crucial difference was a more advanced HF and more comorbidities. Polish patients undergoing ICD implantation were older, more often in NYHA class III, with lower LVEF, and more often with left bundle branch block, diabetes mellitus, and atrial fibrillation. These differences in baseline characteristics were also observed in the exclusive analysis of the group of patients undergoing S-ICD implantation. The possible reasons for this discrepancy may depend on multiple factors. It was already reported that Polish patients at the time of HF diagnosis are younger and have higher LVEF, but are implanted significantly less frequently with devices such as ICD, CRT, and CRT-D, compared to HF patients in other European countries [14]. It seems that, even though HF is diagnosed at a relatively young age in Poland, the decision to implant the

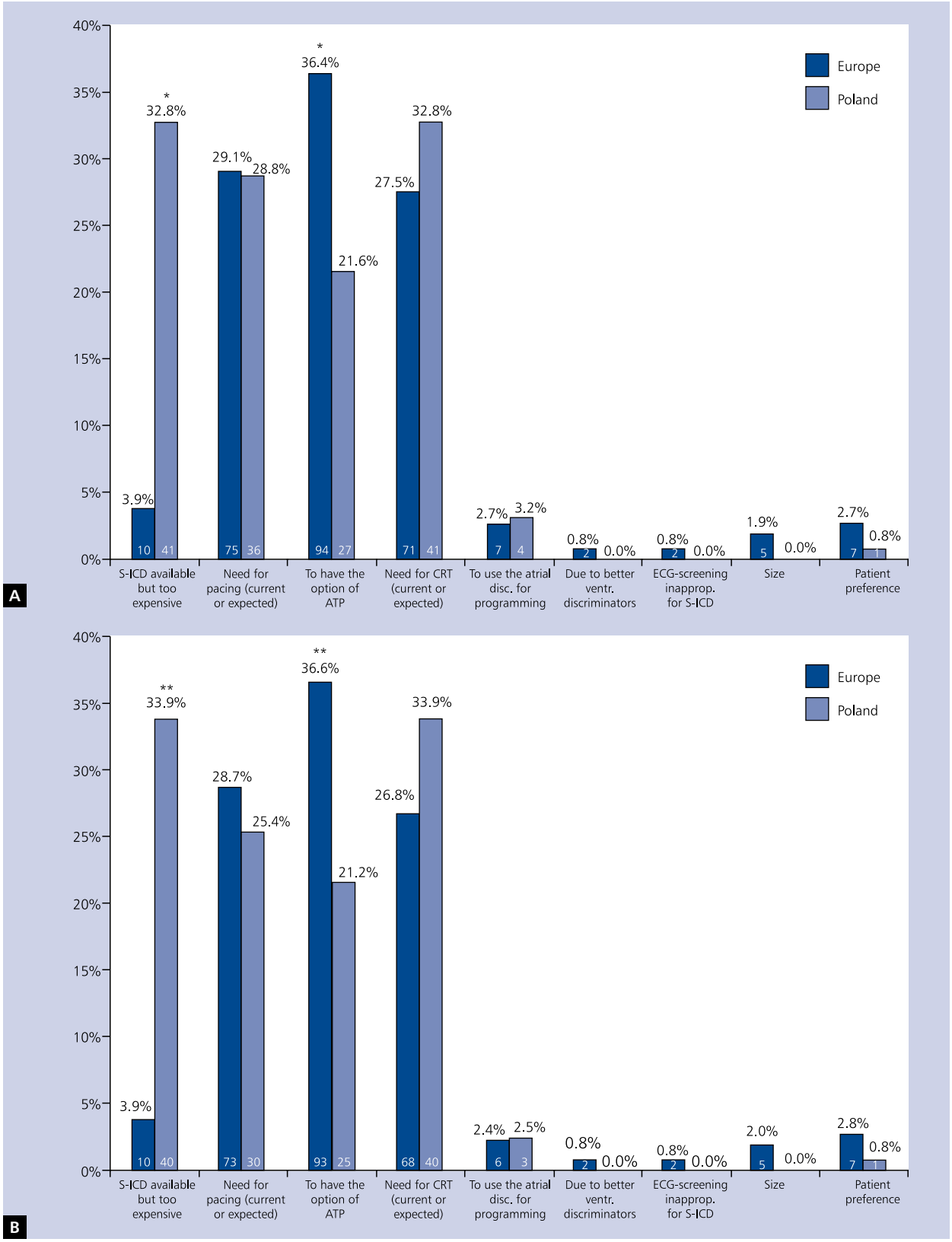

Figure 3. Reasons leading to the implantation of transvenous implantable cardioverter-defibrillator (TV-ICD) in Polish patients vs. other European patients (multiple answers). **A.** All patients; **B.** All patients apart from subjects with sick sinus syndrome. ATP — antitachycardia pacing; CRT — cardiac resynchronisation therapy; ECG — electrocardiogram; S-ICD — subcutaneous implantable cardioverter-defibrillator; *p < 0.05

device is postponed. There are several probable explanations for this phenomenon. As previously demonstrated, only 55% to 60% of patients with the indications for ICD or CRT were referred for device implantation, and in 40% to 44% of cases the procedure was not performed due to physician's doubts or patient's refusal [15]. The model of health care in Poland assumes that patients with diagnosed HF in whom pharmacological treatment was already established should be under the supervision of general practitioners (GPs), with only periodic consultations with a cardiologist. However, it was reported that, although HF pharmacotherapy prescribed by GPs is similar to the treatment recommended by cardiologists in Poland, the perception of indications for cardiac implantable devices differs substantially (outpatients treated by GPs less commonly receive ICDs and CRTs) [16]. What is more, since LVEF in Polish patients is higher at the time of HF diagnosis, a significant proportion of them do not initially have indications for an ICD. An excessive expectation for LVEF to improve with time might also play a role in deferring the decision to implant an ICD. Finally, a significant proportion of younger patients (greater than that of older subjects) refuse to be implanted with an ICD.

Our country-specific data show that the criteria determining the choice between S-ICD and TV-ICD in Polish centres may differ from those used in other countries. This sub-analysis showed that the main reasons leading to the use of a conventional ICD instead of S-ICD in Poland were economic issues. All new technologies are expensive, and their reimbursement in Poland is restricted only to special cases. Our results demonstrate, however, that despite the above there are some groups of Polish patients in whom the S-ICD is preferred over the TV-ICD, although for different reasons than in other European countries. In Poland, the main reasons leading to S-ICD implantation were infections or electrode-related complications, such as previous device infections with removal, anticipated lead-related complications, high risk of infection, or inadequate venous access. This is in contrast with other European countries, where young age of patients was the most common reason for S-ICD use [12]. Problems with transvenous electrodes are the main drawbacks of TV-ICDs, and they were among the reasons to develop the S-ICD system. Subsequently, a body of clinical evidence has been gathered confirming that S-ICD technology is safe and that the midterm efficacy of this therapy is similar to that observed in TV-ICD studies [7, 8]. Consequently, the use of S-ICDs has spread widely, and subcutaneous devices have been implemented not only in patients with difficult venous access or after ICD infections, but also in those requiring long-term ICD therapy. Our sub-study showed that in Polish patients, S-ICD is an alternative to TV-ICD only in very selected cases: mainly when the TV-ICD has led to complications or if no venous access can be found. In other words, standard ICD is the first-line therapy and S-ICD is only chosen when the implantation of a TV-ICD is not possible. Probably due to economic reasons, this is in contrast to other European countries, where the new technology is penetrating daily practice to prevent complications caused by "older technologies."

On the other hand — putting the economic issues aside — the reasons for choosing the TV-ICD were quite similar in Poland and in other European centres. In over 83% of cases they were associated with the limitations of S-ICD systems, such as the need for pacing, CRT, and the possibility to deliver ATP. At present, S-ICD is not conventionally an option for patients who require permanent pacing; nonetheless, when combined with a transvenous pacemaker, such a combination is feasible [17–19].

Finally, the distribution of device types was different in Poland as compared to other European countries. The number of S-ICD implantations was lower, whereas the number of CRT-D devices was higher (reaching over 40% of all ICDs). In other European countries the proportions of ICD-VRs and S-ICDs were comparable. However, in Poland the number of implanted S-ICDs was significantly lower than the number of ICD-VRs, making up only one-sixth of all ICDs. Previously published data show that S-ICD technology penetrates clinical practice in Poland [20–22], but our analysis suggests that this process is slow; similar unfavourable trends were previously observed with the spreading adoption of conventional ICDs [23]. Looking at published data on feasibility and safety, as well as system performance and inappropriate shock rates, which were comparable with those reported for conventional ICDs, it seems justified to suppose that, in the absence of the need for pacing or CRT, S-ICD could gradually replace a considerable percentage of single- and dual-chamber TV-ICDs. This suggestion is supported by the European Society of Cardiology guidelines for the management of patients with ventricular arrhythmias and the prevention of SCD. These recommendations treat S-ICD as an alternative to TV-ICD in patients with an indication for ICD, when pacing therapy for bradycardia support, CRT, or ATP is not needed, and in young patients with a long-term need for ICD therapy. When looking at our data on the reasons for choosing TV-ICD instead of S-ICD, the need for pacing or CRT was comparable in Poland and other European countries, whereas the potential need for ATP was even more common in other European countries. Thus, the percentage of patients in whom S-ICD was not an option was probably comparable in Poland and other European countries. Lastly, CRT-Ds were implanted in a higher percentage of Polish patients when compared to other European countries. This might be the effect of different baseline characteristics of Polish ICD recipients, who had more advanced HF and, probably, greater prevalence of wide QRS complex and left bundle branch block.

Our sub-analysis of this EHRA prospective snapshot survey has several limitations. The main one is the small number of patients with implanted S-ICDs. On the other hand, this finding reflects the real life because the number of S-ICD

implantations in Poland is small, with only 15 patients having received this device in 2015 [24]. Secondly, participation in the survey was voluntary and based on high-volume centres; thus, generalisation of the results must be restricted to tertiary clinical centres. Lastly, the survey was based on data obtained from the questionnaire, which limited the answer options only to the most common ones.

In conclusion, the main reasons leading to S-ICD implantation in Polish patients differ from those adopted by other European countries. Polish patients referred for TV-ICDs and S-ICDs had more advanced HF and more comorbidities in comparison to subjects from other European centres. S-ICD is still underused in Poland.

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WHAT IS NEW?

The main reasons leading to the implantation of subcutaneous implantable cardioverter-defibrillators (S-ICDs) in Polish patients differ from the indications adopted in other European countries. In Poland, the main reasons favouring conventional ICD implantation were of economic nature, whereas the indications for S-ICD were associated with infections, electrode-related complications, or a lack of venous access. In other European countries the majority of patients were implanted with S-ICD because of young age. Polish patients referred for transvenous-ICD and S-ICD implantations had more advanced heart failure and more comorbidities in comparison to their counterparts from other European countries. S-ICD is underused in Poland — the proportion of S-ICD implantations is lower, whereas the ratio of cardiac resynchronisation therapy defibrillator implantations is higher in comparison to other European centres.