

Do we differ in terms of indications and demographics in cardiac resynchronisation recipients in Poland? Insights from the European CRT Survey II Registry

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Abstract

Background: Multiple randomised clinical trials have proven that cardiac resynchronisation therapy (CRT) reduces morbidity and mortality in appropriately selected patients with congestive heart failure and is recommended for such patients as per the European Society of Cardiology guidelines.

Aim: In this paper we compare the indications and demographics in cardiac resynchronisation recipients in Poland and other European countries.

Methods: In 2015 and 2016, physicians from 42 European countries participated in the second edition of the European Cardiac Resynchronisation Therapy Survey. For 14 months, 288 implanting centres gathered data regarding demography, indications, implanting methods, and guidance compatibility from 11,088 patients receiving CRT.

Results: The survey revealed that a vast group of patients were eligible for CRT implantation (although some of them with relatively weak guidance recommendations) and showed essential variety in clinical practice when national data were benchmarked.

Conclusions: The population of CRT recipients in Poland and other European countries did not differ in terms of demographic and clinical characteristics. In most cases, indications for CRT were in accordance with the guidelines; however some devices were implanted in patients beyond the guideline recommendations. For these procedures, the decision regarding CRT implantation relies mainly on the physicians' experience.

Key words: cardiac resynchronisation therapy, chronic heart failure, survey

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INTRODUCTION

The incidence of heart failure (HF) approaches five to ten cases per 1000 people per year, and the prevalence can be estimated as 1% to 2% of the adult population in developed countries, rising to 10% among people over 70 years of age [1, 2]. Throughout the last decades, advancements in therapies and their implementation have improved survival and reduced the hospitalisation rate in patients with congestive heart failure (CHF). One of the treatments, cardiac resynchronisation therapy (CRT), supports cardiac performance in appropriately selected patients, improves symptoms and well-being, and reduces morbidity and mortality [3]. A total of 14 randomised clinical trials (RCTs), involving 4420 patients proved that CRT decreased hospitalisation by 37% and all-cause mortality by 22% [4].

In 1994, Serge Cazeau, a cardiologist at Val d'Or Surgical Centre in St. Cloud, France, implanted the first four-chamber pacing device in a patient with severe CHF [5]. In 2005, CRT was included in the European Society of Cardiology (ESC) guidelines. Since 2011, every year the average CRT implantation rate in western and central Europe was approximately 140 units per million population, with an advantage of CRT-defibrillators (CRT-D) over CRT-pacemakers (CRT-P) [6]. In Poland, since Professor Kutarski implanted the first CRT in 1998, the method has evolved rapidly, reached an important position and was a subject of multiple observations [7].

The aim of CRT is to restore atrioventricular as well as inter- and intraventricular synchrony via three leads positioned in the right atrium, right ventricle (RV), and left ventricle (LV) through the coronary sinus tributary.

Continuous biventricular pacing prevents blockade in the cardiac conduction system. CRT improves the LV function, reduces functional mitral regurgitation, and induces LV reverse remodelling, as shown by an increase in LV filling time and left ventricular ejection fraction (LVEF) and a decrease in LV end-diastolic and end-systolic volumes, mitral regurgitation, and septal dyskinesis [8].

Combined data of sub-groups of patients from the COM-PANION, CARE-HF, MADIT-CRT, REVERSE, and RAFT trials proved that CRT is most beneficial to symptomatic patients (New York Heart Association [NYHA] class II–IV) with complete left bundle branch block (LBBB), QRS duration ≥ 150 ms, and severely depressed LVEF $\leq 35\%$ [6]. Therefore, the current guidelines give strong recommendations for CRT in such patients, who do not respond sufficiently to medical therapy.

In 2015, two ESC Associations, the European Heart Rhythm Society (EHRA) and the Heart Failure Association (HFA), formed the European Cardiac Resynchronisation Therapy Survey II, a 15-month initiative (from October 2015 to December 2016) designed to collect a large volume of clinical and demographic data on the delivery of CRT in European countries [9, 10]. In this paper we present the main differences between the CRT recipients in Poland and other European countries.

METHODS

Thanks to the efforts of medical teams from 288 centres, the survey gathered data from 42 countries involving 11,088 patients and provided information permitting centres and countries to benchmark their practice with international practice.

After providing general information on the implanting centre (facility type, size, operator speciality), each hospital was asked to complete an electronic case report form on consecutive patients who were referred for CRT implantation [11]. The electronic case report form collected data on patients' characteristics, examinations, indications for CRT, implantation procedures, and short-term outcome including adverse events and complications. Information on longer-term outcome was not collected.

The survey was created to investigate only new CRT implantations (either CRT-P or CRT-D), including both successful and unsuccessful procedures. This also included upgrades from previously implanted cardioverter-defibrillators (ICDs) or permanent pacemakers.

Poland provided essential data on 1241 patients with CRT, which comprised 11.2% of the whole survey group. In the present study, Polish patients were compared with the control group of 9847 patients from all other participating countries in terms of each available demographic and procedural parameter.

Ethical approval and written, informed consent were obtained according to the rules for clinical investigations in each participating country at the initiation of the study.

Statistical analysis

Absolute numbers and percentages were shown for categorical variables to describe the patient population, and means (with standard deviations) or medians (with interquartile range) were used for continuous variables. Categorical variables were compared between subgroups by the χ^2 test and continuous variables (numerical values) by the Mann-Whitney-Wilcoxon test.

A significance level of $p < 0.05$ was assumed for the statistical tests. All statistical analyses were performed using SAS statistical software (version 9.1, Cary, NC, USA).

RESULTS

A total of 1192 devices were implanted in Poland, with an advantage of CRT-Ds (87%) over CRT-Ps (13%). In 69.4% of patients receiving CRT-D the clinical indication for the implantation was CHF with wide QRS. On the other hand, 70.3% of patients referred for CRT-P had a pacemaker indication with an expected high percentage of RV pacing. The main differences between CRT-D and CRT-P subgroups are presented in Table 1. In Poland, the mean age of the patients was 67.7 ± 9.7 years compared to 68.6 ± 10.9 years in all other countries (median 68 and 70 years, respectively, $p < 0.00001$). The majority of patients receiving CRT were

Table 1. Characteristics of cardiac resynchronisation therapy-defibrillator (CRT-D) and cardiac resynchronisation therapy-pacemaker (CRT-P) recipients in Poland

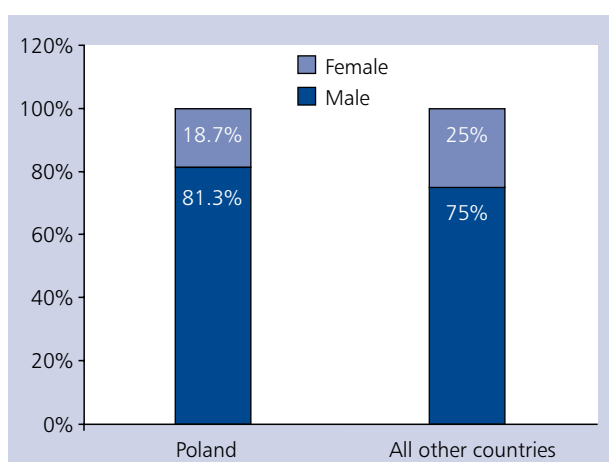
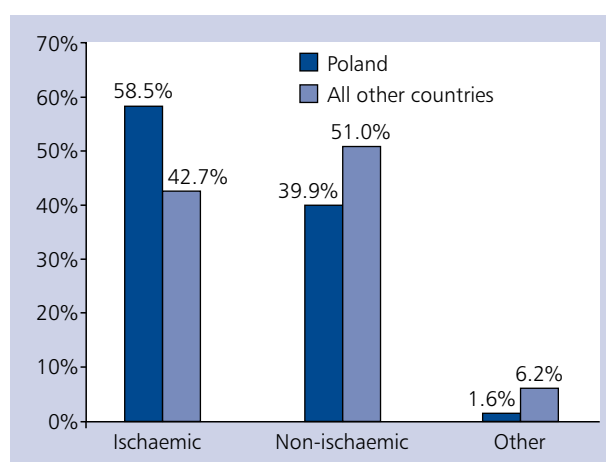
	CRT-D (n = 1137)	CRT-P (n = 115)	p
Mean age [years]	66.6 ± 9.3	74.7 ± 9.7	< 0.00001
Male/female sex	81.7/18.3	77.4/22.6	0.19893
Atrial fibrillation	40.8	57.4	0.00010
Previous pacemaker implantation	8.2	36.1	< 0.00001
Previous ICD implantation	18.2	0	< 0.00001

Data are shown as mean ± standard deviation or percentage. ICD — implantable cardioverter-defibrillator

Table 2. History of patients with ischaemic heart failure

	Poland (n = 1241)	Other countries (n = 9847)	p
Myocardial infarction	48.4	34.7	< 0.00001
Prior revascularisation (PCI/CABG)	51.2	37.3	< 0.00001

Data are shown as percentage. CABG — coronary artery bypass grafting; PCI — percutaneous coronary intervention

**Figure 1.** Sex proportions in the analysed populations ($p < 0.00001$)**Figure 2.** Primary heart failure aetiology ($p < 0.00001$)

men (Fig. 1). Additionally, 47% of the total European group had an HF hospitalisation during the previous year.

There were substantial differences in primary aetiology of HF in Polish patients compared to patients from other countries (Fig. 2). More detailed data from the survey revealed that in Poland there were also a greater number of patients with a history of myocardial infarction and prior revascularisation (percutaneous coronary intervention or coronary artery bypass grafting; Table 2) [12].

The EuroHeart Survey showed that persistent and permanent atrial fibrillation (AF) account for approximately 51% of AF [13]. In the European CRT Survey II, patients with

diagnosed AF formed a large part of the cohort — 43.8% in Poland and 40.5% in all other countries, with the rates of persistent and permanent forms at 55.1% and 67.0%, respectively ($p = 0.00024$).

Patients with CHF tended to have several comorbidities. The management of these is often crucial for successful HF treatment. The major comorbidities occurring in patients with HF and an implanted CRT device are presented in Table 3.

Apart from demographic data and clinical status, another area of interest presented in the European CRT Survey II is indications for device implantation according to the ESC guidelines. The clinical indications for CRT are presented in Table 4.

Table 3. Major comorbidities occurring in patients with congestive heart failure

Comorbidity	Poland	Other countries	p
Hypertension	68.4	63.3	0.00041
Valvular heart disease	32.3	26.5	0.00002
Obstructive lung disease	10.0	12.3	0.019
Diabetes	37.2	30.7	< 0.00001
Anaemia	14.8	15.1	0.8
Chronic kidney disease (eGFR < 60 mL/min/1.73 m ²)	36.0	30.5	0.0078

Data are shown as percentage. eGFR — estimated glomerular filtration rate

Table 4. Clinical indications for cardiac resynchronisation therapy (CRT)

Clinical indication for CRT	Poland	Other countries	p
Heart failure with wide QRS	67.7	59.0	0.0001
Heart failure and indication for ICD	55.5	46.9	0.0001
Pacemaker indication and expected high percentage of RV pacing	22.7	22.8	0.9385
Evidence of mechanical dyssynchrony	14.6	11.1	0.0003

Data are shown as percentage. ICD — implantable cardioverter-defibrillator; RV — right ventricle

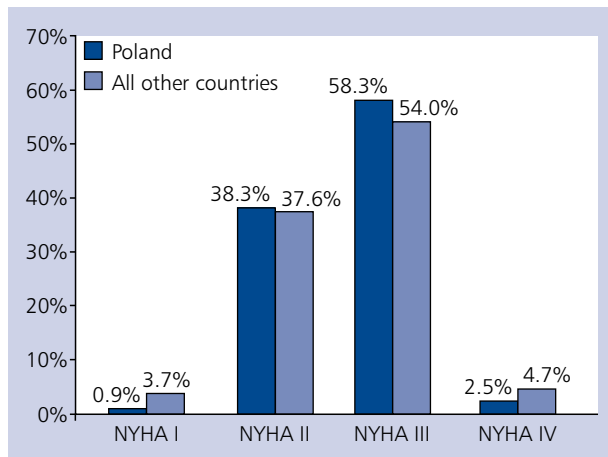


Figure 3. New York Heart Association (NYHA) class in pre-implantation clinical evaluation (p = 0.246)

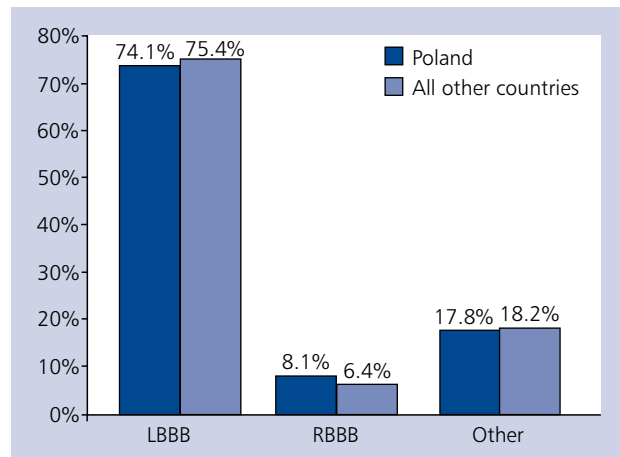


Figure 4. QRS morphology groups; LBBB — left bundle branch block; RBBB — right bundle branch block (p = 0.03336)

Cardiac resynchronisation therapy is recommended for symptomatic patients with HF in NYHA functional class II–IV and a wide QRS. In Poland, 67.7% of patients (vs. 59.0% in all other countries) met these criteria, due to the presence of LV dysfunction and indications for ICD because of wide QRS. Additionally, almost 10% of patients in both compared groups were referred for CRT due to indication for pacemaker and expectation of a high percentage of RV pacing even without HF symptoms (NYHA functional class I) (Fig. 3).

Both in Poland and in other countries, LBBB was present in the majority of patients (Fig. 4). Proportions of pa-

tients with various intrinsic QRS duration are presented in Figure 5.

Another parameter of patient evaluation for CRT is LVEF (Fig. 6). According to data collected in the survey, the most popular imaging method assessing LVEF was echocardiography (99.0% of patients in Poland vs. 91.5% in other countries, p < 0.00001). However, alternative methods of assessing LVEF, such as cardiac magnetic resonance imaging, computed tomography scan, and scintigraphy, were also used. In Poland, these methods were applied in 1.0% of patients, and in other countries this rate was 8.5% (p < 0.05).

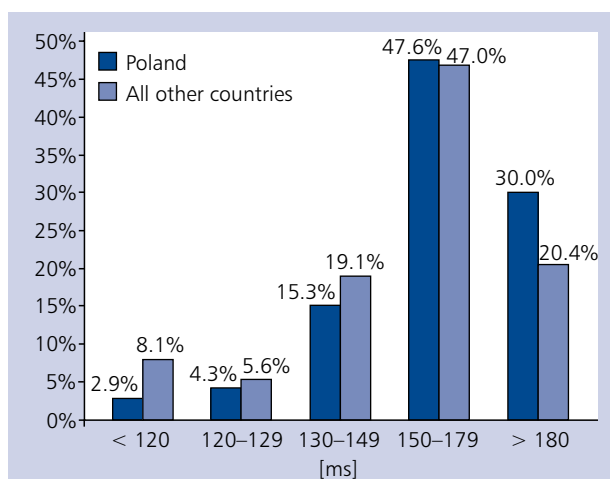


Figure 5. Intrinsic QRS duration ($p < 0.00001$)

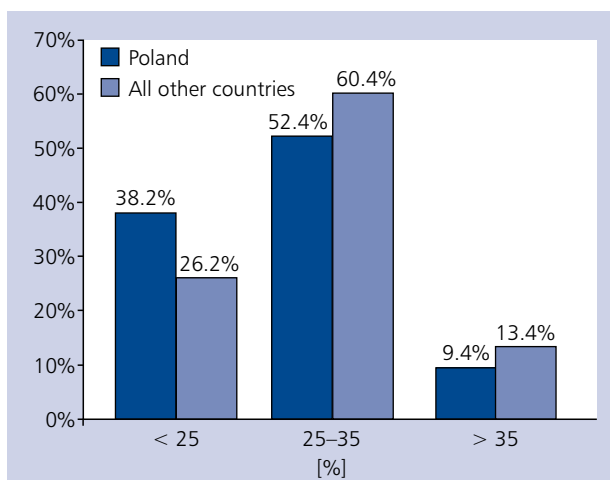


Figure 6. Left ventricular ejection fraction (by any method) measured in pre-implantation imaging ($p < 0.00001$)

DISCUSSION

Patients included in surveys may differ from those enrolled in RCTs due to the distinct methodology of data collection. RCTs have strict protocols concerning patient selection, inclusion and exclusion criteria, and specified outcomes, which is why they include a specific, well-selected group of patients. Conversely, surveys gather a vast amount of data without limitations, demonstrating a wide range of information on selected issues [14].

For Poland, most of the collected data were similar to those obtained from other European nations, but there were also some differences. Compared to patients enrolled in RCTs, Polish patients included in the CRT Survey II were generally older, had narrower QRS complexes, higher LVEF, and more often had AF. However, there was a similar percentage of ischaemic cardiomyopathy and sex proportion [15].

Considering the age of patients included in the survey in terms of the World Health Organization definition of elderly, CRT is a treatment that mostly refers to older people [16].

In both Poland and other European countries, there was a significant difference in the numbers of device implantations in women and men. Women are more likely to experience LBBB and may benefit from CRT at a shorter QRS duration than men [17]. On the other hand, women with HF are older and less likely have severely reduced LVEF [18], which might be the reason why they are much less often referred for CRT device implantation.

In 2013, the ESC in collaboration with the EHRA classified cardiac pacing and CRT patients with persistent and permanent AF as candidates for CRT in their guidelines for the first time. A total of 43.8% patients in Poland and 40.5% in all other countries were diagnosed with AF. Persistent and permanent AF accounted for more than a half of this group [19]. There have been no relevant trials that compared CRT to a control group for patients with AF; however, AF has been shown to decrease biventricular pacing in CRT due to competition with irregular intrinsic atrioventricular (AV) conduction [20]. This could possibly diminish the clinical benefits of device implantation, because CRT requires a high percentage of ventricular pacing to maximise its role in HF therapy. The latest guidelines recommend CRT for patients with AF (class IIa) and stress the importance of biventricular pacing (as close to 100% as can possibly be achieved) either through AV nodal ablation or through pharmacotherapy.

Most patients included in the European CRT Survey II experienced LBBB and an intrinsic QRS duration longer than 150 ms. RCTs meta-analyses have shown that the longer the patient's intrinsic QRS duration, the more beneficial the clinical long-term outcome of CRT implantation [21]. Sub-analyses of RCTs and meta-analyses have shown that the profitable effects of CRT were observed in patients with typical LBBB [22]. Some patients (2.9% in Poland, 8.1% in other countries) received CRT even though they had a QRS duration shorter than 120 ms. Current guidelines based on the ECHO-CRT and LESSER-EARTH trials do not recommend implanting CRT in such cases because there is no evidence of benefit in patients with HF and QRS duration shorter than 120 ms [23, 24].

Both in Poland and in other countries, the majority (90.6% and 86.7%, respectively) of patients had an LVEF of less than 35%. There are only two trials (REVERSE, BLOCK-HF) that enrolled patients with an LVEF greater than 35%. Due to the small group of patients included, the results were inconclusive.

Despite the large number of patients enrolled in the survey, there were huge differences between countries. In countries with only one or two participating centres, results may be inconclusive for the whole country. Moreover, implanting sites may have neglected patients with poor outcome or unsuccessful procedures, because there was no independent monitoring of data collection. During the enrolment period of the survey the new ESC HF guidelines were published. It is difficult to assess their impact on selection and enrolment of patients.

In conclusion, as far as demographic data from the survey are concerned, it can be generally inferred that patients receiving CRT were mainly men with depressed LVEF (mostly less than 35%), LBBB, and an intrinsic QRS duration of more than 150 ms. This was observed for both Poland and other European countries and is in line with the guidance criteria for CRT device implantation.

On the other hand, some devices were implanted in patients with a relatively narrow QRS complex, patients with non-LBBB, and patients with LVEF over 35%. For these indications, guideline recommendations are weak and levels of evidence are low, and the decision regarding CRT implantation relies mainly on the physicians' experience.

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WHAT IS NEW?

In 2015 and 2016, Polish implanting centres participated in the second edition of the European Cardiac Resynchronisation Therapy Survey. For 14 months, European centres gathered a vast amount of data regarding demography, indications, implanting methods, and guidance compatibility from patients with congestive heart failure receiving cardiac resynchronisation therapy. The survey was designed to describe clinical practice regarding implantation of cardiac resynchronisation therapy in a broad sample of hospitals in the European Society of Cardiology member countries. The results enabled an assessment of guideline adherence and demonstrated variations in patient selection, management, implantation procedure, and follow-up strategy. What is more, the survey provided data permitting centres and countries to benchmark their practice with national and international practice.