## Original article

## Spanish Results of the Second European Cardiac Resynchronization Therapy Survey (CRT-Survey II)



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## ABSTRACT

*Introduction and objectives:* We describe the results for Spain of the Second European Cardiac Resynchronization Therapy Survey (CRT-Survey II) and compare them with those of the other participating countries.

*Methods*: We included patients undergoing CRT device implantation between October 2015 and December 2016 in 36 participating Spanish centers. We registered the patients' baseline characteristics, implant procedure data, and short-term follow-up information until hospital discharge.

**Results:** Implant success was achieved in 95.9%. The median [interquartile range] annual implantation rate by center was significantly lower in Spain than in the other participating countries: 30 implants/y [21-50] vs 55 implants/y [33-100]; P = .00003. In Spanish centers, there was a lower proportion of patients  $\geq$  75 years (27.9% vs 32.4%; P = .0071), a higher proportion in New York Heart Association functional class II (46.9% vs 36.9%; P < .00001), and a higher percentage with electrocardiographic criteria of left bundle branch block (82.9% vs 74.6%; P < .00001). The mean length of hospital stay was significantly lower in Spanish centers (5.8  $\pm$  8.5 days vs 6.4  $\pm$  11.6; P < .00001). Spanish patients were more likely to receive a quadripolar LV lead (74% vs 56%; P < .00001) and to be followed up by remote monitoring (55.8% vs 27.7%; P < .00001).

**Conclusions:** The CRT-Survey II shows that, compared with other participating countries, fewer patients in Spain aged  $\geq$  75 years received a CRT device, while more patients were in New York Heart Association functional class II and had left bundle branch block. In addition, the length of hospital stay was shorter, and there was greater use of quadripolar LV leads and remote CRT monitoring.

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# Resultados en España de la encuesta de la Sociedad Europea de Cardiología sobre terapia de resincronización cardiaca (CRT-Survey II)

### RESUMEN

*Introducción y objetivos:* Se describen los resultados en España de la segunda encuesta de la Sociedad Europea de Cardiología sobre terapia de resincronización cardiaca (CRT-Survey II) y se comparan con los de los demás países participantes.

*Métodos*: Pacientes a los que se implantó un dispositivo de terapia de resincronización cardiaca entre octubre de 2015 y diciembre de 2016 en 36 centros participantes. Se recogieron datos sobre las características basales de los pacientes y del implante, y un seguimiento a corto plazo hasta el alta hospitalaria.

**Resultados:** La tasa de éxito del implante fue del 95,9%. La mediana [intervalo intercuartílico] de implantes anuales/centro en España fue significativamente menor que en los demás países participantes: 30 [21-50] frente a 55 [33-100] implantes/año (p = 0,00003). En los centros españoles hubo una menor proporción de pacientes de edad  $\geq$  75 años (el 27,9 frente al 32,4%; p = 0,0071), una mayor proporción de pacientes en clase funcional II de la *New York Heart Association* (el 46,9 frente al 36,9%; p < 0,00001) y un mayor porcentaje de pacientes con criterios electrocardiográficos de bloqueo de rama izquierda (el 82,9 frente al 74,6%; p < 0,00001). La media de la estancia hospitalaria fue menor en los centros españoles (5,8 ± 8,5 frente a 6,4 ± 11,6; p < 0,00001) y una mayor proporción de pacientes a distancia (el 55,8 frente al 27,7%; p < 0,00001).

*Conclusiones*: La encuesta CRT-Survey II muestra que en España hay una menor proporción de pacientes de 75 o más años que reciben un dispositivo de terapia de resincronización cardiaca, una mayor proporción de pacientes en clase funcional II de la *New York Heart Association*, con bloqueo completo de la rama izquierda del haz de His y con seguimiento a distancia, con estancias hospitalarias significativamente menores.

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## Abbreviations

CRT: cardiac resynchronization therapy EHRA: European Heart Rhythm Association ESC: European Society of Cardiology LBBB: complete left bundle branch block LV: left ventricle

## **INTRODUCTION**

Cardiac resynchronization therapy (CRT) has been shown to reduce morbidity and mortality in adequately selected patients with symptomatic heart failure, reduced ejection fraction, and wide QRS.<sup>1–7</sup> For this reason, clinical guidelines issued in Europe and other countries describe the indications for this therapy based on solid evidence and high levels of recommendation.<sup>8–11</sup>

The available scientific evidence on CRT comes from randomized clinical trials, observational studies, and registries. Randomized clinical trials have been designed to answer specific questions, which are clearly defined in their protocols, and have strict inclusion and exclusion criteria. Thus, the results of these studies are only applicable to the population specifically included in each study. In contrast, data from registries and surveys represent daily clinical practice and offer a real-world picture of the use and benefit of a particular medication or device.<sup>12</sup>

The first European Society of Cardiology (ESC) cardiac resynchronization therapy (CRT) survey (CRT-Survey I) was conducted from 2008 to 2009 in 13 member countries of the ESC. The results showed that CRT was being applied in a very broad range of the population, which had not been adequately represented in the randomized clinical trials published until that time.<sup>13</sup> This population, which was poorly represented in the large clinical trials, included patients aged 75 years or more, patients with a narrow QRS, patients with atrial fibrillation, and patients whose conventional pacemaker or implantable cardioverterdefibrillator had been upgraded. In addition, the CRT-Survey I found wide variations in CRT implantation practice both regionally and nationally. Since the CRT-Survey I was first published, relevant changes have been introduced in the ESC clinical practice guidelines on CRT by the Heart Failure Association (HFA) and the European Heart Rhythm Association (EHRA).<sup>8,9</sup> Given this background, both associations decided to conduct a second edition of the ESC-CRT-Survey. The aim was to describe current clinical practice that would be useful for patients, physicians, managers, the pharmaceutical industry, and device manufacturers. We present and compare the results of the Spanish CRT-Survey II with those from the other participating countries.

#### **METHODS**

### Survey design and scientific committee

The survey was designed as a joint initiative of the HFA and the EHRA.<sup>14</sup> The design of the CRT-Survey II and the detailed content of the electronic case report form (eCRF) have been previously published.<sup>14</sup>

Each participating country was represented by a national coordinator appointed by the president of the corresponding national society of cardiology. The national coordinator was responsible for obtaining approval from the ethics committee if needed, recruiting the participating centers, and distributing information from the scientific committee to all participants. In the case of Spain, 54 hospitals were invited to participate, of which 36 actively participated in the survey and included at least 1 patient.

#### Study population and patient inclusion period

The study included any patient selected for implantation with a CRT pacemaker (CRT-P) or CRT defibrillator (CRT-D) in any of the 36 participating Spanish hospitals. Patients were included regardless of procedural success. We included primary implants and upgrading procedures from a previous pacemaker or a previous implantable cardioverter-defibrillator. We excluded generator replacement and surgical revisions of previously implanted devices because the survey was designed to include only the implantation of new CRT devices.

The patient inclusion period was initially planned to last 9 months. The first patient was included on October 1, 2015. Subsequently, the scientific committee decided to extend the inclusion period by 6 months to December 31, 2016, with the aim of increasing the size of the sample in order to increase its

representativeness and thus enable comparisons between the participating countries.

#### Hospital questionnaire

Each of the participating centers completed a questionnaire on its characteristics, such as the size of the hospital (number of beds), the type of center (public/private/university), the catchment population, the operator's degree of specialization, infrastructures, and the routine CRT device implantation protocol used.<sup>14</sup>

### Electronic case report form

The participating centers were asked to include patients who were scheduled to receive a CRT device and to complete an electronic case report form (eCRF) for each patient. The eCRF collected information on patient characteristics, complementary tests performed, indication for CRT, implant procedure, and a short-term follow-up that included adverse events and complications until hospital discharge.<sup>14</sup> No data were recorded on longer-term follow-up. The anonymity of the participating patients was ensured at all times. The study protocol was approved by the Clinical Trials Committee of the *Hospital Universitari i Politècnic La Fe de Valencia*.

#### Data collection and processing

The eCRF, data processing, and statistical analyses were conducted by the *Institut für Herzinfarktforschung*.<sup>15</sup> The daily operational control of the progress of the survey was conducted at Stavanger University Hospital, University of Bergen, Norway.

Continuous variables are expressed as medians [interquartile range]. Discrete variables are expressed as percentages. Data obtained by the Spanish centers and the participating centers were compared using the Student *t* test for continuous variables and the chi square test for discrete variables. A *P* value of  $\leq$  .05 was used as a cutoff for statistical significance.

## RESULTS

The CRT-Survey II included 11 088 patients from 42 countries belonging to the ESC (Table 1). In Spain, the study included 847 patients from the 36 participating hospitals (Table 2). The representativeness of the survey was estimated using data on implants in each country according to the EHRA white paper. Thus, the survey collected information on 20.1% of all predicted CRT implants in Spain during the inclusion period.

#### Characteristics of the participating hospitals

The median number of annual CRT implants reported by the 36 Spanish centers was 30 [21-50], which was significantly less than the median of 55 [33-100] reported by the other participating countries (P < .001) (Table 3). Most of the participating Spanish centers were university hospitals (94.3%), whereas in the other countries there was broad representation of nonuniversity teaching hospitals (25.9%) and private hospitals (8.8%).

#### **Patient characteristics**

In Spain, the median age of the study patients was 69 [62-75] years, which was similar to the other patients (70 [62-76] years)

Participating countries and number of patients included

Country	Patients included, No.
Germany	675
Algeria	66
Armenia	2
Austria	407
Belgium	262
Bulgaria	264
Croatia	115
Czech Republic	931
Denmark	254
Egypt	22
Slovakia	472
Slovenia	119
Spain	847
Estonia	58
Finland	351
France	754
Georgia	24
Greece	137
Hungary	467
Iceland	19
Ireland	85
Israel	39
Italy	526
Kazakhstan	34
Latvia	79
Lebanon	30
Lithuania	173
Luxembourg	36
Macedonia	70
Malta	26
Montenegro	6
Morocco	12
Netherlands	202
Norway	370
Poland	1241
Portugal	58
UK	571
Romania	214
Russia	71
Sweden	255
Switzerland	320
Turkey	424
Total	11 088

(Table 4). There was a lower percentage of patients aged 75 years or more in Spanish centers (27.9%) than in the other centers (32.4%; P = .007). There was a very similar percentage of implants in men and women: 75% and 25% in Spanish centers, respectively, and 75.8% and 24.2% in the other centers, respectively. The percentage of implants conducted via scheduled admission was lower in Spain than in the other countries (68.8% vs 77.6%; *P* < .001). However, the number of patients included in clinical trials was higher in Spain (11.0% vs 8.1%; P = .003). The type of heart disease underlying the need for implantation significantly differed between Spain and the other countries, with a lower percentage of patients with ischemic dilated cardiomyopathy (38% vs 45%), and a higher percentage of patients with

#### Table 2

Spanish centers participating in the crt-survey ii and number of patients included by center

Hospital	Patients included, No.
Hospital General Universitario de Albacete	27
Hospital General de Alicante	34
Hospital de San Juan de Alicante	33
Hospital Araba	24
Hospital Universitario Central de Asturias	30
Hospital Germans Trias i Pujol, Badalona	48
Hospital Clínic de Barcelona	6
Hospital Vall d'Hebron, Barcelona	40
Hospital de Basurto, Bilbao	8
Hospital General Universitario de Castellón	63
Hospital Reina Sofía, Córdoba	22
Hospital Universitario de Getafe	15
Hospital Virgen de las Nieves, Granada	3
Hospital General Universitario de Guadalajara	9
Hospital Insular de Gran Canaria	17
Complejo Hospitalario de León	8
Hospital Arnau Vilanova de Lleida	27
Hospital Clínico de Madrid	10
Hospital 12 Octubre, Madrid	53
Hospital Universitario Gregorio Marañón, Madrid	20
Hospital La Paz, Madrid	1
Hospital Puerta Hierro, Madrid	10
Hospital Son Espases, Mallorca	20
Hospital Costa del Sol, Marbella	17
Hospital Clínico Universitario Virgen de la Arrixaca, Murcia	43
Hospital Morales Meseguer, Murcia	5
Hospital Reina Sofía, Murcia	15
Hospital Universitario de Salamanca	22
Complejo Hospitalario de Santiago de Compostela	31
Hospital Ntra. Sra. de Valme, Sevilla	7
Hospital Virgen del Rocío, Sevilla	32
Hospital Nuestra Señora del Prado, Talavera de la Reina	1
Hospital Joan XXIII de Tarragona	6
Hospital Clínico Universitario de Valencia	31
Hospital Dr. Peset, Valencia	24
Hospital Universitari i Politècnic La Fe, Valencia	85
Total	847

nonischemic dilated cardiomyopathy (NICM) (53.1% vs 49.5%) or with other etiologies of heart failure (8.9% vs 5.4%; P < .001).

In addition, a smaller percentage of patients had a history of atrial fibrillation (34.9% vs 41.3%; P < .001) and valvular disease (21.4% vs 27.7%; P < .001) (Table 4). However, other comorbidities, such as chronic obstructive pulmonary disease, diabetes mellitus, anemia, and kidney disease were more common in the patients included in the Spanish centers. In total, 26.1% of all implants were upgrading procedures in patients who already had a device.

## Clinical assessment prior to implantation

Most patients were in New York Heart Association (NYHA) functional class II (46.9%) or III (47.5%) (Table 5). In contrast to the other countries, a greater percentage of Spanish patients were in class II (46.9% vs 36.9%; P < .001), whereas the percentage of Spanish patients in class IV was negligible (0.7% vs 4.8%; P < .001).

Characteristics of the participating hospitals

	Spain (n=847)	Other countries (n = 10 241)	Р
Catchment area (×100 000)	4 [3-6]	5 [3-10]	.134
Total number of beds	750 [467-999]	600 [303-950]	.169
Cardiology beds, No.	33 [28-58]	60 [36-82]	< .001
CRT implants/y	30 [21-50]	55 [33-100]	< .001
Pacemaker implants/y	278 [200-400]	250 [175-400]	.783
ICD implants/y	54 [30-98]	80 [41-150]	.021
Cardiac surgery available, %	60	70.7	.199
Coronary angiogram/PCI available, %	94.3	96.2	.587
Dedicated electrophysiology rooms	1 [1-2]	1 [1-2]	.947
Number of CRT implanters			.77
Electrophysiologist	3 [2-4]	2 [1-4]	
Interventional cardiologist	0 [0-4]	1 [0-4]	
Heart failure specialist	0 [0-1]	0 [0-2]	

CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; PCI, percutaneous coronary intervention. Unless otherwise indicated, values are expressed as median [interquartile range].

At the time of implantation, 72.6% of the Spanish patients were in sinus rhythm; the percentage of Spanish patients with atrial fibrillation was slightly lower than that of patients in the other countries, although without reaching statistical significance (23.1% vs 25.9%; P = .078). Mean QRS duration was  $159 \pm 24$  ms. In total, 73% of Spanish patients had a QRS equal to or greater than 150 ms and 19.3% had a QRS of 130 ms to 150 ms. These values are similar to those of the other countries. There was a greater percentage of complete left bundle branch block (LBBB) (81.7% vs 72%; P < .001) and complete right bundle branch block (RBBB) (8.9% vs 6.4%; P = .005) (Table 5) in Spanish patients than in the other patients.

In total, 23.3% of the Spanish patients had a left ventricular ejection fraction (LVEF) greater than or equal to 35%, and 33% had at least moderate mitral regurgitation. The most frequent indication for CRT implantation was heart failure and wide QRS

(55% of patients). In total, 55% of patients had heart failure, severe left ventricular (LV) dysfunction, and indication for implantable cardioverter-defibrillator. In 24.8% of patients, the only reason for implantation was the need for stimulation and a predicted high percentage of stimulation.

## **Implant-related parameters**

In Spain, the implant success rate was 95.9% (Table 6). In contrast to the other countries, implants were mainly performed by electrophysiologists (92.9% vs 75.7%; P < .001). The number of unsuccessful implants was significantly higher in Spain (4.1% vs 2.6%; P = .009). In total, the percentages of Spanish patients with CRT-D (68.8%) and CRT-P (31.2%) were similar to those of the other

## Table 4

Patients' demographic characteristics

	Spain (n=847)	Other countries (n = 10 241)	Р
Age, y	69 [62-75]	70 [62-76]	.053
Age $\geq$ 75 y, %	27.9	32.4	.007
Women, %	25	24.2	.623
Main etiology of heart failure, %			<.001
Ischemic	38	45	
Nonischemic	53.1	49.5	
Other	8.9	5.4	
Previous clinical history and comorbidities, %			
Previous myocardial infarction	35.5	36.3	.642
Previous revascularization (PCI/CABG)	33.8	39.3	.001
Hypertension	67	63.6	.047
Atrial fibrillation	34.9	41.3	< .001
Valvular heart disease	21.4	27.7	< .001
Chronic obstructive pulmonary disease	15.4	11.8	.002
Diabetes mellitus	40.8	30.6	< .001
Anemia	21.7	14.5	< .001
Chronic kidney disease (GFR < 60)	35.6	30.8	.003
Hospitalization for HF during the previous year, $\%$	44.9	46.6	.339
Patients included in clinical trial, %	11	8.1	.003

CABG, coronary artery bypass graft; GFR, glomerular filtration rate; HF, heart failure; PCI, percutaneous coronary intervention. Values are expressed as percentage or median [interquartile range].

Clinical assessment prior to implantation

	Spain (n=847)	Other countries (n = 10 241)	Р
NYHA functional class, %			< .001
I	4.9	3.3	
11	46.9	36.9	
	47.5	55.1	
IV	0.7	4.8	
BMI	28 [25-31]	27 [25-31]	.167
Systolic blood pressure, mmHg	122 [110-135]	122 [110-137]	.154
Diastolic blood pressure, mmHg	70 [61-79]	72 [67-80]	< .001
Analytical parameters (most recent)			
BNP, pg/mL	619 [205-1.105]	420 [149-1.115]	.257
NT-proBNP, pg/mL	2469 [978-5250]	2400 [1070-5523]	.667
Serum creatinine, mg/dL	1 [1-2]	1 [1-1]	.309
Hb, g/dL	13 [12-14]	13 [12-15]	< .001
ECG before implantation			
Heart rate, bpm	70 [60-79]	70 [61-80]	< .001
Atrial rhythm, %			.023
Sinus	72.6	68.9	
Atrial fibrillation	23.1	25.9	
Atrial paced rhythm	2.2	2.9	
Other	2.2	2.4	
PR interval, ms	180 [160-210]	180 [160-210]	.877
AV block II/III, %	22.9	18.6	.002
Pacemaker-dependent, %	15.8	13.9	.128
QRS morphology, %			< .001
Left bundle branch block	81.7	72	
Right bundle branch block	8.9	6.4	
Other	9.4	21.6	
QRS duration, ms	160 [145-174]	160 [140-174]	.020
< 120 ms, %	3.7	7.8	
120-129 ms, %	4	5.4	
130-149 ms, %	19.3	18.6	
150-179 ms, %	51.3	46.7	
> 180 ms, %	21.7	21.5	
Clinical indication for CRT, %			
HF with wide QRS	55	60.4	.002
HF or LV dysfunction and indication for ICD	50.2	47.7	.152
Indication for PM and high percentage of predicted RV stimulation	24.8	22.7	.166
Evidence of mechanical asynchrony	8.4	11.8	.002
Other	2.5	4.6	.004
LVEF, %	29 [24-34]	29 [23-34]	.145
LVEF < 25%	26.9	27.6	
LVEF 25-35%	59.2	59.5	
LVEF > 35%	13.9	12.9	
LVEDD, mm	62 [57-68]	63 [58-69]	.002
Mitral regurgitation, %			.478
Mild	44	46.7	
Moderate	25.3	26.6	
Severe	8	6.8	
None	22.7	20	

BMI, body mass index; BNP, brain natriuretic peptide; CRT, cardiac resynchronization therapy; ECG, electrocardiogram; Hb, hemoglobin; HF, heart failure; ICD, implantable cardioverter-defibrillator; LV, left ventricle; LVEDD, left ventricular end-diastolic dimension; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal prohormone of brain natriuretic peptide; NYHA, New York Heart Association; PM, pacemaker; RV, right ventricle. Values are expressed as percentage or median [interquartile range].

Implant-related parameters

	Spain (n=847)	Other countries (n = 10 241)	Р
Scheduled admission, %	68.8	77.6	< .001
Referred from another center, %	24.4	25.4	.537
Time from admission to implantation, d	1 [1-4]	1 [1-4]	.017
Implant success, %	95.9	97.4	.009
Implant failure, %	4.1	2.6	.009
Device type, %			.531
CRT-P	31.2	30.2	
CRT-D	68.8	69.8	
Implanters, %			< .001
Electrophysiologist	92.9	75.7	
HF specialist	0.5	5.4	
Interventional cardiologist	3.7	13	
Surgeon	2.1	4.5	
Other	0.9	1.4	
Duration, min	120 [90-150]	90 [65-120]	< .001
Fluoroscopy time, min	16 [9-28]	13 [8-22]	< .001
Antibiotic prophylaxis, %	99.6	98.6	.011
Defibrillation test, %	1.1	5.1	< .001
First lead implanted, %			< .001
RV	91.4	82.9	
LV	8.6	17.1	
RV lead location, %			< .001
Apical	81.5	59.6	
Septal	16	38.1	
RVOT	2.6	2.3	
LV lead implant success, %	99.3	99.4	.522
Lead implanted via epicardial route, %	11.5	8.8	.011
Type of LV lead, %			< .001
Unipolar	0.7	0.7	
Bipolar	25	43.7	
Multipolar	74.3	55.6	
Coronary venography, %	90.4	91.6	.226
Venography with occlusion, %	58.2	46.2	< .001
Dilatation of the coronary vein, %	1.2	2.5	.025
Checking phrenic nerve stimulation, %	94.1	90.1	< .001
Assessment of the position of the LV lead, $\%$	98.6	97.3	.001
Dual-plane view	92.6	87.8	
Single-plane LAO	6.8	11.5	
Single-plane RAO	0.7	0.7	
Position in LAO projection, %			.645
Lateral	86.7	83.9	
Posterior	10	11.7	
Anterior	3.3	4.4	
Position in RAO projection, %			
Medial	72.9	71	
Basal	13	15	
Apical	14.1	14	
Optimization of the LV lead position, %	17.7	35.2	< .001

CRT-D, cardiac resynchronization therapy with implantable automatic defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; LAO, left anterior oblique; LV, left ventricle; RAO, right anterior oblique; RV, right ventricle; RVOT, right ventricular outflow tract.

Unless otherwise indicated, values are expressed as median [interquartile range].

countries. More CRT-Ds than CRT-Ps (80.1% vs 19.9%) were implanted in patients with ischemic dilated cardiomyopathy than in patients with NICM (64.7% and 35.3% respectively; P < .001). A higher percentage of CRT-Ps than CRT-Ds (58.5% vs 41.5%) were implanted in patients whose indication was the need for

stimulation or a predicted high percentage of stimulation. In Spain, the median duration of the implantation procedure was significantly higher than the mean (120 [90-150] minutes vs 90 [65-120] minutes; P < .001). In total, 11.4% of LV leads were surgically implanted in the epicardium. Multipolar LV leads

were used in 74.2% of patients; this percentage was much higher than that registered in the other countries. The LV lead was in lateral segment locations in 86.7% of patients and in medial segment locations in 72.9% of patients. The periprocedural complication rate was 7.2%, which was significantly higher than the mean of 5.4% reported by the other participating countries (P = .028) (Table 7).

## **Postimplant parameters**

Median hospital stay was significantly lower in Spain than in the other countries: 2 [2-7] vs 3 [2-7] days (P < .001) (Table 8). The major adverse event rate during hospitalization was 3.5%, including a mortality rate of 0.4%. Before hospital discharge, AV and VV intervals were reprogrammed using device-specific software in 35% of patients. In 98% of patients, postimplant follow-up was performed in the same implantation center. In total, 55.8% of the patients were followed up by remote monitoring; this percentage was significantly higher than that in the other countries (27.7%; P < .001).

#### DISCUSSION

The CRT-Survey II provides a real-world picture of the type of patients who are actually receiving a CRT device in Spain. The survey goes beyond the profiles provided by large clinical trials or clinical practice guidelines.

In line with data published by Eucomed, the EHRA, and Spanish pacemaker and implantable cardioverter-defibrillator

registries,<sup>16–19</sup> the CRT device implantation rate in Spanish hospitals was significantly lower than the mean implantation rate in the other participating countries. The median age of patients who received a CRT device was around 70 years, less than 30% were older than 75 years (in contrast to those from the other countries), and only 1 in 4 implants were performed in women. In Spain and the other countries, the main etiology underlying the need for CRT implantation was NICM. However, it is worth noting that a significantly higher percentage of Spanish patients had NICM than dilated ischemic cardiomyopathy compared with the other countries. The explanation could be that, given the lower total implant rate in Spain, implants are carefully selected. Therefore, implants would be favored in those patients who have been shown to obtain the greatest benefit from CRT, as is the case of patients with NICM.<sup>20</sup> Consistent with this argument, the vast majority of Spanish patients who received a CRT device were in NYHA functional class II and III, whereas the number of patients in NYHA functional class IV was negligible (0.7%).

As recommended in the guidelines,<sup>8,9</sup> patient selection was based on QRS morphology and width: nearly 83% of the patients included in Spanish centers had LBBB in the baseline electrocardiogram. This percentage was significantly higher than that in other participating countries. Similarly, 73% of patients had a QRS width equal to or greater than 150 ms, and only 7.7% had a QRS width of less than 130 ms. In both cases, the percentages were significantly higher in Spain than those of the other participating countries, which suggests that candidate selection for CRT might be better in Spain than in the other countries. However, implantation is still performed in patients with RBBB (up to

#### Table 7

Procedural complications and complications before hospital discharge

	Spain (n=847)	Other countries (n = 10 241)	Р
Procedural complications, %	7.2	5.4	.028
Death, %	0.1	0.1	.604
Bleeding, %	0.9	1	.927
Intervention needed	0	0.4	.088
Pocket hematoma	0.9	0.8	.536
Pneumothorax, %	0.5	1	.103
Hemothorax, %	0.1	0.1	.694
Dissection of the coronary sinus, %	3.7	1.8	< .001
Cardiac tamponade, %	0.3	0.2	.539
Other, %	1.9	1.5	.407
Major adverse events during hospitalization, %	3.5	4.9	.082
Myocardial infarction	0	0.1	.417
Stroke	0	0.1	.482
Systemic infection	0.4	0.6	.446
Worsening of heart failure	1.1	0.7	.187
Worsening of renal function	1.5	0.9	.127
Arrhythmias	0.5	1.2	.054
Other	0.9	2	.019
Complications needing intervention, %	2.4	4.2	.009
Phrenic nerve stimulation	1	1.1	.647
Lead dislocation	0.7	1.8	.021
Right ventricle	0.1	5.3	.437
Left ventricle	0.5	0.9	.480
Right atrium	0.1	0.3	.872

Postimplantation parameters

	Spain (n=847)	Other countries (n = 10 241)	Р
ECG postimplantation	·		
Stimulated QRS, ms	134 [120-146]	138 [120-152]	.013
Device programming			
AV interval programmed before discharge	63.8	57.4	< .001
VV interval programmed before discharge	64.1	55.7	< .001
AV and VV optimization using device software	35	36.5	.888
Status at time of discharge, %			.447
Alive	99.8	99.6	
Dead	0.4	0.4	
Total hospital stay, d	2 [2-7]	3 [2-7]	< .001
Planning follow-up, %			
Implant center	97.8	85.4	< .001
Other hospital	1.9	8.6	< .001
Cardiologist in private clinic	0.2	5.7	< .001
Primary care physician	0.4	0.9	.110
CRT/PM unit	11.8	10.3	.159
HF unit	6	2.2	< .001
Other	0.2	0.3	.695
Pharmacological treatment at discharge, %			
Loop diuretics	81	81.1	.989
ACEI/ARB	87.5	86.3	.359
Antimineralocorticoid	70.2	62.6	< .001
Beta-blockers	87.5	89.1	0.165
Ivabradine	13.6	4.9	< .001
Digoxin	9.1	10.5	.205
Calcium channel blockers	7.1	9.1	.047
Amiodarone	16	17.4	.302
Other antiarrhythmic agents	0.7	1.8	.024
Oral anticoagulation	43.6	46.8	.069
Vitamin K antagonists (warfarin/acenocoumarol)	81.9	69.4	< .001
Dabigatran	3.6	6.9	.017
Rivaroxaban	5.6	12.9	< .001
Apixaban	8.4	10.5	.202
Edoxaban	0.6	0.4	.531
Antiplatelet drugs, %	42.3	43.8	.379
Aspirin	39.3	41.5	.221
Clopidogrel	10	12.6	.030
Ticagrelor	1.5	1.3	.652
Prasugrel	0.9	0.2	.002

ACEI, angiotensin-converting enzyme inhibitors; ARB, angiotensin receptor blockers; AV, atrioventricular; CRT, cardiac resynchronization therapy; HF, heart failure; PM, pacemaker; VV, interventricular.

Unless otherwise indicated, values are expressed as median [interquartile range].

8.8%), even though published data indicate the lack of efficacy of CRT in this patient subgroup.<sup>21</sup> Likewise, up to 14% of the Spanish patients had an LVEF greater than 35%, although it is very likely that a large part of this percentage comprised patients with an indication for permanent stimulation whose reduced LVEF led to the implantation of an LV stimulation lead. It is striking that only 25% of implants were performed in women because it is known that a higher percentage of women with heart failure and reduced LVEF have LBBB, and that women with LBBB benefitted from CRT at a shorter QRS duration than men with LBBB.<sup>22,23</sup>

Regarding technical aspects, a high success rate was achieved with CRT implantation (96.3%) and LV lead implantation (99.3%). It is noteworthy that up to 11.4% of the leads were implanted in

the epicardium, although the survey did not collect information on the reasons for this approach. This large percentage was probably due to the inclusion of patients with previous failure of the transvenous route, as well as to the inclusion of other patients with an indication for CRT who had received an LV lead during concomitant cardiac surgery. Another novel finding of the survey was the widespread use of quadrupole leads, which already comprise almost 75% of the total number of LV leads implanted in Spanish centers. This percentage is much higher than that in the other participating centers. However, the survey did not gather information on whether the implanted generators had multipoint stimulation or whether they were activated in the implant.

It is also noteworthy that the periprocedural complication rate was significantly higher in Spanish centers than in the other centers. However, analysis of the causes of these complications shows that the difference was due to a higher rate of coronary sinus dissection (50% of all periprocedural complications in Spanish centers vs 32.6% in the other countries). In general, coronary sinus dissection is a complication that does not typically lead to severe repercussions for the patient and does not even prevent LV lead implantation in most patients.<sup>24</sup> On the other hand, the rate of other complications was similar in Spain and the other countries, but there was a significantly lower rate of pneumothorax in Spain (0.46% vs 1.06%; P = .011). The periprocedural mortality rate was very low (0.11% in Spanish centers), and other severe complications, such as cardiac tamponade, were observed in only 0.23% of patients. The periprocedural complication rate reported in other large published series, such as a US registry that included more than 439 000 inpatients who received an CRT device,<sup>25</sup> was similar to the 7% reported in Spain.

## Limitations

This study is limited by its use of a survey format, which only collects pre-established data from the time of implantation to the time of hospital discharge. Therefore, the validity of the data on complications and morbidity and mortality may be limited by their being underestimated due to the lack of patient follow-up. In addition, only 20.1% of the total number of predicted CRT implants were collected by the survey during the inclusion period and therefore the data obtained may not reflect the current situation in Spain. More extensive surveys could be conducted to confirm these findings.

#### **CONCLUSIONS**

The results of the CRT-Survey II provide a clear picture of the current use of this therapy in Spain. The results show a high rate of implant success (96.3%). In Spanish hospitals, there was a lower percentage of patients aged 75 years or older, and a higher percentage of patients in NYHA functional class II with LBBB, remote monitoring, and significantly shorter hospital stays.

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#### **CONFLICTS OF INTEREST**

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## WHAT IS KNOWN ABOUT THE TOPIC?

- CRT reduces the morbidity and mortality of patients with heart failure, left ventricular dysfunction, wide QRS, and optimal pharmacological treatment.
- Clinical practice guidelines have established the key indications for CRT based on the results of large randomized clinical trials.

## WHAT DOES THIS STUDY ADD?

- The CRT-Survey II survey provides a clear picture of the use of CRT in Europe.
- These data reflect current clinical practice, unlike those obtained from large randomized trials.
- The Spanish results help identify the characteristics of the patients who have received a CRT device, the approach followed, and the short-term outcomes.
- The survey allowed comparison of the Spanish results with those of the other countries participating in the CRT-Survey II.

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