Should physicians instead of industry representatives be the main actor of cardiac implantable electronic device follow-up? (Super Follow-up)

Çağın Mustafa Üreyen, Cem Yunus Baş, İsa Öner Yüksel, Görkem Kuş, Göksel Çağırcı, Şakir Arslan

Department of Cardiology, Antalya Education and Research Hospital; Antalya-*Turkey*

Abstract

Objective: This retrospective study sought to research the adequacy of the follow-up and optimization of cardiac implantable electronic devices (CIEDs) performed by industry representatives.

Methods: A total of 403 consecutive patients (35% females; median age, 67 years; age range 18–97 years) with either pacemakers (n=246), implantable cardioverter-defibrillators (ICDs), (n=117) or cardiac resynchronization therapy with defibrillator (CRT-D) (n=40) applied to our hospital's outpatient pacemaker clinic for follow-up. These patients had been followed up by industry representatives alone until September 2013 and then by a cardiologist who is dealing with cardiac electrophysiology and has a knowledge of CIED follow-up.

Results: It was ascertained that 117 (47.6%) of 246 patients with pacemakers had a programming error. Forty-three (36.8%) of 117 patients were symptomatic, and after reprogramming, all symptoms diminished partially or completely during the follow-up. Moreover, 30 (25.6%) of 117 patients with ICDs had a programming error. Furthermore, 6 (15%) of 40 patients with CRT-Ds had a programming error. To conclude, when all patients with CIEDs were assessed together, it was ascertained that 153 (38%) of 403 patients had programming errors.

Conclusion: The prevalence of inappropriate programming of CIEDs by industry representatives was quite higher than expected. Therefore, our study strongly demonstrates that CIED follow-up should not be allowed to be performed entirely by manufacturers' representatives alone. *(Anatol J Cardiol 2017; 18: 23-30)*

Keywords: cardiac resynchronization therapy, follow-up, implantable cardioverter-defibrillator, optimization, pacemakers, programming errors

Introduction

There is an increased trend for the implantation of all cardiac implantable electronic devices (CIEDs) (1–3). As the number of implanted CIEDs increases, follow-up of these CIEDs becomes a heavy workload. In developed countries, the follow-up is mainly performed by clinically employed allied professionals and/or trained medical doctors. However, the follow-up may unfortunately be allowed to be performed by industry representatives alone, particularly in developing or underdeveloped countries. To the best of our knowledge, there is no article in the English medical literature evaluating not only the efficacy of the follow-up by industry representatives but also comparing it to the follow-up by medical doctors. Our study strongly demonstrates why medical doctors instead of industry representatives should perform follow-up and optimization in patients with CIEDs.

A satisfactory follow-up and optimization of implanted CIEDs according to patients' needs is of great importance. Therefore, papers assessing the adequacy of follow-up by industry representatives might lead to medical doctors paying more attention to the follow-up.

Methods

The SUPER FOLLOW-UP study was conducted at the Cardiology Department of the Antalya Education and Research Hospital in Antalya, Turkey, between September 2013 and July 2015. The population of this all-comers study, which is retrospective, included 403 consecutive patients who had either an implanted pacemaker, implantable cardioverter-defibrillator (ICD), or cardiac resynchronization therapy with defibrillator (CRT-D) and had applied to our hospital's outpatient pacemaker clinic for CIED follow-up. In our Cardiology Department, all CIEDs such as single/dual-chamber pacemakers, ICDs, and CRT-Ds had been implanted for 5 years, and all follow-up procedures had been performed in the pacemaker outpatient clinic after September 2013 by a cardiologist, who dealt with cardiac electrophysiology and had a background in implantable cardiac device follow-up.

Address for correspondence: Dr. Çağın Mustafa Üreyen, Antalya Eğitim ve Araştırma Hastanesi Varlık Mahallesi, Kâzımkarabekir Caddesi, Soğuksu, Muratpaşa, PK: 07100 Antalya-*Türkiye*
E-mail: drcaginureyen@gmail.com

Accepted Date: 15.03.2017 **Available Online Date:** 19.04.2017

DOI:10.14744/AnatolJCardiol.2017.7374

Before this date, all regular follow-ups of all CIEDs were mainly performed by five industry representatives alone, and they consulted medical doctors only when they could not solve a problem that they detected or informed the medical doctor only when they found any malfunction in the devices.

At our pacemaker outpatient clinic, we possess the manufacturer's special programmers, although we do not have the capability of transtelephonic monitoring of CIEDs. In our daily practice, we prefer an initial monitoring 1 day after the implantation before discharge. After 4 weeks of implantation and at the 3rd month, two visits are conducted. The initial pacing voltage of pacemakers is standardized to 5 volts (V). Therefore, we diminish the pacing thresholds at the end of the 3rd month, unless there is a malfunction of the device or leads. Thereafter, follow-up visits are conducted twice a year for ICDs, CRT-Ds, and dual-chamber pacemakers and once a year for single-chamber pacemakers, unless any malfunction of the devices is detected. The frequency of visits is increased when the voltage of the battery approaches the end of life. This general follow-up approach, which was also recommended by Wilkoff et al. (4), was used in this study.

After September 2013, a systematic approach for patient follow-up was used by a cardiologist who had a background in pacemaker follow-up and optimization without any industry backup. First, a full history, which ascertained whether there was any symptom or complaint related to CIED, was taken, and an examination of electrocardiography (ECG) and the implantation site of CIED was carried out. Thereafter, pacing and sensing threshold values, lead impedances, pacing ratios, and battery voltages and impedances were measured. Moreover, the total atrial refractory period (TARP), including the atrioventricular interval (AVI) and postventricular atrial refractory period (PVARP); lower rate; upper tracking rate; and/or upper sensor rate (UTR/USR) were assessed. Sensed and paced AVIs were left as 120 and 150 ms, respectively, in patients with a permanent AV block. On the other hand, they were set to higher values (usually 200 ms or higher) in patients with intermittent AV block and sick sinus syndrome (SSS) and in those whose pacemakers lacked algorithms that could minimize unnecessary RV pacing. Moreover, the ventriculoatrial conduction time was measured, and 25–50 ms was added to this time interval to set PVARP, unless an auto-PVARP mode was present. UTR/USR was calculated as (220– age) × 85%. The necessity of a rate-adaptive mode or hysteresis was evaluated, and the presence or absence of over- or undersensing, cross-talk, or far-field sensing was recorded during each follow-up. The rate-adaptive mode was supposed to be "on" in patients with SSS and atrial fibrillation (AF) with slow ventricular response, whereas it was supposed to be "off" in patients with only AV block (5).

The effort capacity of patients was assessed via asking what they could do or could not do and converted to the metabolic equivalent of task (MET) by means of a METs chart before and after reprogramming. An increase in the effort capacity of 1 MET or more for elderly patients and/or physically handicapped patients, as well as 2 METs or more for young patients, after reprogramming was supposed to be effective, and the symptoms that were relieved at least partially after reprogramming were supposed to be related to pre-settings.

Additionally, it was also assessed whether antitachycardia pacing (ATP) or shocks were present, and the appropriateness of the shocks was evaluated in patients with ICDs and CRT-Ds. This study complies with the Declaration of Helsinki, and the research protocol was approved by the Local Ethics Committee.

Statistical analysis

Statistical analyses were performed using (SPSS Inc., Chicago, IL, USA). Age and the base rate of ICD variables were assessed using an analytical method (Kolmogorov–Smirnov test) to determine whether they were normally distributed or not. Since they were not normally distributed, age and the base rate of ICDs were presented using a median and range.

Results

A total of 403 patients (262 males and 141 females) with CIEDs, 15.4% of who had undergone implantation in different hospitals, were enrolled in the study. Of them, 61% patients received pacemakers, 29% received ICDs, and 9.9% received CRT-Ds. The median age of the patients was 67 (range: 18–97) years. The percentage of patients with single-chamber pacemakers was 9.8%, whereas it was 90.2% for those with dual-chamber pacemakers. The main indications for pacemaker implantation were SSS in 65 patients (26.4%), atrioventricular (AV) conduction disturbances in 155 patients (63%), AF with slow ventricular response in 21 patients (8.5%), and both AV conduction disturbance and SSS in 5 patients (2%). Thirty-three (28.2%) ICDs were implanted for secondary prevention, whereas 84 (71.8%) ICDs were implanted for primary prevention. Forty patients with CRT-D had a history of heart failure, with an ejection fraction of less than 35%. None of these patients with CRT-D had an indication of brady-pacing. The baseline characteristics of the patients are demonstrated in Table 1.

A total of 246 patients had pacemakers. The rate response (R) mode was "off" in 11 (4.5%) patients despite the fact that R mode should have been "on." Six patients had SSS, and 5 patients had AF with slow ventricular response. These 11 patients had a non-varying rate histogram. Each patient was to some extent symptomatic, with mild-to-severe exertional dyspnea. The patients' effort capacity was assessed via asking what they could do or could not do and converted to MET. After 1 month of R mode activation, the patients' effort capacity was again assessed via asking what they could do then. The effort capacity of elderly patients increased by at least 1 MET, and the effort capacity of young patients increased by at least 2 METs. Moreover, as the effort capacity of the patients increased, exertional symptoms were relieved partially in 1 patient and completely in 10 patients

Table 1. Baseline characteristics of 403 patients enrolled in the SUPER FOLLOW-UP study

	n	%
Male	262	65.0
Age, median, range	67 (18–97)	
History		
Hypertension	226	56.1
Diabetes mellitus	106	26.3
Smoking	85	21.1
Hyperlipidemia	202	50.1
Coronary artery disease	195	48.3
Congestive heart failure	157	38.9
Cerebrovascular accident	31	7.6
Implantation in another hospital	62	15.4
Type of implantable cardiac device		
Pacemakers (n=246)		61.0
Single chamber	24	9.8
AAIR	3	1.2
VVIR	21	8.5
Dual chamber	222	90.2
DDD	155	63.0
DDDR	67	27.2
ICDs (n=117)		29.0
Primary prevention	33	28.2
Secondary prevention	84	71.8
CRT-D (n=40)		9.9
Main indications for implantation of pacemakers		
Sick sinus syndrome, tachybradycardias	65	26.4
Atrioventricular conduction disturbances	155	63.0
Atrial fibrillation with slow ventricular response	21	8.5
AVCD + SSS	5	2.0

AVCD - atrioventricular conduction disturbances; CRT-D - cardiac resynchronization therapy with defibrillator; ICD - implantable cardioverter defibrillator; SSS - sick sinus syndrome

after switching on the R mode. R mode was "on" in 21 (8.5%) patients with only AV block despite the lack of a necessity for the R mode (no chronotropic incompetence). The R mode may result in redundant atrial pacing. Hence, the R mode was switched off. After 1 month of reprogramming, these patients still had a normal varying rate histograms.

UTR/USR was incompatible with the ages of 29 (11.8%) patients who were younger than 50 years, 23 of whom were younger than 35 years and symptomatic, having some degree of exertional dyspnea. The history of these 23 young patients revealed that they were not able to carry on jogging, and hence, they had an effort capacity of <7 METs. The manufacturer's default setting for UTR/USR was 130 beats per minute (bpm), and it was recognized that UTR/USR was not adjusted according to the age of these young patients, which, therefore, led to the symptoms. After correction of the UTR/USR according to patients' ages, all these patients were at least able to jog and even run.

Ventricular pacing (Vp) occurred in 18 patients with SSS due to a short AV interval setting (sensed and paced AVIs were 120 and 150 ms, respectively, which were the factory defaults) in the absence of a concomitant AV node disease. The Vp ratio ranged between 14% and 42% in these 18 patients with SSS. The pacemakers of these 18 patients did not possess any algorithm to minimize RV pacing. Therefore, the AVI setting gained more importance in these patients. Prolongation of the sensed/paced AV interval up to 200/225 ms in 17 patients and 250/275 ms in 1 patient solved the problem of redundant RV pacing in our study, and RV pacing diminished to less than 10% in all patients and less than 1% in 11 patients after 1 month of reprogramming. Furthermore, 2 patients with intermittent complete AV block were found to be paced 100% due to a shorter AV interval (120 ms in both patients) compared with the intrinsic AV interval. Prolongation of the sensed and paced AV intervals to 275 and 300 ms, respectively, dramatically solved the problem of excessive pacing and let the intrinsic ventricular rhythm dominate. After initialization of the Vp ratio, 14% and 28% Vp were found after 1 month.

PVARP was very prolonged in 14 patients (5.7%), 6 of whom were younger than 35 years and symptomatic, having exertional dyspnea due to a prolonged TARP, leading to an earlier 2:1 AV block (Wenckebach block) even at moderate work levels (around 5 METs), and none of these patients could jog (exercise capacity <7 METs). The pacemakers of these 14 patients did not have an auto-PVARP mode; hence, a fixed PVARP was present and set to 350 ms or more in all 14 patients. The reason for the unnecessarily longer PVARP was the alerts of pacemaker-mediated tachycardia (PMT) in all patients. After examination of recordings of PMT alerts, it was noticed that only 3 patients had true PMT attacks. In 11 patients, PVARP was made longer even without confirmation of PMT alerts and whether they were right or wrong. Moreover, PVARP was set to 375 ms in 2 patients and 400 ms in 1 patient who had true PMT alerts. The VA conduction time was measured in all patients, and shorter PVARP intervals (VA conduction time plus 25–50 ms) were reprogrammed. PVARP was set to 200 ms in patients without VA conduction at rest.

The right ventricular pacing amplitude was higher in 5 patients (2%), although 2.5 V was enough. All patients' pacing thresholds were lower than 1 V; therefore, all pacing amplitudes were set to 2.5 V.

Seventeen patients (6.9%), who developed paroxysmal AF after implantation, had DDD pacemakers, and the DDIR mode was set to the VVIR mode by the manufacturer's representatives during PAF attacks despite the fact that pacemakers successfully autoswitched to DDIR mode during PAF attacks and the patients lacked any symptoms. Pacemakers continued to function in the VVIR mode during sinus rhythm, which was less physiological and caused pacemaker syndrome in 3 patients. On examination of the pace-

makers it was found that ascertained PAFs were the first attack in 7 patients and PAF attacks were not more frequent than 6 months in the other 10 patients. DDD was reprogrammed, and symptoms of pacemaker syndrome disappeared in these 3 patients.

A total of 117 patients with ICDs with Vp backup (VR-ICD) were evaluated. None of these patients had brady-pacing indication. The base rate of VR-ICDs was found to be 60 bpm in 23 patients (19.6%), which led to <1% to 54% RV pacing, with a median of 23% pacing. After resetting the base rate to 40 bpm and the initialization of pacing ratios, RV pacing was reduced to below 1% after 1 month in all patients except one with an RV pacing ratio of 2.4%.

ICD shocks were ascertained in 71 of 117 patients after examination of the devices. However, 7 patients (6%) had ICD shocks without ATP therapy due to an arrangement of the VF zone to over 200 bpm. All VTs of these 7 patients were between 202 and 223 bpm, and none of these patients mentioned any symptom other than palpitation. None of them had dyspnea, angina, presyncope, or syncope during palpitation (VT attack). Therefore, the VF zone was enhanced to 230 bpm, and an option of ATP as an initial therapy was reset to preclude redundant ICD shocks.

A total of 40 patients with CRT-D were assessed. The biventricular pacing ratio was enhanced to >98% in 3 patients (7.5%) by means of shortening the AV interval to 120 ms. AV intervals were 150 ms in 2 patients and 180 ms in 1 patient with initial biventricular pacing ratios of 89%, 93%, and 81%, respectively.

One patient had left ventricular (LV) lead dysfunction, and even 7.5 V was not enough to pace LV. Therefore, only RV pacing was present, with a 98% pacing ratio due to a short AV interval setting (120 ms). The discharge report revealed that a single branch of the coronary sinus was found to be not sufficient to transmit the stimulus. Moreover, the patient was recommended for a surgical implantation of the LV lead, but he refused. However, RV pacing should not have been allowed after the patient's refusal of the surgical LV lead implantation. Unnecessary RV pacing might further deteriorate the LV function and make the patient more symptomatic. We again recommended a surgical LV lead implantation, but the patient was still reluctant to have any reoperation or surgical implantation of the LV lead. Therefore, the pacing mode was shut down, and only the defibrillator mode was kept on. On the other hand, the base rate would have been otherwise diminished to 40/min.

The pacing amplitude of LV was unnecessarily higher in 2 patients (3.5 V and 5 V) despite well-adjusted RV and atrial pacing amplitudes. LV pacing thresholds were measured as 0.5 V and 0.75 V; hence, LV pacing amplitudes were reset to 2.5 V in both patients.

Discussion

On evaluating the errors made by industry representatives regarding the settings of pacemakers, first, we ascertained that the R mode was unnecessarily switched on in 8.5% of pacemaker patients, whereas it was incorrectly switched off in 4.5% of patients with pacemakers and chronotropic incompetence. An inconvenient active R mode leads to unnecessary pacing, which reduces battery longevity. Moreover, a switched-off R mode in patients with chronotropic incompetence results in a continuation of symptoms, particularly exertional dyspnea. Therefore, each patient should be cautiously assessed regarding the necessity of the R mode. Examination of rate histograms can be helpful to ascertain whether there is a need for R mode. Activation of the R mode in 11 patients relieved their symptoms partially or completely in our follow-up.

Second, UTR/USR was not properly adjusted in 29 patients (11.8%) who were younger than 50 years, 23 of whom were younger than 35 years and to some extent symptomatic. UTR/USR was reset according to the ages of patients. All 23 young patients had an increase of at least 2 METs after resetting according to their ages. UTR/USR gains importance particularly in young patients. Because factory default settings of UTR/USR are never sufficient to compensate for the metabolic requirements of patients as their age diminishes, the significance of individualized settings is obviously confirmed with this example.

Third, unnecessary RV pacing was present in 20 patients (8.1%) with pacemakers, 18 of whom had SSS and 2 of whom had intermittent complete AV block. It is quite important that RV pacing is not expected in patients with SSS, unless they have an additional AV conduction disorder. Therefore, AVI must be attentively assessed when RV pacing is present, particularly in patients without any algorithm to minimize RV pacing. Andersen et al. (6) stated that after a long-term follow-up, the lesser Vp is associated with a significantly higher survival rate, less AF, fewer thromboembolic complications, and less heart failure. RV pacing diminished to less than 10% in 18 patients with SSS after reprogramming. In our study, a cut-off of 10% was chosen for Vp because Sweeney et al. (7) stated that a cumulative Vp of <10% was associated with the lowest rates of congestive heart failure hospitalizations (2% for DDDR). Furthermore, a Vp of 40% or more in DDDR mode leads to a 3-fold increased risk of heart failure hospitalizations.

Moreover, 100% pacing is also anticipated in patients with intermittent complete AV block, unless they have a bizarre or very prolonged first-degree AV block while in sinus rhythm. Therefore, we should again pay attention to the basal intrinsic AV interval while setting the sensed and paced AV intervals, particularly of pacemakers that do not have any algorithm to minimize RV pacing. Factory default settings of AVI should be applied in patients with permanent AV block. Nevertheless, factory default settings are not generally a good option and should not be routinely applied to patients with intermittent AV block.

To conclude, pacemakers with algorithms to minimize RV pacing are better to preclude unnecessary RV pacing in patients with not only SSS but also intermittent AV block (8). However, pacemakers without these algorithms should be more carefully evaluated, and a more careful setting of AVI is nece-

ssary for these patients because an extended AVI (300 msec) was demonstrated to be more effective than an AVI of 150 ms or shorter in patients with SSS regarding lesser RV pacing (Vp 17% vs. 90%) (9).

Fourth, PVARP was found to be very prolonged in 14 patients (5.7%), 6 of whom were symptomatic during activities of 4–5 METs. The main reason for the prolongation of PVARP to high levels (350–400 ms) was PMT alerts that were not validated, and PMT alerts were correct only in 3 patients. PVARP should not be prolonged without confirmation of PMT alerts, and the VA conduction time should be measured in patients with PMT and thereafter reprogrammed to a minimum sufficient level in pacemakers without auto-PVARP. All PVARPs were reset to a lower value after measuring VA conduction times. Reprogrammed lower PVARPs decreased TARP, precluded premature Wenckebach block, and alleviated symptoms of 6 patients who were younger than 35 years. All 6 patients could at least jog (7 METs) after reprogramming. It is vital to emphasize that prolongation of PVARP also prolongs TARP. A prolonged TARP may gain importance, particularly in young patients, by virtue of the fact that earlier 2:1 AV block (Wenckebach block) occurs even with relatively moderate heart rates, which leads to exertional dyspnea.

Fifth, RV pacing amplitude was detected as 5 V in 5 patients (2%) with a pacing threshold lower than 1 V in each patient. Pacing amplitudes are generally programmed to a higher level (generally 5 V) for 1–3 months after implantation to preclude complications from a possible increase in pacing thresholds. However, it is generally reprogrammed to a lower level (usually 2–2.5 V) after measuring pacing thresholds after 1–3 months. Follow-up of patients with an unnecessary higher pacing amplitude reduces pacemaker longevity.

Sixth, switching the DDD/DDIR mode to VVIR is not necessary for patients with paroxysmal AF, unless AF is accepted to be permanent, because nowadays, the software of pacemakers can easily recognize AF and switch to DDIR mode; hence, patients are usually not symptomatic. Switching to VVIR routinely in patients with infrequent PAF results in loss of AV synchrony and might cause pacemaker syndrome. Switching the DDIR mode, which would later return to the DDD mode at the end of PAF automatically, to the VVIR mode during PAF attacks was completely unnecessary and resulted in pacemaker syndrome in 3 patients. DDD was reprogrammed, and the symptoms of pacemaker syndrome disappeared.

To conclude, 117 (47.6%) of 246 patients with pacemakers had a programming error. Forty-three (36.8%) of 117 patients were symptomatic, and after reprogramming, all symptoms diminished partially or completely during the follow-up.

If we evaluate the errors made by industry representatives regarding the settings of ICDs, first, we found that the base rate of VR-ICDs in 23 (19.7%) of 117 patients was set to the default setting, 60 bpm. This base rate may cause unnecessary RV pacing, particularly in patients with optimal beta-blocker therapy and with a heart rate below 70 bpm, as recommended in heart failure guidelines (10). The main objective of VR-ICDs is to defibrillate or convert ventricular tachycardias to sinus rhythm, but not to pace. Therefore, RV pacing in patients with VR-ICDs should alert medical doctors whether RV pacing is necessary (a newly developed brady-pacing requirement) or not. Vp leading to ventricular dyssynchrony is hazardous even in patients with preserved LV systolic functions and might result in an enhanced risk of heart failure hospitalizations and AF (7, 11). Additionally, Steinberg et al. (12) demonstrated that RV pacing not only enhanced heart failure episodes but also increased VT/VF, requiring ICD therapy in patients with ICDs. Furthermore, expert consensus statement on optimal ICD programming and testing stated that ventricular stimulation should be minimized via adjusting the pacing parameters to improve survival and reduce heart failure hospitalizations in patients with ICDs and in those without guideline-supported indications for bradycardia pacing (13). RV pacing ratios were between <1% and 54% (median: 23%) in these 23 patients despite the fact that no patient had any indication of brady-pacing. The base rate of VR-ICDs in 23 patients was reprogrammed to 40 bpm; hence, the mean RV pacing ratio of all patients was reduced to <1%, except 1 patient with an RV pacing ratio of 2.4% after 1 month.

Second, setting VT-VF zones is quite important. Not to miss any ventricular tachyarryhythmia and a decrement of ICD shocks by ATPs are the main objectives of ICD programming. Therefore, the specification of VT-VF therapy zones becomes important. There is a trend and new recommendations for higher ranges of therapy zones to preclude ICD shocks. A VF zone over 230 bpm rather than 200 bpm reduced ICD shocks and hospitalizations and was demonstrated to be safe (14). Moreover, ATP therapy is recommended to be active for all ventricular tachyarrhythmia detection zones to include arrhythmias up to 230 bpm for reducing total shocks (13). In our study, 7 patients (6%) had ICD shocks due to VTs with a range of 202–223 bpm and a VF zone set to 200 bpm and above. None of these patients had symptoms of hemodynamic instability, as mentioned in the Results section, during VT attacks. Therefore, the VF zone of 200 bpm should have been increased to 230 bpm to provide an option of ATP as an initial therapy to preclude redundant ICD shocks. To conclude, 30 (25.6%) of 117 patients with ICDs had a programming error.

If we again evaluate the errors made by industry representatives regarding the settings of CRT-Ds, first, we ascertain that the AV interval was longer in 3 patients (7.5%), resulting in lesser biventricular pacing, as mentioned in the Results section. The main objective is completely different in CRTs compared with pacemakers. The higher the pacing ratio, the better the efficacy of CRTs. Therefore, the AV interval should be programmed at a lower limit, generally 100–120 ms and sometimes an even shorter interval that does not compromise ventricular filling. Reprogramming of the AV interval to 120 ms was adequate for 3 patients to have acceptable biventricular pacing ratios. Moreover, a patient with frequent ventricular extrasystole (VES) had a biventricular pacing ratio of 89%. The relatively lower biventricular

Table 2. Types of erroneous CIED programming

	n	%
Pacemakers	**246**	
Inconvenient active R mode	21	8.5
Inconvenient inactive R mode	11	4.5
Improper UTR/USR setting	29	11.8
Improper AVI setting*	20	8.1
Inappropriate PVARP setting	14	5.7
Inappropriate RV pacing amplitude	5	2
Improper manual mode switching	17	6.9
Total programming errors among pacemakers	117	47.6
ICDs	**117**	
Improper base rate setting	23	19.7
Improper VT-VF zone determination	7	6
Total programming errors among ICDs	30	25.6
CRT-Ds	**40**	
Improper AVI setting leading to biventricular underpacing	3	7.5
Improper LV pacing amplitude	2	5
Inappropriate single RV pacing	1	2.5
Total programming errors among CRT-Ds	6	15
Programming errors among all CIEDs	153/403	38

AVI - atrioventricular interval; CIED - cardiac implantable electronic device; CRT-D - cardiac resynchronization therapy with defibrillator; ICD - implantable cardioverter defibrillator; LV - left ventricle; PVARP - postventricular atrial refractory period; R - rate response; RV - right ventricle; USR - upper sensor rate; UTR - upper tracking rate; VF - ventricular fibrillation; VT - ventricular tachycardia. *leading to unnecessary RV pacing

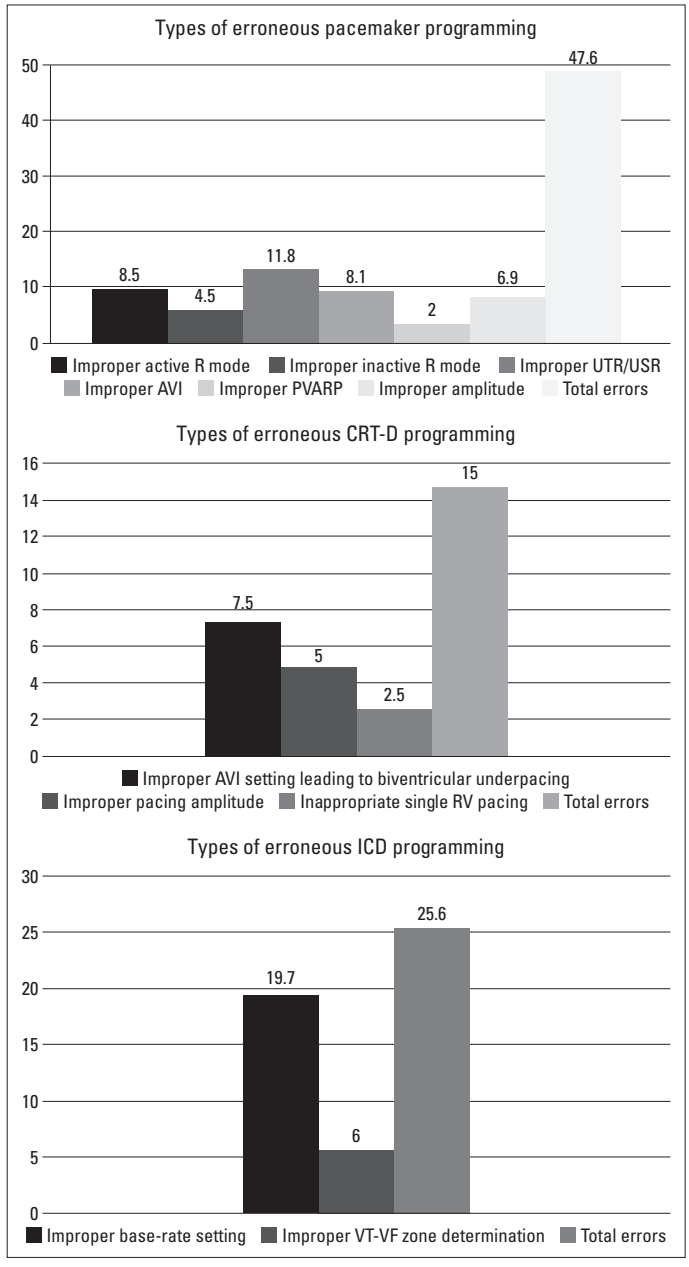

Figure 1. Percentages of erroneous programming of CIEDs
AVI - atrioventricular interval; CIED - cardiac implantable electronic device; CRT-D - cardiac resynchronization therapy with defibrillator; ICD - implantable cardioverter defibrillator; PVARP - postventricular atrial refractory period; R - rate response; RV - right ventricle; UTR/USR - upper tracking rate/upper sensor rate; VT-VF - ventricular tachycardia-ventricular fibrillation

pacing ratio was not related to the AV interval: it was related to frequent VESs. The average heart rate was 82 bpm; hence, the beta-blocker dose was doubled, and the biventricular pacing ratio was 95% after 1 month, which was still not optimal but better. This data was not reported in the table of erroneous settings by virtue of the fact that it was not a programming fault of industry representatives. However, this case demonstrates that not only technical information on CIEDs but also medical experience is needed during follow-up of patients.

Second, the pacing amplitude of the LV lead was improperly higher in 2 patients (5%) despite low and stable LV pacing thresholds. This could be due to the fear of a potential LV lead dislocation and increased pacing thresholds; however, it is still not a proper setting for follow-up; therefore, pacing amplitudes were reduced to 2.5 V in each patient.

Third, it is important to emphasize that RV pacing should not be allowed in cases of dysfunctional LV leads. In our study, one patient with CRT-D had a dysfunctional LV lead and RV pacing of 98% due to an AV interval of 120 ms. RV pacing should not have been allowed after the patient's refusal of surgical LV lead implantation. Unnecessary RV pacing might further deteriorate LV function and make the patient more symptomatic. Therefore, the pacing mode was shut down, and only the defibrillator mode was kept on. Alternatively, the base rate could have been diminished to 40 bpm. To conclude, 6 (15%) of 40 patients with CRT-Ds had a programming error.

In general, when all patients with CIEDs were assessed together, we ascertained that 153 (38%) of 403 patients had programming errors. All programming errors regarding CIEDs are shown in Table 2 and Figure 1.

In Europe and most parts of the world, CIEDs are commonly implanted. There are educational courses demonstrating how

these devices should be implanted. Unfortunately, the importance attached to the implantation training is not attached to the training of the follow-up and optimization of these devices because the follow-up is generally performed by industry representatives instead of medical doctors, particularly in developing or underdeveloped countries. There are no precise data in the English medical literature, even in developed countries, regarding who performs the follow-up and optimization of CIEDs, but some articles give some idea that the follow-up in developed countries is mainly performed by cardiologists or pacemaker technicians, whereas only 1% of follow-ups are performed only by industry representatives (15). Moreover, the percentage of follow-ups by industry representatives is not precisely known in developing and underdeveloped countries, and it is thought to be quite high. While many cardiologists perfectly implant these devices, they usually remain in the background during the follow-up due to limited time or inadequate experience and knowledge. Hayes (16) stated that management of CIEDs has proceeded to a technologically more complex stage at a pace that is difficult for most medical doctors to keep up with. Therefore, this condition forces medical doctors to rely on industry representatives for their technical expertise regarding follow-up. Thus, most of the patients' device settings are adjusted by industry representatives, particularly in developing and underdeveloped countries. Therefore, the level of adequacy of the follow-up depends on the knowledge and experience of industry representatives.

There is no clinical trial evaluating the efficacy of follow-up and optimization by industry representatives. Our study strongly demonstrates why medical doctors instead of industry representatives should perform follow-up and optimization in patients with CIEDs. In the Western world, the role of industry representatives is quite clear (4). They should provide technical support to the implant as well as the technical assistance of their companies' programmers in the follow-up clinics. They should not provide technical support in a clinic when they are alone and unsupervised. Trained medical doctors or clinically employed allied professionals supervised by trained medical doctors are allowed to perform follow-up in developed countries; however, this may not be the case in the developing or underdeveloped countries. Unfortunately, industry representative may sometimes be more experienced than the "supervisor" medical doctor or the supervisor medical doctor may be very "busy." Thus, the follow-up and optimization of CIEDs regrettably depend on the knowledge and experience of industry representatives.

Some of the errors in programming that were mentioned above seem blatantly wrong. This may be because some manufacturers provide a well-organized training program for their employees before they start to work in the field, whereas some of the subcontractor companies (instead of the original manufacturers) may not pay the same attention to this topic. Therefore, inexperienced industry representatives working with inexperienced "supervisor" medical doctors may end up with catastrophic outcomes.

At first glance, it may be questionable how to apply this study to Europe and the United States; however, the significance of this study may be more explicit when it is considered that more than half of the population of the world still lives in developing or underdeveloped countries.

Study limitations

The exercise capacity of the patients was evaluated via asking what they could do or could not do before and after reprogramming. Nevertheless, it would have been more objective if the exercise capacity of the patients was assessed by means of an exercise test or if quality of life survey was used.

Conclusion

To conclude, medical doctors have the capability to assess the patients as a whole; thus, CIEDs should be followed up by medical doctors instead of industry representatives alone. However, this recommendation may exclude pacemaker technicians, who are supposed to have adequate training in follow-up and optimization and who are collaboratively working with medical doctors. Additionally, there is a need for education in the follow-up and optimization of CIEDs along with training in device implantation. We suggest that the training in follow-up and optimization should be incorporated into the training in CIED implantation in order to enable medical doctors to keep up with the technological advancements of CIEDs.

Conflict of interest: None declared.

Peer-review: Externally peer-reviewed.

Authorship contributions: Concept – Ç.M.Ü., C.Y.B., G.K., G.Ç.; Design – Ç.M.Ü.; Supervision – Ç.M.Ü., G.Ç., Ş.A.; Analysis &/or interpretation – Ç.M.Ü., C.Y.B., G.K., İ.Ö.Y.; Literature search – Ç.M.Ü., İ.Ö.Y.; Writing – Ç.M.Ü., G.Ç., Ş.A.; Critical review – Ç.M.Ü., İ.Ö.Y., C.Y.B., G.K., Ş.A.

References

1. Eucomed. Medical Technology - Key Facts and Figures.http://www.eucomed.org/ medical-technology/facts-figures
2. Greenspon AJ, Patel JD, Lau E, Ochoa JA, Frisch DR, Ho RT, et al. Trends in permanent pacemaker implantation in the United States from 1993 to 2009: increasing complexity of patients and procedures. J Am Coll Cardiol 2012; 60: 1540-5. [CrossRef]
3. John Camm A, Nisam S. European utilization of the implantable defibrillator: has 10 years changed the 'enigma'? Europace 2010; 12: 1063-9. [CrossRef]
4. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM, et al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. Heart Rhythm 2008; 5: 907-25. [CrossRef]
5. Shapland JE, MacCarter D, Tockman B, Knudson M. Physiologic benefits of rate responsiveness. Pacing Clin Electrophysiol 1983; 6: 329-32. [CrossRef]

6. Andersen HR, Nielsen JC, Thomsen PE, Thuesen L, Mortensen PT, Vesterlund T, et al. Long-term follow-up of patients from a randomised trial of atrial versus ventricular pacing for sick sinus syndrome. Lancet 1997; 350: 1210-6. [CrossRef]
7. Sweeney MO, Hellkamp AS, Ellenbogen KA, Greenspon AJ, Freedman RA, Lee KL, et al. Adverse effect of ventricular pacing on heart failure and atrial fibrillation among patients with normal baseline QRS duration in a clinical trial of pacemaker therapy for sinus node dysfunction. Circulation 2003; 107: 2932-7. [CrossRef]
8. Gillis AM, Pürerfellner H, Israel CW, Sunthorn H, Kacet S, Anelli-Monti M, et al. Reducing unnecessary right ventricular pacing with the managed ventricular pacing mode in patients with sinus node disease and AV block. Pacing Clin Electrophysiol 2006; 29: 697-705.
9. Nielsen JC, Kristensen L, Andersen HR, Mortensen PT, Pedersen OL, Pedersen AK. A randomized comparison of atrial and dual-chamber pacing in 177 consecutive patients with sick sinus syndrome: echocardiographic and clinical outcome. J Am Coll Cardiol 2003; 42: 614-23. [CrossRef]
10. McMurray JJ, Adamopoulos S, Anker SD, Auricchio A, Böhm M, Dickstein K, et al. ESC Guidelines for the diagnosis and treatment of acute and Chronic Heart Failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur Heart J 2012; 33: 1787-847. [CrossRef]
11. Kachboura S, Ben Halima A, Fersi I, Marrakchi S, Zouaoui W, Kammoun I. Assessment of heart failure and left ventricular systolic dysfunction after cardiac pacing in patients with preserved left ventricular systolic function. Ann Cardiol Angeiol (Paris) 2008; 57: 29-36. [CrossRef]
12. Steinberg JS, Fischer A, Wang P, Schuger C, Daubert J, McNitt S, et al. The clinical implications of cumulative right ventricular pacing in the multicenter automatic defibrillator trial II. J Cardiovasc Electrophysiol 2005; 16: 359-65. [CrossRef]
13. Wilkoff BL, Fauchier L, Stiles MK, Morillo CA, Al-Khatib SM, Almendral J, et al. 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. Heart Rhythm 2016; 13: e50-86. [CrossRef]
14. Çay S, Canpolat U, Uçar F, Özeke Ö, Özcan F, Topaloğlu S, et al. Programming implantable cardioverter-defibrillator therapy zones to high ranges to prevent delivery of inappropriate device therapies in patients with primary prevention: results from the RISSY-ICD (Reduction of Inappropriate ShockS bY InCreaseD zones) trial. Am J Cardiol 2015; 115: 1235-43. [CrossRef]
15. van Eck JW, van Hemel NM, de Voogt WG, Meeder JG, Spierenburg HA, Crommentuyn H, et al. Routine follow-up after pacemaker implantation: frequency, pacemaker programming and professionals in charge. Europace 2008; 10: 832-7. [CrossRef]
16. Hayess JJ, North American Society of Pacing and Electrophysiology (NASPE); Association of Perioperative Registered Nurses; American College of Surgeons. The role of industry in the implantation and follow-up of devices: a practitioner's perspective. Card Electrophysiol Rev 2003; 7: 58-9. [CrossRef]

From Prof. Dr. Hasan Veysi Güneş's collections