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# Should the battery of the implantable cardioverter defibrillator be changed or not, due to depletion and the fact that it has never been discharged?

*¿Se debe cambiar o no la batería del desfibrilador cardioversor implantable, debido a que se está agotando y a que nunca se ha descargado?*

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## ABSTRACT

The use of Implantable Cardioverter Defibrillators (ICDs) has proven to be effective and useful to improve survival rates after Sudden Cardiac Death (SCD) in patients with clinical indications for their use. However, replacing a generator that has never administered electrical therapies and now shows battery depletion can generate controversy. In this paper, we analyze different factors that must be considered prior to the generator's replacement in this subset of patients. The main points are improvement or not of the Left Ventricular Ejection Fraction (LVEF), risk re-stratification at the time of replacement, the presence or absence of inappropriate ICD therapies, the severity of the heart disease, the prognosis at the time of the substitution, present comorbidities, life expectancy and advancing age, the possible complications of the new procedure, the possibility of de-escalating the device, financial factors, as well as the patient's own decision and the underlying clinical discussion.

## Abbreviations:

CRT = Cardiac Resynchronization Therapy  
ERI = Elective Replacement Indicator  
HFrEF = Heart Failure and Reduced Ejection Fraction  
ICD = Implantable Cardioverter Defibrillators  
LVEF = Left Ventricular Ejection Fraction  
SCD = Sudden Cardiac Death

## RESUMEN

El uso de desfibriladores cardioversores implantables (DCI) ha demostrado ser eficaz y útil para mejorar las tasas de supervivencia tras una muerte súbita cardíaca (MSC) en pacientes con indicaciones clínicas para su uso. Sin embargo, el reemplazo de un generador que nunca ha administrado terapias eléctricas y que ahora presenta agotamiento de la batería puede generar controversia. En este artículo, analizamos diferentes factores que deben tenerse en cuenta antes del reemplazo del generador en este subgrupo de pacientes. Los puntos principales son la mejora o no de la fracción de eyección del ventrículo izquierdo (FEVI), la reestratificación del riesgo al momento del reemplazo, la presencia o ausencia de terapias inapropiadas del DCI, la gravedad de la enfermedad cardíaca, el pronóstico al momento de la sustitución, las comorbilidades actuales, la esperanza de vida y la edad avanzada, las posibles complicaciones del nuevo procedimiento, la posibilidad de reducir la intensidad del dispositivo, los factores económicos, así como la decisión del propio paciente y la discusión clínica subyacente.

## INTRODUCTION

Implantable cardioverter-defibrillators (ICDs) have been shown to significantly reduce mortality in patients with ischemic and nonischemic cardiomyopathy who are at high

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risk for ventricular arrhythmias and Sudden Cardiac Death (SCD).<sup>1,2</sup> The main advantage of these devices has been demonstrated in subjects with reduced Left Ventricular Ejection Fraction (LVEF), although other cardiomyopathies and channelopathies also benefit from ICD-delivered therapies.<sup>2,3</sup> These devices' battery lifespans can vary depending on several factors, but they will eventually be depleted and require replacement.<sup>4</sup> Some studies have proposed different criteria to determine when not to do so; however, there are often controversies in this matter. They can be related to the patient's life expectancy, the current state of heart disease at the time of replacement, the number of therapies delivered by the device, and even economic factors.<sup>5,6</sup>

Replacing an ICD generator, as with any other medical procedure, involves a comprehensive clinical evaluation rather than proceeding in an automatic manner. In some subjects it will be a simple decision, but in others, the medical team and the patient will have to consider all the aspects mentioned plus other clinical problems such as the complication rate and an ethical discussion.

SCD accounts for approximately 50 to 70% of all cardiovascular deaths. In up to 50% of cardiovascular patients, SCD is the first manifestation of heart disease.<sup>7-9</sup> ICDs have demonstrated a positive effect on survival in several patient groups. Their placement is a common intervention in subjects who have survived cardiac arrest or have presented with significant ventricular arrhythmias in different pathological settings.<sup>2</sup> Emergency cardiac care has become more efficient and, although there are significant differences in survival rates between different countries, regions, and populations, there is a tendency toward lower mortality from the acute cardiac arrest event.<sup>10,11</sup> As a result, the number of ICD implants has increased, as well as generator replacement procedures. The Spanish Society of Cardiology reported in 2023 an ICD implantation rate of 162:1'000,000 inhabitants.<sup>12</sup> They also found a steady increase in the rate of ICD implants, although the COVID-19 pandemic slowed that trend from 2020 to 2022. It is worth mentioning that Spain shows lower implant rates compared to other European countries. Most

ICDs are implanted due to an indication for secondary prevention,<sup>12</sup> but new information has expanded the indications for primary prevention. In both scenarios, patients may not experience ICD therapy, especially high-energy therapies, for extended periods, although the risk of ventricular arrhythmias persists.

The high cost of implantable electronic devices, especially ICDs, is an issue that must be considered, even if several studies have proven their profitability.<sup>13,14</sup> In Mexico, their use might represent an important bill that can have different implications. From a physician's perspective, to establish the implantation indication, the complications inherent to the procedure and follow-up concerns are likely more significant, but all aspects of their use impact overall medical care costs. This is most evident considering that the number to be treated in primary prevention for SCD is relatively high, even if there is a 28% reduction in mortality with a hazard ratio (HR) 0.72.<sup>14-16</sup> In the context of secondary prevention of SCD, ICD implantation is widely accepted in the absence of reversible causes.<sup>17,18</sup>

When an ICD generator must be replaced, a careful clinical evaluation must involve the patient in overall decision-making. Aspects such as their life expectancy and expectations, their wishes about quality of life and current comorbidities, as well as how many times the ICD has provided therapies, the implications of repeated high-energy treatments (especially when ablations may or may not be performed or are successful or not), disease progression, costs of devices and procedures (in a private practice setting), should be discussed. Ideally, this should be addressed in a meeting with the patients, their family members, and the medical team to reach the best possible decision. This is particularly important when a patient has a limited life expectancy or an advanced, incurable disease. If prolonging life expectancy is no longer the main goal and the focus shifts to palliative care, the implications of the replacement are different. The same occurs when the patient's clinical situation changes significantly. In these cases, the objective is to prioritize quality of life and avoid unnecessary, distressing, high-energy shocks.<sup>19</sup> An example is the eldest geriatric patients with diabetes and

advanced chronic kidney disease, a group where ICD implantation has shown virtually no benefit. Again, individualization is key.<sup>20-22</sup> Several trials (e.g. AVID trial) have demonstrated a significant reduction in mortality in patients with an ICD for secondary prevention, compared to medical therapy alone (28% reduction, HR 0.72; 95%CI 0.6-0.87;  $p = 0.0006$ ).<sup>15,16,18</sup> The same effect is not widely replicated in patients with non-ischemic systolic heart failure.<sup>23,24</sup>

The lifespan of the ICD battery depends on the implantation parameters (impedance and stimulation thresholds for both pacing and shocks, among others) and the number of low- and high-energy therapies required by the patient. When the battery is depleted, an elective replacement should be envisaged, but there are few studies that address the ideal decision-making route in that context.<sup>25</sup>

As in other countries and Latin America, a common practice in Mexico is to check any implantable device in a pacemaker clinic, where a team composed of a cardiologist (ideally an electrophysiologist), a nurse, and a technician checks the device and adjusts the parameters according to the patient's clinical condition. During those visits, or through remote monitoring at home, the Elective Replacement Indicator (ERI) will be detected, and the elective replacement should be planned.<sup>26-28</sup> [Table 1](#) shows several factors to consider when replacing the generator.

### RELEVANCE OF THE IMPROVEMENT OF LEFT VENTRICULAR EJECTION FRACTION (LVEF)

The LVEF is an important element in the decision process to implant an ICD.<sup>29,30</sup> Patients with a LVEF of 35% or less benefit from an ICD, which reduces SCD by 27%.<sup>19,31</sup> In recent years, optimized therapy for heart failure has shown significant improvement in ventricular function, but the risk of SCD appears to remain, as in some patients there are fluctuations in LVEF during follow-up.<sup>32</sup> The DANISH trial (Defibrillator implantation in patients with non-ischemic systolic heart failure) highlighted that these reductions in mortality are less clear in contemporary patients with non-ischemic heart failure.<sup>24,33</sup> Another study showed a worse prognosis in patients with Heart Failure

and Reduced Ejection Fraction (HFrEF) (LVEF 35%) who received an ICD generator and had a proportional risk of arrhythmic death of 43% compared to controls without ICD. A total of 32 patients with resynchronization therapy were excluded.

Apparently, an improvement in LVEF, because of optimized therapy, can reduce the burden of arrhythmias<sup>34-36</sup> and, therefore, the need for electrical therapies. There is an apparent time-dependent behavioral change of arrhythmia burden under several conditions.<sup>37</sup> A relevant factor is optimized medical therapy. Ablation of ventricular tachycardia has also shown significant benefits.<sup>38</sup> Rordorf et al.,<sup>39</sup> found that the risk of adequate high-energy therapies after an ICD generator replacement is three times lower in patients with LVEF less than 35% compared to patients with LVEF above 35% and an indication for primary prevention. Several studies suggest that LVEF improvements resulting from optimal medical therapy with angiotensin receptor blockers, neprilysin inhibitors, SGLT2 inhibitors, beta-blockers, aldosterone antagonists, diuretics, etc. are associated with a reduction in arrhythmia burden and thus, a reduced need for ICD therapies. Thirty percent of patients no longer meet the initial implant criteria at the time of generator replacement. It has also been observed that the risk of inappropriate shocks is higher in older subjects or patients with normal or above 35% LVEF.<sup>40-42</sup>

These findings have prompted discussion about the possibility of de-escalating the device in patients with a Cardiac Resynchronization Therapy (CRT) pacemaker with defibrillator (CRT-D) to a CRT-alone device. Further studies are needed to better define which patients are suitable candidates for such a change, especially when the device was implanted for primary prevention.<sup>43,44</sup>

The *Seattle Proportional Risk Model* (SPRM) estimates the risk of SCD in patients with heart failure based on variables such as sex, age, New York Heart Association (NYHA) functional class, digoxin use, diabetes, body mass index, serum creatinine, systolic blood pressure, sodium level, pro-brain natriuretic peptide (Pro-BNP) level, and LVEF.<sup>45,46</sup> This risk model could be a useful tool for determining whether a patient is a good candidate for a generator or

**Table 1: Factors to be considered before replacement of an Automatic Implantable Cardioverter-Defibrillator (AICD) generator battery.**

|                                                           |
|-----------------------------------------------------------|
| Related with the cardiac condition                        |
| Type of cardiac disease                                   |
| Primary or secondary prevention for the AICD implant      |
| LVEF at the time of the replacement                       |
| LVEF when the AICD was inserted                           |
| Number, history and type of correct AICD therapies        |
| Number, history and type of incorrect AICD therapies      |
| Cardiac NMR findings (late enhancement)                   |
| Not related to a cardiac condition itself                 |
| Economic problems (high cost)                             |
| Patient decision                                          |
| Advanced life                                             |
| Low life expectancy                                       |
| Multiple comorbidities, life style, not independent, etc. |
| Others                                                    |

device replacement.<sup>47,48</sup> Delayed myocardial enhancement with gadolinium (LGE) on cardiac magnetic resonance imaging (MRI) may play an important role in the decision to replace the battery, as large fibrotic areas act as ventricular arrhythmia substrates even with slight variations in LVEF.<sup>49,50</sup> On the other hand, an upgrade from ICD to CRT-D should be considered in patients with symptomatic HFrEF, especially among subjects with high ventricular pacing rates. In this subset, the insertion of an additional electrode to stimulate the left ventricle is often performed at the time of a generator replacement. Upgrading to CRT-D in patients with symptomatic HFrEF improves cardiac remodeling.<sup>51,52</sup> Thomas et al., found that 25% of patients have some degree of LVEF recovery at the time of generator replacement, but 75% of those who do not have high mortality rates in a three-year follow-up.<sup>53</sup> These results should be validated in subjects receiving left bundle branch stimulation.<sup>2,54</sup>

#### **RISK RE-STRATIFICATION AT THE TIME OF ICD REPLACEMENT AND INAPPROPRIATE ICD THERAPIES**

International guidelines on ICD indications do not distinguish between early ICD implants and generator replacement, and there are few

clinical trials looking at events following this procedure. There seems to be a gray area in patients who need replacement of an implanted ICD for primary prevention but never received any form of electrical therapy (either low or high energy). Further doubt arises when there is an improvement in ventricular function and the patient no longer meets the original criteria for the implant. In a study of 231 patients with ICD implanted for primary prevention who required generator replacement due to battery depletion, nearly 26% were no longer compliant with the indication for ICD at the time of replacement due to improved LVEF. There was also a significant difference in the incidence of appropriate therapies after generator replacement among patients who still had an indication for ICD at the time of replacement compared to those who did not (2.8 vs 10.7% patients/year).<sup>55</sup> The MADIT-CRT trial showed that 7.3% had a normal LVEF, and after a two-year follow-up, only one patient had ventricular tachyarrhythmia. The authors concluded that there was a reduction in ventricular arrhythmias when ventricular function improved.<sup>56</sup> Several studies have shown that up to 65% of patients with an ICD implanted for primary prevention did not receive any therapy during a five-year follow-up.<sup>33,57</sup> It has been found that 21 to 27% of patients without shocks after the first implant received at least one shock after the device change. On the other hand, when the patient has received shocks and the battery needs to be replaced, the chance of receiving appropriate therapies in the future is three times higher.<sup>41,58</sup> These findings suggest that lack of therapies is not an appropriate criterion to decide whether to replace a generator or not. On the other hand, generator replacement is usually mandatory if the ICD has administered appropriate electrical therapies.

#### **SEVERE DISEASE WITH POOR PROGNOSIS AND CARDIAC INSTABILITY**

Patients with end-stage congestive heart failure (NYHA class IV), who are not candidates for a heart transplant or other advanced therapies, may not benefit from ICD replacement. Similarly, replacement is not recommended in patients with incessant ventricular tachycardia

or fibrillation, as ICD therapy would not be effective in controlling the condition.

### COMORBIDITIES, LIFE EXPECTANCY AND ADVANCED AGE

Age is not a factor in determining whether a generator should be replaced. The possibility of death from non-cardiac causes in elderly subjects could reduce the usefulness of an ICD. It is crucial to understand patients' expectations, life expectancy, existing conditions, and the status of their heart disease. Frailty syndrome should also be considered and ideally evaluated by a gerontologist.<sup>59</sup>

If the patient's life expectancy is less than one year, ICD generator's replacement may not be beneficial. High-energy therapy can cause pain and distress without significantly prolonging life.

### SEVERE DISEASE WITH POOR PROGNOSIS

Patients with end-stage congestive heart failure (NYHA class IV), who are not candidates for heart transplantation or other advanced therapies, may not benefit from ICD replacement, as previously said. Reoperations on cardiac implantable devices are associated with an increase in complications, including infections, present in 1.4% of patients, while in first-time implants, that rate was 0.8%.<sup>60,61</sup>

The replacement of the ICD generator is associated with a significant risk of complications; within six months after the procedure, the risk of major complications is 4%, and the risk of minor complications is 7.4%.<sup>60</sup> Main complications include displacement or damage of the electrode(s), infection of the device requiring removal of the entire ICD system, significant bleeding requiring evacuation of the ICD pouch, and prolonged hospitalization. Minor complications include nerve injury, minor bleeding, skin infection, and pain. The risk of device infection is particularly concerning, as it usually requires the removal of the entire ICD system.

This procedure is associated with substantial cardiac perforation risk with or without tamponade, vascular damage, and even death.<sup>62,63</sup>

An ICD replacement is not recommended when the risks of surgery outweigh the potential benefits to the patient. This decision is based on a thorough assessment of the patient's health and treatment goals, especially in the context of end-of-life or other serious illnesses.

### SERIOUS COMPLICATIONS

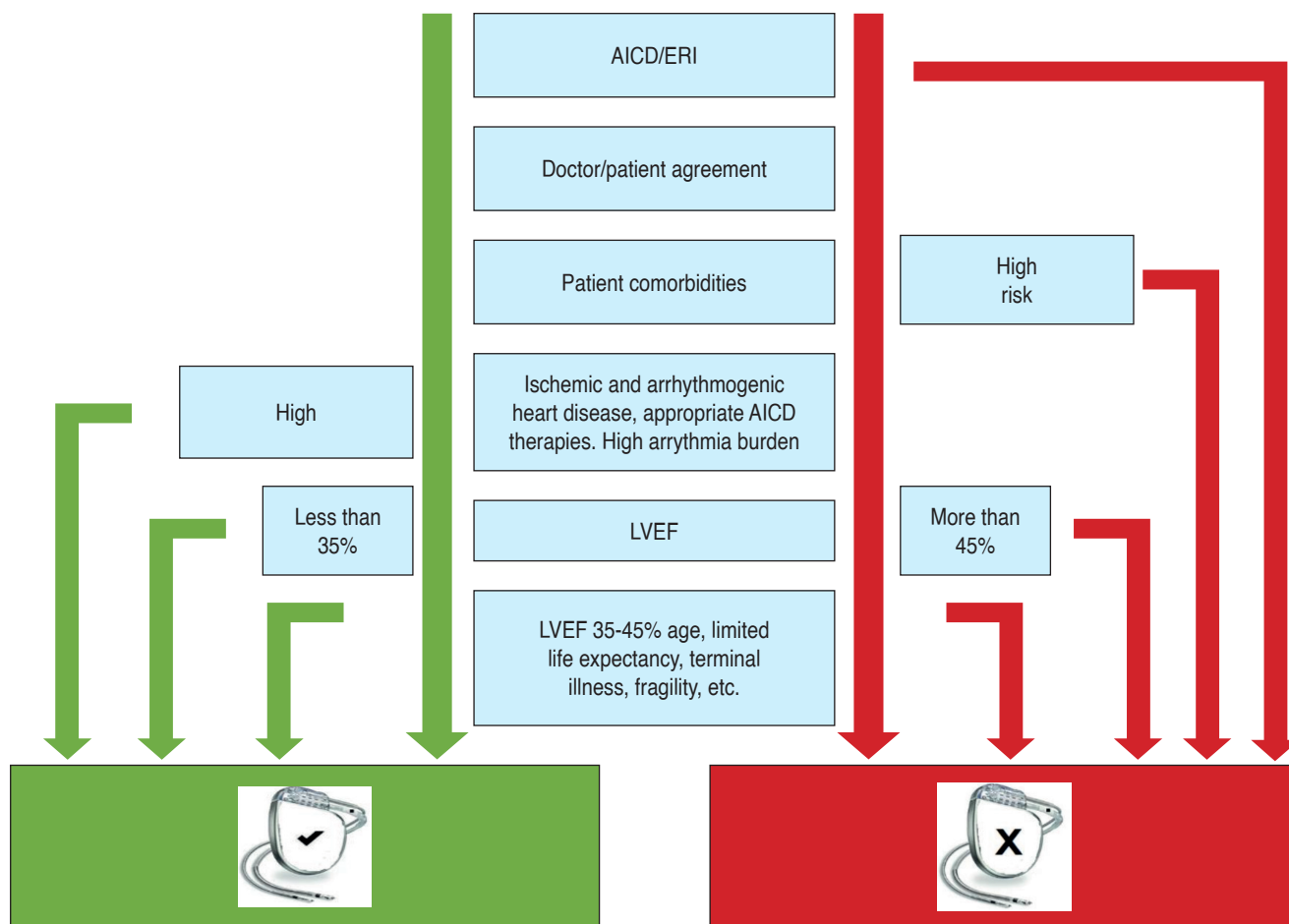
A replacement may not be advisable if the patient has experienced severe complications, such as an infection that requires removal of the entire ICD system.

These features, along with a clear explanation of the hazards of a device replacement (infections, for example), should be discussed to arrive at the best possible decision for the patient. Again, individualization is key.<sup>64</sup>

### THE PATIENT'S PERSPECTIVE

Most patients are unaware that replacement of the ICD generator is optional, and more than 25%, knowing it, would consider not doing it in our country. Many patients must cover the financial costs of the new generator by themselves because insurance often does not do it. In a significant proportion, this is a factor in the decision to avoid replacement. The perspective of SCD is appealing for some patients with deteriorated functional class and disease progression, so they prefer not to replace the generator. It is also important to clearly state that SCD is a real possibility whenever the patient decides not to replace the generator.

It is of vital importance that the physician guide the patient's decision-making process in collaboration with the cardiology/geriatrics team. The patient must understand that even in low-risk situations, there is a chance of ventricular arrhythmias.<sup>65,66</sup> The team must ensure that the patient and their family understand that declining an ICD replacement may be contrary to proper medical judgment. This medical opinion, as well, must be based on an objective risk-benefit evaluation in the patient's best interest. If the patient decides to decline the replacement, she/he must also be reassured that the medical team will deliver the best available care to preserve quality of



**Figure 1:** Decision-making diagram for generator replacement.

Modified from: Martínez M et al. Considerations involved in elective generator replacement of implantable cardioverter-defibrillators: balancing risks, benefits and individual factors. *Rev Esp Cardiol.* 2024; 77 (1): 2-5.

AICD = Automatic Implantable Cardioverter-Defibrillator. ERI = Elective Replacement Indicator. LVEF = Left Ventricular Ejection Fraction.

life when possible, and administer palliative care as needed.

### DE-ESCALATION TO ANOTHER DEVICE

Many patients will not undergo an ICD replacement although they might require pacing and/or resynchronization therapy. This implies installation of a new ventricular pacing electrode(s) or the selection of a DF-4 compatible generator. In this case, a previous CRT-D device, only the left ventricular electrode could be connected to a conventional pacemaker. If biventricular pacing is to be maintained, the implantation of a new pacing electrode in the right ventricle should also

be considered, with an increased risk of complications.

### CLINICAL DECISIONS AND IMPLICATIONS

We need comparative studies in our country to assess the benefit of generator replacements in patients with an ICD. *Figure 1* shows a decision-making diagram for generator replacement. The main problem lies in SCD prediction, something that is harder in certain subgroups such as the elderly.

Among patients with LVEF recovered after resynchronization and optimal medical therapy, without ventricular LGE on MRI, the risk of malignant arrhythmias is reduced. Therefore,

avoidance of ICD replacement could be considered in patients with ICDs placed as primary prevention and who show a recovered LVEF (greater than 45%) in the absence of adequate electrical therapies by the ICD.

Anyway, there is a residual risk, mainly among elderly patients with ischemic heart disease, that must not be neglected, even if the device has not administered any electrical therapy. This specific group of patients is one of the most hesitant in the decision of whether to replace the generator or not, and even more so when it is explained to the patient.<sup>67</sup>

### CONCLUSION

The decision to perform an elective generator replacement in a patient with an ICD in ERI is not a simple one. It requires a careful and individualized exhaustive analysis of the risk-benefit ratio in each case and a comprehensive discussion with the patient. Priority considerations are LVEF modifications, etiology of the underlying heart disease, indication for first-time placement, whether it is primary or secondary prevention, whether there have been appropriate therapies or not, life expectancy and quality of life and existing comorbidities. The patient must be involved in the final decision after an explanation about the risks, benefits, and possible complications.

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