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DEVICES

Longevity and potential reusability of cardiac implantable electronic devices explanted in funeral homes Publisher

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Abstract

Background: While in high-income countries (HICs) the implantation of cardiac implantable electronic devices (CIEDs) is common, in certain low- and middle-income countries (LMICs) access to devices is limited and insufficient to meet the demand. Between 17% and 30% of CIEDs explanted post-mortem in HICs appears to have enough battery life to be reused but devices are not routinely programmed to no pacing output and continue to consume battery after the patient's death. Therefore, we conducted a prospective analysis of CIEDs collected from funeral homes, controlling variables such as the date of explantation and limiting the time until the date of interrogation to 6 months. The objective was to perform an accurate analysis of the reusability of post-mortem explanted CIEDs to assess the possibility of implementing a local effort of CIED reuse in LMICs.

Methods: A descriptive study of post-mortem explanted CIEDs in funeral homes was conducted. Participating centers stored all devices explanted between December 2020 to December 2021 for collection and interrogation.

Results: The participating centers attended 6472 deaths (28.05% of total deaths registered in the region). Two hundred fourteen CIEDs were collected (90.2% pacemakers and 9.8% defibrillators). Of the 214 collected devices, 100 CIEDs (46.7%) had >4 years or >75% battery remaining, preserved external integrity, and no evidence of malfunction and therefore were considered reusable.

Conclusions: Based on stablished criteria 46.7% of recovered devices were considered reusable. Therefore, recovery from funeral homes of HICs comprises a potential source of reusable devices for LMICs.

KEYWORDS
CRT, ICD, pacemaker, post-mortem, reuse

1 | INTRODUCTION

Cardiovascular diseases are one of the major causes of mortality worldwide.[1] CIED implantation has been shown to reduce mortality and morbidity in patients with specific cardiovascular pathologies.[2] While in HICs the implantation of such devices is commonplace, in

Abbreviations: CIEDs, Cardiac implantable electronic devices; CRTs, Cardiac resynchronization therapy devices; HICs, High-income countries; ICDs, Implantable cardiac defibrillators; LMICs, Low- and middle-income countries.

certain LMICs access to devices is limited and insufficient to meet the demand.[3] Thus, lack of access to CIEDs is estimated to account for around 1 million deaths per year in LMICs.[4]

CIEDs must be explanted before the cremation of a deceased patient in funeral homes and crematoria, due to the risk of explosion of the device when subjected to high temperatures.[5] Between 17% and 30% of CIEDs explanted post-mortem in HICs such as the United States have enough battery life to be reused in other patients.[6,7] Device reuse is considered a safe and ethical alternative when new devices are not available.[8] Therefore, post-mortem CIED recovery from HICs is advocated as a mean to alleviate the high demand in LMICs where patients do not have the means to access new devices.[9]

Previous studies that have analyzed the remaining longevity and reusability of CIEDs after post-mortem explantation in funeral homes collected the samples without being able to control the time elapsed from the date of explantation to the date of analysis.[10–12] Thus, considering that most CIEDs are not routinely programmed to no pacing output and continue to consume battery power after the patient's death, it is reasonable to expect that controlling the influence of these factors, the percentage of potentially reusable devices would be higher.

Therefore, we conducted a prospective analysis of CIEDs collected from funeral homes, controlling variables such as date of explantation and limiting the time that could elapse until the date of interrogation to 6 months. The objective was to perform an analysis of the reusability of explanted CIEDs to assess the possibility of implementing a local effort of device reuse in LMICs.

2 | METHODS

A descriptive study of post-mortem explanted CIEDs was carried out in funeral homes of the Basque Autonomous Country, in Spain. All funeral groups of the region were contacted to explain the purpose of the research and were provided with informed consent for participation to be completed by the relatives of the deceased, as well as a guide for explantation, handling, and storage of the devices. Participating centers stored prospectively all explanted cardiac devices for a period of one natural year, from December 2020 to December 2021. The devices were collected every 6 months and analyzed in the electrophysiology department of the Universitary Hospital of Basurto, using the specific programmers of each manufacturer.

Data on the total number of deaths and cremations during the study period from each of the participating centers were collected. Variables such as collection date, interrogation date, manufacturer, device type, device subtype, implantation date, explantation date, external physical integrity, whether interrogation was possible or not, estimated longevity of the devices (by analyzing voltage, percentage of remaining battery, estimated years of life until elective replacement date or taking the mean value between the estimated minimum and maximum longevity) and evidence or alarms of malfunction were analyzed. Inaccurate alerts triggered by post-mortem extraction and resulting in automated algorithms of capture threshold, detection, or impedances were not considered significant and were not categorized as a failure or malfunction.

The estimation of device longevity was performed after devices were reprogrammed to no pacing output or the lowest possible pacing output expressed in volts and pulse width. If devices had remote monitoring, it was turned off. Also, for devices that indicated elective replacement of the generator due to battery depletion, the date on which the alarm was generated was collected.

As in previous similar studies, devices with an estimated remaining longevity of >75% or >4 years were considered reusable.[10–14] Devices were also only considered reusable if they maintained a preserved external integrity and if they had no evidence of malfunction.

2.1 | Statistical analysis

For the description of quantitative variables, the mean and standard deviation, minimum and maximum values were used. For qualitative variables, frequencies and percentages were used. Qualitative variables were compared using Pearson's Chi-square test. After exploring the distribution of quantitative variables, they were compared using the Kruskal–Wallis test. A p-value $< .05$ was considered statistically significant. All analyses were performed using IBM SPSS Statistics Version 23.

3 | RESULTS

Nine funeral groups participated attending a total of 6472 deaths. Therefore, the study accounted for 28.05% of the total number of deaths registered in the Basque Autonomous Country during the data collection period.[15] Of the total number of deaths, 4162 cremations were carried out (cremation percentage = 64.3%).

A total of 214 cardiac implantable electronic devices were collected (88.3% pacemakers, 8.9% ICDs, and 2.8% CRTs). Two implantable cardiac monitoring devices were also collected but were not analyzed as they were not the focus of the present study. Table 1 shows a summary of the total number, types, and subtypes of devices recovered with respect to the different manufacturers.

Total of 96.4% of the devices had optimal external physical integrity, while 3.6% of the devices had some minor damage (minor scratches or dents in the metal casing) with no loss of integrity in the generator housing.

The devices have interrogated an average of 0.31 ± 0.17 years after their explant date at the funeral homes. The Guidant manufacturer's device could not be interrogated due to the unavailability of the manufacturer's programmer at the hospital. None of the devices that could be interrogated were considered non-reusable due to the presence of a critical malfunction reading or error.

The mean device usage time, calculated from the date of implantation to the date of death, was 4.9 ± 3.22 years, with a minimum of 0.01 and a maximum of 12.51 years. Table 2 shows the calculated usage times based on device types and manufacturers.

TABLE 1 Number of devices with respect to type, subtype, and manufacturer.

	Device type						
	Pacemaker		Defibrillator		Cardiac resynchronization therapy device		
	Single-chamber	Dual-chamber	Single-chamber	Dual-chamber	CRT-P	CRT-D	
	n (%)						Total
Medtronic	45 (47.4)	51 (54.3)	1 (11.1)	1 (10)	1 (25)	1 (50)	97 (50.3)
St. Jude Medical	17 (17.9)	24 (25.5)	5 (55.6)	4 (40)	2 (50)	0 (0)	43 (22.3)
Biotronik	10 (10.5)	8 (8.5)	0 (0)	3 (30)	0 (0)	0 (0)	18 (9.3)
Sorin group	15 (15.8)	7 (7.4)	0 (0)	0 (0)	0 (0)	0 (0)	22 (11.4)
Boston Scientific	5 (5.3)	3 (3.2)	3 (33.3)	2 (20)	1 (25)	1 (50)	9 (4.7)
Vitatron	3 (3.2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (1.6)
Guidant	0 (0)	1 (1.1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.5)
Total	95 (44.4)	94 (43.9)	9 (4.2)	10 (4.7)	4 (1.9)	2 (0.9)	214 (100)

TABLE 2 Time of use in years of analyzed devices with respect to type and manufacturer.

				Time of use		
				n	m ± sd	[min–máx]
	Pacemaker	Manufacturer	Medtronic	96	5.40 ± 3.37	[0.01–12.51]
			St. Jude Medical	41	4.55 ± 2.56	[0.37–10.49]
			Biotronik	18	3.83 ± 2.90	[0.16–8.29]
			Sorin group	22	0,.6 ± 0.27	[0.07–0.46]
			Boston Scientific	8	3.42 ± 2.46	[0.30–6.31]
			Vitatron	3	7.86 ± 0	[7.86–7.86]
			Guidant	1		
Device type	Defibrillator	Manufacturer	Medtronic	2	3.63 ± 3.84	[0.92–6.34]
			St. Jude Medical	9	4.54 ± 3.56	[0.03–8.28]
			Biotronik	3	5.80 ± 5.95	[1.60–10.01]
			Sorin group	0		
			Boston Scientific	5	3.20 ± 2.41	[1.49–4.90]
			Vitatron	0		
			Guidant	0		
	CRT	Manufacturer	Medtronic	2	3.83 ± 3.60	[1.28–6.38]
			St. Jude Medical	2	5.98 ± 0	[5.98–5.98]
			Biotronik	0		
			Sorin group	0		
			Boston Scientific	2	4.21 ± 5.92	[0.02–8.40]
			Vitatron	0		
			Guidant	0		

In terms of remaining longevity, 88 pacemakers (46.6%), 10 defibrillators (52.6%), and two CRTs (33.3%) still had >4 years or >75% battery remaining, accounting for a total of 100 reusable devices (46.7%). Among the 100 devices with sufficient battery to be considered reusable, 48 were single-chamber pacemakers (22.4%), 40 were dual-chamber pacemakers (18. 7%), five were single-chamber ICDs (2.3%), five were dual-chamber ICDs (2.3%), and two were CRT-P (0.9%). Since all devices had preserved integrity and no evidence of malfunction was recorded in any of the devices, the remaining longevity was the only considered reusability criteria. Table 3 shows in greater depth the remaining longevity of the analyzed devices in relation to device types.

TABLE 3 Estimated longevity in years of analyzed devices in relation to device types.

		Estimated longevity							
		<1 year	1–4 years	4–7 years	7–10 years	10–14 years	>14 years	Total	*p*-value
					n (%)				
Device type	Pacemaker	9 (6.6)	39 (28.7)	29 (21.3)	15 (11)	35 (25.7)	9 (6.6)	136 (100)	.175
	Defibrillator	2 (16.7)	0	2 (16.7)	4 (33.3)	4 (33.3)	0	12 (100)	
	CRT	0	2 (50)	0	0	2 (50)	0	4 (100)	
Total		11 (7.2)	41 (27)	31 (20.4)	19 (12.5)	41 (27)	9 (5.9)	152 (100)	

TABLE 4 Correlations between the estimated battery longevity and device time of use, in years.

	Time of use		
Estimated longevity	*n*	m ± sd [min–máx]	*p*-value
<1 year	8	6.26 ± 3.04 [0.59–10.02]	<.001
1–4 years	35	5.15 ± 2.43 [0.38-10-30]	
4–7 years	18	4.74 ± 3.13 [0.01–10.49]	
7–10 years	13	2.73 ± 2.73 [0.03–8.04]	
10–14 years	28	2.33 ± 1.96 [0.02–7.39]	
>14 years	8	1.49 ± 1.09 [0.02–2.76]	

The mean time of use of the devices was calculated with respect to having sufficient remaining battery life to be considered reusable. Overall, reusable devices were implanted for a mean of 2.95 ± 2.62 years in patients, while non-reusable devices were implanted for a mean of 6.55 ± 2.74 years. Table 4 shows a summary of the usage time of the devices analyzed with respect to the remaining battery time. These data indicated, as logic, that the remaining battery life was related to device usage time ($p = < .001$).

4 | DISCUSSION

The findings of this study, as in the previous studies, show that a considerable percentage of devices explanted post-mortem in funeral homes could be reused.[7,10,11] In addition, the establishment of a maximum time of 6 months for device collection and interrogation meant that almost one out of every two devices were reusable.

Based on the results obtained in this study as a rough estimate and considering the annual mortality rate of the country and the annual cremation rate of around 45%, we estimated that around 5000 potentially reusable devices are explanted and discarded every year in funeral homes of Spain.[16,17] Moreover, it should be noted that this might be higher in the coming years, due to the gradual increase in the annual percentage of cremations.

The European legal framework allows the reprocessing of single-use medical devices, such as the CIEDS analyzed in this study, leaving it up to the member countries the specifications regarding this type of practices.[18] The most recent meta-analysis found no significant differences in infection, malfunction, premature battery depletion, or related deaths when comparing reused CIEDs with new CIEDs.[19] Even so, regulation in Spain does not allow the reprocessing and reimplantation of used CIEDs, because re-sterilization would mean using the devices outside the specifications for which they were manufactured. However, shipment of post-mortem explanted reusable devices to third LMICs where regulation does allow CIED reuse may provide a vital treatment to patients with no other alternative.[20,21]

The donation of used CIEDs to LMICs is not a new concept, different programs in the United States or France collect explanted devices to provide treatment to patients without resources from LMICs.[22,23] Also, a recent study showed that the majority of physicians of the Spanish Rhythm Association were in favor of this type of practice.[24] Therefore, considering that approximately half of the CIEDs explanted in funeral homes could be reused, establishing an initiative for collection, analysis, reconditioning of devices for shipment to LMICs seems feasible in Spain.

4.1 | Limitations

Remaining battery longevity may vary greatly depending on pacing frequency, device programming and type. These data, as well as the baseline bradyarrhythmia to be treated, were not analyzed in this study meaning that the results on remaining longevity in relation to device types and manufacturers should be interpreted considering the influence of these factors. In addition, the interrogation was done with no leads in the port plugs. Therefore, we acknowledge a potential overestimate of remaining battery longevity.

5 | CONCLUSIONS

A local controlled collection and interrogation of routinely explanted CIEDs in funeral homes was conducted in this study. Based on criteria of >75% or >4 years of remaining battery life, preserved external integrity, and no evidence of malfunction, 46.7% of the devices were considered reusable. Therefore, recovery from funeral homes comprises a potential source of reusable devices. Implementing a local device reuse program could help to alleviate the demand in patients unable to afford new devices in low- and middle-income countries.

5.1 | What is known about it?

Post-mortem explanted cardiac implantable electronic devices in high-income is advocated as a means to provide treatment to needy patients of low- and middle-income countries unable to access new devices. In Spain, although devices are routinely explanted in funeral homes after patients' death, the percentage of potentially reusable devices is unknown.

5.2 | What's new?

With a biannual collection and interrogation and based on criteria of >75% or >4 years of remaining battery life, preserved external integrity, and no evidence of malfunction, nearly half of the explanted devices are reusable.

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CONFLICT OF INTEREST STATEMENT

The author declares no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data on which this article is based will be shared on reasonable request to the corresponding autho.

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