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Battery life of cardiac implantable electronic devices explanted in funeral homes - A potential resource for underserved nations

Abstract:

Introduction: CIEDs (Cardiac implantable electronic device) could still have adequate battery life and functionality when are explanted after the death of the carrier, supposing an important resource for **low- and middle- income** countries where patients cannot afford new devices.

Objective: The aim was to analyse the remaining battery life and reusability of CIEDs recovered from funeral homes.

Method: A descriptive study of postmortem explanted CIEDs was conducted. Devices were collected from three funeral homes in **the Spanish region of the Basque Country** (participation rate 33.3%). Devices with a remaining battery life of >75% or > 4 years, preserved external integrity and no evidence of malfunction were considered reusable.

Results: A total of 188 CIEDs were collected (175 pacemakers and 13 defibrillators). Of the total number of devices, 95 (50.5%) had enough battery to be interrogated. Among the interrogable devices, a total of 20 pacemakers (22.4%) had an estimated battery life of more than 4 years, as well as preserved integrity and no record of malfunction.

Conclusions: A non-negligible number of postmortem explanted devices had battery life, external integrity and functionality to be considered reusable. Postmortem CIED donation could provide treatment to patients unable to afford new devices.

Keywords: Pacemaker, Implantable defibrillator, longevity, reuse.

Introduction:

Cardiovascular diseases (CVD) are one of the leading causes of mortality worldwide, as well as a major cause of premature death, disability and healthcare cost[1, 2]. More than 75% of global CVD mortality occurs in low- and middle-income countries[3, 4]. The lack of access to health systems or unaffordable expenses for patients, are some of the known reasons for the high mortality from CVD in low- and middle- income countries[4, 5]. This situation is especially evident in the field of cardiac electrostimulation. **For example, when stratifying pacemaker implantation rates in Europe according to countries' Gross National Income, it stands out that while high-income countries perform an average of 830.4 (CI 717.6-943.9) implantations per million inhabitants, middle income countries perform an average of 148 (CI 54.7-309.6) implantations**[6]**. In contrast, some low-income countries of other continents do not even perform CIED implantation surgeries**[7]**.** Therefore, it is estimated that between 1 and 2 million people die annually in low- and middle- income countries due to lack of access to these therapies[8, 9].

In order to fill the need for cardiac pacing devices in **low- and middle- countries**, small-scale reuse programmes of postmortem explanted devices have been carried out in recent years[10–12]. Used CIED reprocessing and reimplantation is not a new concept, as it was a common practice in the decades prior to the 1990s in European countries such as Sweden[9]. Recent meta-analyses have found no significant differences in infection (OR 0.98; 95% CI 0.60 – 1.60), malfunction (OR 1.58; 95% CI 0.56 – 4.48), premature battery depletion (OR 1.96; 95% CI 0.81 – 4.72) or related deaths between reused and new CIEDs[13]. Therefore, device reuse is defended as a feasible alternative when there is no possibility of accessing new devices[14–16]. The reprocessing of **CIEDs** for their reimplantation is not allowed within the Spanish national territory, since it would mean unlawfully modifying the device outside the manufacturer's indications[17]. However, there are no prohibitions on collecting used explanted CIEDs and donating them to countries where reprocessing and reuse of this type of devices is allowed[18].

CIEDs must be removed in funeral homes when a deceased carrier is prepared for the cremation process, due to the risk of explosion of the devices when subjected to high temperatures[19]. In previous studies, it has been indicated that a considerable number of CIEDs explanted postmortem still have enough battery life and could potentially be reused[11, 20, 21]. Thus, postmortem donation could be an important source of devices for **low- and middle- income countries** where patients cannot afford a new one[4, 9, 10, 22]. **However, such studies have only been carried out only in the United States. So, although a priori**

similar results are assumed, it is not known whether a country like Spain, with patients of different sociodemographic characteristics and an eminently public health system, could also comprise a potential source of reusable devices. Therefore, the aim of this study was to analyse the potential for reuse of postmortem explanted cardiac devices recovered from funeral homes **in Spain**.

Methods:

Funeral groups in **the Spanish region of the Basque Country** were contacted by telephone or corporate email to participate in the research and asking them to donate, **if they had in their facilities**, explanted pacemakers or defibrillators (n=9). Three of the centres reported having explanted CIEDs stored in their facilities (participation rate = 33.3%). The devices were collected in person in December 2020.

The recovered CIEDs were interrogated in the department of **electrophysiology of Basurto university hospital** in January 2021, using the specific programmers of each manufacturer. Variables such as manufacturer, device type, model, implantation date, explantation date (**estimated by recording date of ohms rise >3000, which probably indicated lead cut on device extraction**), interrogation date, external physical integrity, battery percentage or estimated years of life to elective replacement date, and evidence of malfunction were analysed.

Similar to the previous studies carried out by Baman et al and Laslett et al, devices with a remaining battery life >75% or > 4 years, preserved external integrity and no evidence of malfunction were considered reusable[21, 23]. **Inaccurate technical alerts triggered by post mortem extraction and resulting on automated algorithms of capture threshold, detection or impedances were not considered significant and were not categorized as a failure or malfunction.**

Statistical analysis:

The statistical processing of the data was carried out with the SPSS v.27 program. Qualitative variables were expressed by frequencies and percentages. For the analysis of quantitative variables, normality tests were performed and described by mean and standard deviation. The comparison of the reusability of the devices according to the commercial house was analyzed using Pearson's chi-square test. **The comparison of the quantitative and qualitative variables was analyzed using Mann-Whitney's U or Kruskal-Wallis tests**. The level of statistical significance was established with a p-value <0.05.

Results:

A total of 188 CIEDs (175 pacemakers and 13 defibrillators) were collected from Biotronik, St Jude, Medtronic, Boston Scientific, Soringroup, Vitatron, Guidant, ELA, Pacesetter and Englewood manufacturers. Of the 188 CIEDs, only 95 (50.5%) had sufficient battery life and functionality to be detected by the programmers and interrogated. 89 pacemakers (27 single-chamber, 59 dual-chamber and 3 **pacemakers with cardiac resynchronization therapy**) and 6 defibrillators (1 single-chamber, 3 dual-chamber and 2 **defibrillators with cardiac resynchronization therapy**) were interrogated.

The devices in which interrogation by programmers was possible where explanted a mean of 3.35 ± 2.29 years after the implantation date. Table 1 shows the mean use time in year of recovered devices according to interrogated manufacturers. Devices were analysed 6.72 ± 2.75 years after implantation date. In terms of longevity estimation, 60 devices had an estimated battery life of <1 year (67.4%), 9 devices of 1-4 years (10.1%) and the remaining 20 devices (22.4%) had an estimated > 4 years, which is considered an adequate battery to be reused. Furthermore, 14 of these reusable devices had an estimated battery life of more than 10 years (15.7%). External integrity was preserved in all of the reusable devices and no malfunction record was detected. In addition, all 20 devices that met the stablished reusability criteria were pacemakers (10 single-chamber and 10 dual-chamber).

For the 20 pacemakers that had adequate battery life to be considered reusable, the mean time from implantation to the date of explantation was 2.22 ± 2.91 years. The 75 non-reusable devices were explanted a mean of 3.42 ± 2.27 years after implantation date. Also, a mean of 1.45 ± 1.53 years elapsed from the date of removal of the reusable devices and 4.34 ± 2.94 years until the date of interrogation in the non-reusable devices (p=0.046).

Only devices from Biotronik, St Jude, Medtronic, Boston Scientific, Soringroup, Vitatron and Guidant manufacturers were interrogable. The manufacturer was related to the estimated remaining battery life of the devices (p<0.001). Thus, 88.2% of Biotronik, 60% of St Jude and 3.3% of Medtronic devices had > 4 years of estimated battery life. Figure 1 shows graphically the count of reusable and non-reusable devices where interrogation was possible with respect to the different manufacturers.

Discussion:

This is the first study to date on the reuse potential of postmortem explanted CIEDs in funeral homes in Europe. This paper adds relevant information to the similar studies carried out previously in the United Stated, with the aim of analysing the reuse potential of postmortem explanted devices[4, 12, 21].

The reuse of CIEDs has been performed for years in **low- and middle income countrie**s on a small scale, presenting itself as a viable and safe alternative in cases where a new device is not available[24]. Devices are usually recovered from deceased patients for functionality interrogation, sterilisation and reimplantation, reducing considerably the cost of bradyarrhythmia treatment[9]. Previous studies have indicated that international donation of CIEDs from **high income countries to low- and middle- income countries** is supported by the general population, professionals and patients in potentially donor countries such as the United States and by patients in potentially recipient countries such as Nicaragua, Pakistan, Ecuador, and Lebanon[25]. **A recent study also points that electrophysiologist of the Heart Rhythm Society of Spain are in favour of these practices**[26]**.**

Our results, compared with previous related studies, also show that a substantial number of CIEDs explanted postmortem in funeral homes in Spain have an adequate battery life, function and integrity to be reused in other patients[21, 23]. Thus, the overall percentage of reusable devices in our study (22.4%) is very similar to those performed in the United States by Baman et al (21%) and Laslett et al (22%)[21, 23]. Furthermore, in our study 88.2% of Biotronik, 60% of St Jude and 3.3% of Medtronic devices retained a battery life greater than 4 years, describing significant differences between manufacturers and estimated battery life ($p<0.001$) **even if mean use time was not significantly different.**

At the national level, according to data from the latest Spanish pacemaker registry, the number of conventional pacemaker generators consumed in the country in 2020 was 759 units per million respectively, although the actual number would be even higher according to manufacturers data[27]. As for the characteristics of the recipient patients, the median age at implantation was 78.8 years[27].

The survival after pacemaker implantation in elderly patients in Spain is an average of 4.7 years and the longevity of a conventional pacemaker is between 10 and 12 years[28, 29]. Therefore, the postmortem recovery of reusable CIEDs in funeral homes and crematoria would be a potential source of resources for **low- and middle- income** countries, as the current incineration rate in Spain is 45% and is expected to increase in the coming years[30].

In the present study, an average of 4.42 ± 2.67 years elapsed from the date of implantation of the reusable devices (n=89) to the date of analysis. The non-reusable devices (n=75) were interrogated an average of 7.42 ± 2.68 years after the date of implantation, while an average of 2.66 ± 2.67 years elapsed from the date of explant until an alarm for battery depletion and elective replacement of the devices was recorded. Therefore, **even if pacing parameters were**

not collected, it could be inferred that devices with a shorter time of use have a longer battery life and therefore a greater potential for reuse. These data suggest that, if devices were interrogated immediately after explantation, the percentage of reusable devices would be even higher as was seen in the study in a tertiary hospital setting carrier out by Gakenheimer et al[31].

Device reuse is advocated as a safe, cost-effective and ethical practice to provide patients without access to new devices with a treatment alternative[32–34]**. Even so, refurbished devices are used outside the manufacturer's specifications, which means that most high-income countries governments prohibit this type of practice for legal and safety reasons on the principle of increasing life expectancy and quality of life in patients with no other alternative, low- and middle- income countries governments allow such practices.**

Another issue to consider would be the procurement of new electrodes needed for refurbished devices. While a priori some device manufacturers might show resistance to reuse, new leads would be routinely required, so a reuse programme could also potentially be of interest to the industry as well, although legal and liability issues would be concerns to address.

The implementation of a standardised cleaning and sterilisation protocol for reusable devices could open the door to an international device reuse programme[35]. As CIED donation programmes would require consent of the carrier or relatives, it would be interesting to describe the perspectives of device carriers in Spain on whether they would support postmortem donation of devices to **low- and middle- income** countries. Physicians could play a key role on providing a consent for donation[26]. In the most favourable scenario, a non-negligible number of CIEDs could be recovered to provide a vital treatment to many patients unable to access new devices.

Limitations:

The study has several limitations. On the one hand, the devices were donated without knowing the exact date of explantation, which meant that this data was estimated using the date of recording the increase in ohms >3000. Also, most devices (83.5%) were donated from a single centre, so the results of the study may not be generalisable to other locations or at the national level. Moreover, the estimated battery life may vary depending on pacing frequency and programming parameters of devices, which could not be analysed. Therefore, the results on remaining battery life in relation to the different manufacturers should be interpreted with caution.

Conclusions:

A non-negligible number of devices analysed in our study had the enough longevity, integrity and functionality to be considered reusable. Postmortem device donation from funeral homes and crematoria of Spain could be a potential source of resources for **low- and middle- income** countries. The implementation of a national cardiac device reuse programme could provide treatment for financially unable patients in **low- and middle- income** countries.

Author contributions: All authors contributed to the conception and design, analysis and interpretation of the data. All authors reviewed and approved the final version of the manuscript.

Ethical statement:

This research was approved by the ethics committee of the Basque Country: The code of the project is PS2020052 and was authorized on 28/10/2020.

Data availability statement:

The data underlying this article will be shared on reasonable request to the corresponding author.

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