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Post mortem pro life - Should we analyse the implantable devices after death? A systematic review

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ABSTRACT

Aim: Post-mortem interrogation of the cardiac implantable electronic devices (CIEDs) in combination with autopsy findings can provide additional information regarding device functioning after implantation or the mechanism of death. The aim of the study is to review the available data on the post-mortem interrogation of CIEDs and its possible clinical implications.

Methods and results: A systematic review of the published studies has been performed. Out of 762 unique citations 14 have been retained for final analysis. Post-mortem CIED interrogation reliably detects both serious device malfunctions and lead disorders but also improper device programming. As the need for CIED implantation is growing in the low-income countries, currently available data on battery longevity of devices explanted and destined for re-use have been reviewed.

Conclusions: Post-mortem CIED interrogation provides a unique opportunity to explore different mechanisms of death, often unavailable for distinction during regular in-hospital observation or in autopsy analysis.

1. Introduction

Cardiovascular Implantable Electronic Devices (CIED) implantation has become a routine procedure and the number of implanted devices is growing annually [1]. Current European Society of Cardiology guidelines on cardiac pacing and cardiac resynchronization therapy along with mutual HRS/EHRA/APHRS/SOLAECE expert consensus clearly describe the indications for the implantation and programming of the devices [2,3]. A properly programmed CIED, especially ICD or cardiac resynchronization therapy-implantable cardioverter-defibrillator (CRT-D) should not only protect the patients from bradyarrhythmia, asystole or dangerous ventricular arrhythmias but also inadequate and unnecessary interventions. The patients after implantation should undergo a regular device interrogation, either during routine visits in the outpatient clinic or with the newly developing system of remote monitoring.

Despite the well-developed system of care, there is still a certain percentage of patients with CIED, who suffer from a sudden cardiac death (SCD). Moreover, the mechanism of their death is frequently unknown. In a limited population of patients dying suddenly, the exact cause of death can be ascertained during autopsy analysis. However, the post-mortem interrogation of CIED is not a standard practice, even though their storage and analysis is suggested by the 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, along with the guidelines for autopsy investigation of SCD of the Association for European Cardiovascular Pathology from the same year [4,5]. One of the possible explanations of this diagnostic inertia could be the fact that the devices are more often considered as irrelevant medical waste, rather than sources of valuable information, as noted by Kirkpatrick et al., who stated that 44% of the American morticians consider the CIEDs as a useless medical waste [6]. Although the up-to-date clinical evidence is not prolific, it may suggest post-mortem analysis of CIED, autopsy findings and their combination can have a significant clinical merit, penetrating a field of cardiology of still limited knowledge. This study, including a systematic review, is a review of the available data on the post-mortem interrogation of CIEDs and its possible clinical implications.

2. Methods

Relevant articles assessing the clinical value of post-mortem CIED interrogation were searched using PubMed (MEDLINE), EMBASE and the Cochrane Central Register of Controlled Trials. The terminology searched for is as follows: post-mortem CIED, CIED interrogation, post-mortem pacemaker, post-mortem defibrillator, sudden death CIED, autopsy CIED, pacemaker retrieval, defibrillator retrieval, autopsy pacemaker analysis and autopsy defibrillator analysis. In addition, due to lack of review articles focused specifically on this field of medicine, the references mentioned in the original papers were searched as well in order to find their original sources of information. All the titles and abstracts from the search along with full text (if necessary) were investigated by two independent reviewers: any occurring discrepancies were clarified by constructive discussion. According to the

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inclusion criteria, the articles must have been written in English on post-mortem human CIED interrogation correlated with autopsy findings from January 1, 1990 (around the time of the first third-generation ICDs introduction) till July 1, 2018. Term "third-generation ICD", according to the literature, describes a transvenous device fully capable of delivering an anti-tachyarrhythmic treatment including high voltage therapies along with its ability to store intracardiac electrograms derived from the episode of tachyarrhythmia [7].

E-publications (articles not yet published, although available online) were not searched. Case reports, conference abstracts and letters to the editors along with review articles or guidelines were excluded. Furthermore, in order to summarise the potential clinical value of continuous assessment of post-mortem CIED interrogation conducted in the large cardiovascular centres, studies consisting of less than an arbitrary number of 15 patients were excluded from analysis. Institutional review board approval was not obtained, as our systematic review involved the retrospective analyses of de-identifying studies that had already been published.

3. Results

Searching the literature returned 762 unique citations but for the sake of relatively limited data accuracy, all three sources were analysed independently. Afterwards, they underwent duplicate removal. After a thorough analysis of full article texts, 8 studies have been chosen. Further analysis of twelve full texts available from the search of all reference sources of relevant articles allowed including additional six studies finally making up 14 studies retained for the analysis. The flowchart presenting the literature search is presented in Supplementary Figure.

The selection of major studies in which CIEDs were interrogated post-mortem is presented in Table 1. Across 12 studies we have selected, post-mortem interrogation of CIEDs was performed with the rate varying between 31% and 100% [7–18]. Post-mortem CIED analysis was further correlated with autopsy findings in 8 studies. The number of interrogated devices also differed between the studies and was the lowest (19) in the study by Nagele et al. [13] and the highest in the study by Bartsch et al. [12]. In 10 studies, clinical follow-up from implantation to death was available for analysis. The elements found during post-mortem device interrogation are presented in Fig. 1.

In recent years, there has been a tendency to monitor whether it's doable for the devices explanted during the autopsy to be reused. Therefore, it's vital to properly examine the CIED before confirming its suitability for reuse, since the device functionality depends not only on the producer's guarantees but also different factors including its functional mode and frequency of intervention. The two major studies specifically assessing this issue are listed in Table 2.

The average time from implantation to death was similar in both studies (2.5 ± 2.3 years vs 2.84 ± 2.32 years). However, the authors declared that not all explanted devices were suitable for reuse, namely the remaining battery longevity was shorter than a year in 33% of CIEDs in the study by Zamani et al. [19], and 44% of CIEDs in the study by Sinha et al. [20] unsuitable for repeat implantation. Therefore, there is still a need to examine the devices in order to appropriately choose those suitable for reuse.

3.1. Post-mortem CIED interrogation - logistic issues

Not all studies included in the analysis utilised the same CIED interrogation technique. Although in the majority of the reports regular post-explantation analysis has been performed, there were few exceptions from that rule. In the study by Bartsch et al., the devices were interrogated before the cremation of the cadaver using in-situ technique [12,21]. This approach allows the interrogator to perform the tests with an independent set of devices including an oscilloscope, pre-amplifier and a test pacemaker, right after the patient's death, and then to compare the results with those derived from the explanted device interrogated with a programmer. Therefore, any differences between those results may indicate a dysfunction of the circuitry. One of the major limitations of this technique in comparison with the regular analysis using a manufacturer-derived programmer is the need to obtain the aforementioned set of devices and the need to perform the scans before the device has been explanted. Therefore, in the context of routine post-mortem interrogation, the technique would require simplification in order to be used on a larger scale.

The most frequently used technique was a standard interrogation using a manufacturer-specific computer programmer. We conclude that as the programmers are widely present in centres implanting CIEDs, its routine use does not require additional investments and provides reliable and reproducible data on the device functioning.

The recent progress made in the remote monitoring of the devices prompts the theories that in the future, their interrogation might be performed remotely. The technology enables the clinician being stationed in the reference centre to evaluate multiple devices from many, sometimes unapproachable locations and was shown to improve outcomes in patients with HF [22]. However, its major limitation in the discussed field is its usability only in patients equipped in the system before death. Nonetheless, its likely wider utilisation in the future might also enable its more frequent use post-mortem.

4. Discussion

The number of CIEDs implanted across the globe is rising and each year more than 700,000 new PPMs and 200,000 ICDs are implanted globally [23]. Apart from their basic functions, currently available CIEDs have been designed to allow a long-term monitoring of its functional parameters, along with arrhythmia recordings, which if properly utilised might have valuable clinical implications.

As stated in the ESC guidelines for the management of patients with ventricular tachyarrhythmias and the prevention of SCD, in the last 20 years, the mortality due to cardiovascular causes has decreased, mostly due to preventive measures [24]. Although these results are convincing, cardiovascular diseases are still responsible for 17 millions of worldwide deaths, with 25% attributed to SCD. The occurrence of SCD is reckoned globally at 1.40/100,000 and 6.68/100,000 person-years in women and men respectively [25]. Therefore, the prevention of sudden cardiac death in the shape of risk stratification and an early detection of the risk groups should be considered as one of the most important challenges facing modern medicine.

The guidelines point that the successful finding of the underlying cause of SD in the deceased may raise awareness also in the family members, who might be at high risk of SD too. Hence, it is recommended that all subjects dying suddenly in an unexplained mechanism should be examined post-mortem in order to establish the cause of death, even though in 2–54% of SD victims the autopsy does not yield the explanation of the unforeseen end of life [26]. One of the possible explanations could be that in a number of patients, SD is not caused by the visually distinguishable disease but by the various arrhythmic causes, which require ECG recording to be noticed and stored [5].

Taking into consideration all arguments presented above, the introduction of CIED interrogation correlated with autopsy results, information concerning the circumstances of death and the medical records of the patient seems to bring additional benefits into this field of practice. The analysis of the literature included in this study allowed us to draw such conclusions. Although the autopsy examination combined with CIED interrogation is performed rarely, it appears that its broader introduction into the clinical practice could become a precious addition into the total diagnostic-therapeutic process. As summarised in our study, it allows to: 1) More adequately define the cause of death (in 1–61% of the cases) as presented in Table 3 2) Define the terminal rhythm in patients dying suddenly (in 14–100% of the cases) 3) Assess the efficacy of cardiac pacing and/or detection or therapy of ventricular tachyarrhythmias in patients with CIED (25% and 85% depending on the study) 4) Discover potential CIED damage, malfunction or improper programming (1–18% depending on the study). All the aforementioned information could be of substantial usefulness for the clinicians (as it may suggest them the feasible direction of diagnostics in patients with decompensated HF, suggest the patients at increased risk of premature death, as presented

Table 1
The selection of studies investigating the post-mortem interrogation of cardiac implantable electronic devices (CIEDs) summarised in the chronological order.

Main author, date, journal	Cases analysed	Follow up/indications for implantation	Age of the analysed patients, in years, mean ± SD	The purpose of the study	Terminal rhythm analysis	Average time from implantation to death	Autopsy results
Pratt, 1996, Circulation, [8]	109 with ICD	Yes/NA	61.0 ± 13.0 (at implantation)	Analysis of the precision of sudden death diagnosis. Determination of the impact of CIED interrogation on the death classification	Stored in 53% of the patients' devices	Not specified	In 27%
Grubman, 1998, JACC [7]	119 with ICD	Yes/yes	67.1 ± 8.2	Analysis of terminal rhythm and mechanism of death	Stored in 31% of the patients' devices	11.5 ± 11.9 months	In 15%
Pires, 1999, Journal of Cardiovascular Electro-pathology [9]	74 with ICD	Yes/yes	68.0 ± 10.0	Analysis of terminal rhythms Investigation of potential causes and predictors of sudden death	Derived from emergency medical service or hospital monitor 28 ICDs interrogated	13 ± 8 months	No
Pires, 1999, JACC [10]	25 with ICD, OOH	Yes/yes	62.0 ± 10.0	Determination of the arrhythmic event associated with SD Identification of clinical and device-related contributors to SD	Stored in 88% of the patients' devices/ Obtained by the emergency services or hospital monitor	13 ± 11 months	In 12%
Mitchell, 2002, JACC [11]	320 with ICD	Yes/yes	68.0 ± 11.0	Determination of the mechanism of death in patients with ventricular tachyarrhythmias	Stored in 44% of the patients' devices,	4.7 ± 4.3 months	NA
Bartsch, 2005, Europace [12]	415 with PPM	No/no	84.7 ± 19.6 (at death)	Assessment of device dysfunction occurrence	NA	48 months	Yes
Nagele, 2007, Europace [13]	19 with PPM	Yes/yes	59.0 ± 13.0	Assessment of mechanism of sudden out of hospital death	In 89% of patients' devices	25 ± 17.3 months	In 5 patients
Duray, 2009, Europace [14]	225 with ICD	Yes/yes	63.0 ± 11.0	Evaluation of cause-specific mortality Assessment of predictors of death in a large cohort of unselected ICD recipients	Stored in 59% of devices from patients dying suddenly	39–43 + 30 months	No
Stroobandt, 2012, PACE [15]	37: 20 with CRT-D 17 with ICD	No/no	NA	Analysis of changes in lead impedances of ICDs at the time of death and afterwards	In 100% of devices from patients	Not specified	No
Tseng, 2016, JAMA [16]	22: 14 with PPM 8 with ICD	Yes/NA	72.0 ± 16.0	Determination of causes of SCD in patients with CIED Full autopsy, toxicology, histology, device interrogation	From interrogation of 95% devices and/or emergency medical systems	Not specified	Yes
Sinha, 2016, JACC [17]	84: −37 with PPM −47 with ICD	No/yes	64.3 + 16.8	Utility of CIED removal and analysis at autopsy	Obtained from interrogation of 92% of devices in patients with sudden death	PPM: 3.0 ± 2.5 years ICD: 2.7 ± 2.2 years	Yes
Lacour, 2018, Circulation [18]	151: −109 with PPM −35 with ICD −7 with ILR	Yes/no	76.3 ± 12.8	Determination if postmortem CIED interrogation can improve clarification of cause and time of death and detect safety issues related with CIEDs	Obtained from interrogation of 100% of devices	Not specified	Yes

Abbreviations: CIED-cardiac implantable electronic device, OOH-out-of-hospital, PPM-permanent pacemaker, ICD-implantable cardioverter-defibrillator, ILR-implantable loop recorder, NA-not available SD-sudden death, SCD-sudden cardiac death.

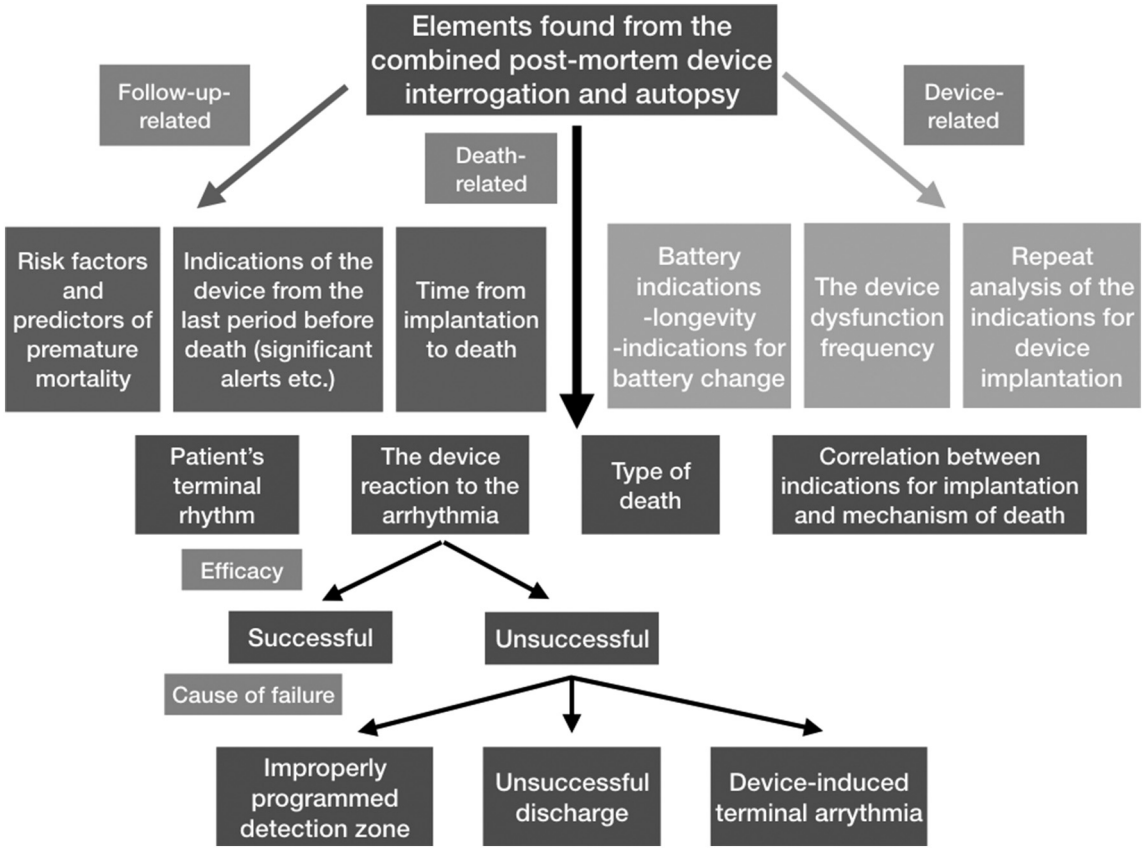

Fig. 1. Elements found during the post-mortem device interrogation according to the currently available studies.

in Supplementary table, or increase the number of patients monitored remotely) and for the CIED manufacturers (as it might influence the components of the devices).

In order to visualise the analysed subject, we would like to share a case of the 74-year old male with CRT-D implanted four years before due to ischemic cardiomyopathy. On account of the severe progression of coronary disease, the patient was admitted to the cardiac surgery department for off-pump coronary artery bypass graft surgery (OPCAB). The second day after the successfully performed OPCAB, the clinical conditions of the patient deteriorated significantly without any new findings in echo examination responsible for the clinical condition. The patient presented with pulmonary oedema and required catecholamines infusion. In the urgent coronary angiography performed, good patency of implanted grafts and native arteries was observed. During the transfer from the cath lab to the intensive care unit, the patient went into cardiogenic shock due to PEA. Despite the immediately undertaken CPR, the patient died. In autopsy no signs supporting the cardiac cause of death were found. However, in the post-mortem CIED interrogation of his CRT-D we discovered that the patient had asymptomatically lost the biventricular pacing a week before the surgery. Probably, the general stress associated with cardiac surgery and general anaesthesia could have caused the HF decompensation in this patient and in a short period of time could have led to death. Here, the post-mortem CIED interrogation enabled us to modify our assertions on the cause of death derived from the clinical profile of the patient and autopsy results.

4.1. Limitations of the studies

Despite the thorough interrogation of the devices, in some cases it is hard to describe the exact rhythm at the time of death. The devices are equipped with their individual timekeepers but especially in the older-generation CIEDs they often lack precision and major discrepancies between the CIED time indication and real hour were previously described [27]. Furthermore, some terminal rhythms might not meet specific criteria for device recording, thereby they cannot be retrieved afterwards. It can occur that the CIED reaches its elective replacement indicator and therefore stops storing any EGMs. Also, the time passing from the device explantation to the interrogation may significantly attenuate the battery longevity measurements due to the battery self-discharge processes. In the other cases, the establishment of an exact

Table 2
Currently available studies focused specifically on the longevity and potential to reuse the explanted CIEDs.

Main author, date, journal	Number of investigated devices (PPM/ICD)	Average time from implantation to death	Prognosed average time for implantation
Zamani, 2012, American Journal of Cardiology [19]	27: −17 PPMs −10 ICDs	2.5 ± 2.3 years	33%: <1 year 37%: 1–4 years 30%: ≥4 years
Sinha, 2016, Heart Rhythm [20]	84: −37 PPMs −47 ICDs	2.84 ± 2.32 years	4.79 ± 3.41 years

Abbreviations: PPM-permanent pacemaker, ICD-implantable cardioverter-defibrillator.

Table 3
Possible causes of death found during post-mortem CIED interrogation with their occurrence in the studies included in the review.

Clinical findings	Occurrence in the included studies	Device findings	Occurrence in the included studies
Asystole/PEA	9.0%–60.0%	Improper detection	1.3%–14.0%
Bradyarrhythmia	5.7–7.9%	No/unsuccessful high voltage therapy	1.4%–34.0%
VT/VF	19.0%–89.0%	Battery end of life	1.7–5.0%
		Improper device programming	2.0%–14.0%
		No defibrillation option in patients with VT/VF and PPM	5.0%–11.6%

Abbreviations: PEA-pulseless electrical activity, PPM-permanent pacemaker, VF-ventricular fibrillation, VT-ventricular tachycardia.

cause of death can be truly troublesome, as the other concomitant diseases can severely obscure the clear view of a case.

The other important aspects, which contribute to the significant heterogeneity of such a limited number of studies, are the differences in technical approaches taken by the consecutive authors. Out of 14 studies discussed in brief in this review, multiple interrogation techniques were applied (as discussed previously).

4.2. Possible future amendments

Currently, post-mortem interrogation of CIEDs is conducted very rarely, even though the information gathered in the device memory might bring valuable data not only into the establishment of an individual cause of death. Therefore, we reckon that actions aimed at raising awareness among the clinicians and morticians could yield in their higher immersion in the subject. Furthermore, it is crucial to establish specified guidelines of behaviour for the morticians in order to retrieve the devices more frequently. The protocol of device retrieval and storage, which at the beginning may just be an implementation of the mentioned before guidelines in the routine practice only during the post-sudden death autopsy [4,5], might be then expanded into the patients after non-sudden death. A successful protocol of action must then include an interrogation and data storage by the trained electrophysiologist. The technologies of the 21st century allow us to speculate that in cooperation with major device producers and distributors the data may be stored on the cloud storage, thus being available for inspection and analysis from anywhere across the globe by the authorised specialists.

In order to improve the parameters of devices implanted in the future populations of patients, it is important to expand the horizon of diagnostics currently scanning data obtained during the routine patients' clinic visits. If conducted more often, the currently rare analysis of putative mechanical failures may lead to modification of materials used in the production of leads or devices themselves. More frequently conducted post-mortem analysis of battery parameters and detection of malfunctions might lead to further improvement of the longevity and electricity consumption. Moreover, retrospective analysis of terminal rhythms may inspect the current indications for device implantation and help to more precisely select the future patients eligible for specific types of devices and/or programming details. All the aforementioned alterations may improve the short- and long-term outcomes in future patients with implanted CIEDs, reduce the number of avoidable defects and improve the quality of life of patients.

5. Conclusions

Even though post-mortem interrogation of cardiac implantable electronic devices (CIEDs) is not a regular practice, studies have shown its great potential to explore different mechanisms of death, often unavailable for distinction during regular in-hospital observation or in autopsy.

Since the CIEDs are implanted more frequently every year, there is a need to expand knowledge in that direction in order to establish potential algorithms in the prevention of sudden cardiac death or unforced device malfunctions. Furthermore, there is a need to strengthen our engagement in the field of post-mortem CIED interrogation. In order to retrieve more CIEDs after death, implementation of protocols of their collection and storage after death is necessary. If in the future the devices are more frequently saved during the autopsy for the post-mortem interrogation correlated with a clinical inquiry, our building knowledge might result in the other suggestions of modifications for the device manufacturers to be entered into clinical practice. Moreover, autopsy supplied with information derived from the post-mortem CIED analysis would be a much more irrefutable source of information when compared with the standard interrogation and may bring substantial discoveries to the clinical practice. All aforementioned actions along with a better selection of the devices destined for implantation to certain patients may finally lead to a decrease in the occurrence of events requiring intervention, as the saying goes that "prevention is better than cure".

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