Healthcare Management

Perspectives on the Longevity of Cardiac Rhythm Management Devices

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Abstract

Cardiac arrhythmias are a major cause of morbidity and mortality. Cardiac rhythm management devices (CRMDs) are used to diagnose and treat heart rhythm abnormalities. Many prospective randomized trials over the past decade have established the efficacy of CRMD therapy in reducing all-cause mortality and improving the quality of life. The manufacturer of every device provides its longevity in its technical characteristics, which are, as studies show, shorter in practice. Patients are concerned about the replacement procedure due to the risk of the procedure and other socioeconomic reasons. The longer the longevity of the devices, the better for the patients, the payers, the doctors and the health care systems. Given the recently redefined term of health technology assessment on a European level, a new regulatory framework has been proposed. Its intention is that, across different healthcare systems, the upfront costs and the reimbursement costs of these devices should be proportional to their longevity.

Keywords: Cardiac arrhythmia; Cardiac rhythm management devices (CRMDs); Longevity of CRMDs; Health technology assessment (HTA); Real word data (RWD)

Introduction

Cardiac pacemakers (PMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices with pacing or defibrillator capabilities are potentially lifesaving devices in the event of cardiac arrhythmias. After a long-term clinical practice of over half a century, cardiac rhythm management devices (CRMDs) have proven their clinical effectiveness in terms of patients' quality of life, morbidity and mortality.

The broadening of CRMD implantation recipients and the demographic growth lead to an increase in the implantation of such devices, which in turn generates a greater number of replacements than implantations [1].

The industry has achieved enormous advances in implantation technology, including smaller, leadless, highly sophisticated devices, physiologic sensors, magnetic resonance imaging (MRI) conditional pacing systems, telemetric communication and programming [2].

The longevity of a CRMD is defined as the period that starts after the implantation of the CRMD, more specifically with the device's beginning of service, and lasts until the end of service (EOS) or battery depletion requiring a replacement. The length of this period depends on the energy consumption of the CRMD and battery capacity.

The longevity of every device is estimated by the manufacturer of the device [2]. The longevity of CRMDs has a crucial impact on the follow-up costs, costs per month and cost-effectiveness of these devices, and all the above trigger highly controversial issues raised by governments and third-party payers [3].

Perspectives on CRMD Longevity

Patients' Perspective

The most common question asked by patients who will undergo CRMD implantation after being informed by their doctors is about the longevity of the device. The longer the device works, the more relieved the patients are.

From the patient's point of view, the most frequently asked questions concern the stress of the pre-hospitalization and hospitalization period, physical and psychological pain, anxiety, the risks of the procedure, concerns about the device after implantation, and, in extreme cases, life-threatening events [4].

Moreover, socioeconomic consequences such as the disruption of families, extra payments, and the fear of the above can occur repeatedly in the future. Furthermore, many of these problems reappear during every routine follow-up, particularly when the battery has reached the end of service, especially in device-dependent patients. All these thoughts become increasingly burdensome in a patient's mind. It is more than certain that all patients wish that their devices would last for

the rest of their lives. Real world data has shown that patients prefer larger devices with greater longevity to prolong the time until the replacement procedure [5].

Payers' perspective

Social insurance funds, private insurances and governments share the same perspectives. This is a "deus ex machina" for their rising healthcare costs. The non-pharmacological therapy of arrhythmias with expensive, state-of-the-art technology of innovative devices such as ICDs and CRT devices causes high upfront costs, while unexpected complications related to the replacement procedure create additional costs for the healthcare system.

Doctors' (and Human Resources Involved with the Procedure of Replacement's) Perspective

From the doctors' (and the staff's) point of view, a lot of time will be saved when replacements due to the end of battery life become obsolete. For one, medical staff will no longer be involved in procedures that pose a risk. There will not be any dilemma between replacement or no replacement of a CRMD in a moribund patient or in patients whose life expectancy is shorter than the lifespan of the device, regardless of the patient's or their family's wishes. Unexpected complications during or after the replacement procedure will be eradicated. Doctors, nurses and medical administrative staff will be able to provide their services in other medical areas, and patients will receive improved health-care service.

All relevant stakeholders involved in the procedure of CRMD replacement will only be involved for specific reasons, such as device infection, manufacturer recall, lead revision, patient discomfort, device system upgrade or device failure, except for battery depletion.

Real World Data on CRMD Longevity

In ICD reports, more than a quarter of the devices did not meet the longevity that was predicted by the manufacturer. Additionally, longevity can vary between different models from the same manufacturer [1]. It should be emphasized that proper device programming by medical or technical personnel is key for the longevity of CRMDs.

As previously mentioned, prolonging the battery life of ICDs to seven or nine years reduces the risks and costs for patients [6].

The European Society of Cardiology (ESC), specifically the European Heart Rhythm Association (EHRA), provides unique and up-to-date data on the number of CRMD implantations in the ESC territory through the EHRA White Book. The annual replacement rate is increasing following the increase in initial device implantations [7].

Owing to technical, clinical, and economic aspects, the long-term costs of device treatment are affected by the battery life, which subsequently affects the choice of device [3].

To save money, or in cases where there is none, systems and patients are forced to find other solutions. In the case of PMs, studies have shown that in developing countries, after proper sterilization, the reuse of PMs derived from richer countries is feasible, safe and effective. The reused PMs save lives and improve the quality of life for patients in need [8, 9].

Future Trends

If we assume that the industry has exhausted its potential to extend the battery life of CRMDs, we must consider alternative approaches that promise different kinds of solutions in order to avoid frequent replacements due to battery depletion. One of these alternative approaches suggests that the solution may originate within the patient's own body.

Bioengineering has shown that self-powered technologies provide a path for the future. The human body is a source of energy. Kinetic (based on electromagnetic, electrostatic, and piezoelectric conversion) and thermal energy are the main energy sources of the human body. Researchers harvest energy from body heat, breathing and the movement of every body part, arm, leg, or muscle [10].

Conclusions

Health technology assessment can be defined as a multidisciplinary process that uses specific methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-makers to promote an equitable, efficient and high-quality health care system.

The longevity of CRMDs has both clinical and economic implications. It is crucial to know the true longevity of a device because behind every device is a human life.

In accordance with this definition, particularly with regard to the dimensions of efficiency and quality, a new regulatory framework must be proposed at the European level, linking the reimbursement across different health systems with the longevity of each device.

According to the data, this will have a positive impact on the financial sustainability of health care systems while at the same time accelerating the industry's efforts to design devices that do not need to be replaced. Finally, it is a great challenge for the industry to adapt and support this proposal as part of its ethical, economic and corporate social responsibilities, resulting in a genuine capacity for improved effectiveness within the economic and health care system.

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Conflict of Interest Statement

The author has no potential conflicts of interest to declare.

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