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Ethical Considerations in Cardiac Pacemaker Therapies

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ABSTRACT

Cardiac pacemaker therapies, such as implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices, have transformed the management of cardiac arrhythmias and heart failure, improving patient outcomes. However, these therapies raise significant ethical challenges, including conflicts of interest in device selection, dilemmas in pacing mode choices, and decisions surrounding device deactivation at end-of-life. This article focuses on the interplay between ethical principles, patient autonomy, and resource allocation in these contexts, proposing practical solutions and exploring cultural and legal perspectives. Addressing these challenges is essential to ensure patient-centered, ethically sound cardiac care.

Introduction

The integration of cardiac pacemakers into modern medical practice has significantly enhanced the management of arrhythmias and other cardiac conditions, improving patient outcomes and quality of life. However, the widespread adoption of these devices necessitates a thorough examination of the ethical considerations inherent in their use. Addressing these ethical issues is crucial to ensure that patient care remains patient-centered, respects individual autonomy, and aligns with broader societal values.

One primary ethical concern involves the deactivation of pacemakers in terminally ill patients. As patients approach the end of life, decisions regarding the continuation or cessation of life-sustaining treatments become paramount. The ethical principles of autonomy and informed consent dictate that competent patients have the right to refuse or discontinue medical interventions, including pacemaker therapy. However, healthcare providers may experience moral distress or uncertainty when considering pacemaker deactivation, fearing that it may hasten death or be perceived as euthanasia. Clarifying that deactivation, when aligned with a patient's wishes, is ethically and legally permissible is essential for guiding clinical practice.[1]

Beyond end-of-life considerations, several other ethical issues warrant attention. The potential for conflicts of interest arises, particularly concerning the involvement of industry-employed allied professionals in pacemaker care. These professionals may face pressures related to commercial competition and the drive for device innovation, which could inadvertently influence clinical decisions. Additionally, the advent of remotely accessible pacemaker software introduces risks related to cybersecurity and patient privacy. Unauthorized access or software vulnerabilities could compromise patient safety, underscoring the need for robust security measures and ethical guidelines governing data management.[2]

The current state of ethical discourse in cardiac pacing emphasizes a comprehensive approach that encompasses these diverse concerns. Recent literature advocates for the development of clear guidelines and decision-making frameworks to assist clinicians in navigating the complex ethical landscape associated with pacemaker management. For instance, proposed algorithms aim to balance the technical aspects of device management with ethical principles, facilitating patient-centered care that honors individual preferences and values.[3]

In this article, we try to introduce three central ethical issues related to cardiac stimulation therapies:

- Conflicts of interest in device selection.
- Ethical dilemmas in device selection and pacing modes.
- Ethical implications of deactivating devices.

Metodology

The methodology for the literature search focused on identifying high-quality, peer-reviewed articles addressing ethical considerations in cardiac pacing. The process involved the following steps:

DATABASES SEARCHED: PubMed, Embase, and Google Scholar were the primary databases used for the search to ensure a broad and comprehensive review of available literature.

SEARCH TERMS: A combination of Medical Subject Headings (MeSH) terms and free-text keywords was employed, including:

- "ethics" AND "cardiac pacing"
- "pacemaker deactivation ethics"
- "ethical issues in cardiac implantable devices"
- "pacemaker cybersecurity" AND "privacy"
- "reuse of pacemakers" AND "ethical considerations"

Additionally, the specific MeSH query ("Ethics, Clinical"[Mesh:NoExp]) AND "Cardiac Pacing, Artificial/ethics"[Majr:NoExp] was tested to refine the search. However, no articles were found using this combination, highlighting a significant gap in the indexed literature addressing these overlapping topics comprehensively.

SEARCH TERMS: euthanasia law in Belgium, Netherlands, Luxemburg, United Kingdom, Spain.

FILTERS APPLIED:

Publication Date: Articles published between 2010 and 2025 were included to focus on recent advancements and ethical debates in cardiac pacing.

Article Type: Preference was given to original research, systematic reviews, and clinical guidelines. Opinion pieces and case reports were included if they provided significant ethical insights.

Inclusion Criteria: Articles discussing ethical principles related to cardiac pacing, including autonomy, informed consent, and end-of-life decision-making.

Studies addressing technological challenges, such as cybersecurity and data privacy.

Research examining equity in access to cardiac pacing technologies and device reuse.

Exclusion Criteria: Studies with no clear ethical focus or those addressing purely technical or physiological aspects of cardiac pacing.

Articles older than 2010 unless cited in more recent publications for foundational context.

ARTICLE SCREENING: Titles and abstracts were reviewed to assess relevance. Full-text articles were retrieved for those meeting the inclusion criteria.

DATA EXTRACTION AND SYNTHESIS: Key information and themes were extracted from selected articles and synthesized to develop the introduction and discussion on ethics in cardiac pacing.

Conflicts of interest in cardiac device selection

INDUSTRY INFLUENCE ON DEVICE SELECTION
The relationship between healthcare professionals and medical device manufacturers raises ethical concerns, especially regarding device selection. Financial ties with manufacturers may introduce bias, either consciously or unconsciously, in decision-making, leading to the selection of certain devices over others. While these relationships may improve technological advancement, they can also result in the overuse of costly devices, such as ICDs and CRTs, which may not always be necessary for all patient populations.[4,5,6]

NEEDS WHEN CHOOSING A PACING DEVICE
Reduce or eliminate the existence of a bias in decision-making: the relationship with the industry may lead healthcare providers to favor high-cost devices, potentially overlooking simpler alternatives that might be more appropriate for some patients.

Achieve financial transparency: The failure to disclose ties between healthcare institutions or professionals and the industry can create an environment conducive to subjective decision-making, harming the doctor-patient relationship.[4,7]

MANAGEMENT SOLUTIONS TO ADDRESS INDUSTRY INFLUENCE ON DEVICE SELECTION
Achieve transparency: Legislative efforts, such as the European Union's Medical Device Regulation (Regulation (EU) 2017/745 on Medical Devices), require the disclosure of financial relationships between healthcare providers and medical device manufacturers, aiming to mitigate potential biases in clinical practice.

Promote institutional oversight: Hospitals are obligated to establish clear protocols to prevent conflicts of interest from influencing clinical decisions, ensuring that patient welfare remains the primary focus. This necessity is underscored by the European Commission's Implementing Regulation (EU) 2024/2745, which sets forth rules for managing conflicts of interest in joint health technology assessments. These regulations aim to ensure that EU-level assessments of new health technologies are conducted independently, impartially, and transparently, free from conflicts of interest. By aligning with these regulations, hospitals can maintain the integrity of clinical decision-making and uphold patient trust.

Include training in bioethics: Healthcare providers should receive training in ethical decision-making, awareness of industry biases, and strategies for prioritizing patient care over financial incentives.

Ethical dilemmas in device selection and pacing modes

Choosing the appropriate device for a patient can present significant ethical dilemmas, especially when balancing cost, functionality, and the overall quality of life of the patient. What type of device should be selected? The more costly device with advanced functionalities aimed at maximizing the patient's quality of life, or a simpler, more affordable option that enables the patient to live with their underlying condition? Will the use of a highly advanced and expensive device genuinely result in an improvement in the patient's quality of life?

When faced with clinical scenarios involving elderly patients with limited life expectancy, healthcare professionals must navigate complex ethical dilemmas. One such scenario is the choice between an ICD and and a cardiac resynchronization therapy defibrillator (CRT-D). On one hand, CRT-Ds are powerful devices that can save lives by preventing sudden cardiac arrest and And potentially improve heart failure in patients with a wide QRS complex and reduced left ventricular ejection fraction, but their high cost and associated risks—especially in patients with limited life expectancy—raise significant ethical questions. Is it ethical to recommend an expensive, high-risk device when the likelihood of its benefits may not outweigh the risks for the patient? Should the healthcare provider prioritize the potential life-saving benefits of an CRT-D, or should they opt for a more cost-effective and less invasive treatment, such as a left bundle branch pacing pacemaker?[8]

The ethical principle of beneficence suggests that healthcare professionals must prioritize the patient's well-being, ensuring they receive the most appropriate treatment for their condition. But does beneficence always mean choosing the most advanced option, or should it sometimes mean opting for a simpler, less costly solution when the patient's condition and prognosis warrant it? In cases of limited life expectancy, a pacemaker might offer the patient a treatment that aligns better with their quality of life, without burdening them with the potentially overwhelming risks and costs of an CRT-D.

A similar ethical dilemma arises in the context of heart failure and the use of cardiac resynchronization therapy (CRT) devices. CRT can improve the quality of life and reduce hospitalizations for patients with heart failure, but the high cost of these devices raises questions: Is it justifiable to allocate substantial resources to a patient who may not have sufficient life expectancy to fully benefit from the treatment? How do we weigh the potential benefits of a CRT device in frail, elderly patients with poor prognoses? Should limited healthcare resources be used to benefit a small subset of patients, or is there an ethical obligation to ensure that treatments are distributed fairly among all patients?[8]

This dilemma brings us to the ethical principle of justice, which requires a fair distribution of resources. In this case, healthcare professionals must balance justice with beneficence—ensuring that the resources are used in ways that maximize the patient's benefit. Is it fair to provide an expensive treatment to a patient whose prognosis is poor, or would that be an unjust allocation of scarce resources that could benefit other patients with better survival chances?

Finally, a central ethical principle in both scenarios is patient autonomy. As healthcare providers, it is essential to involve patients in the decision-making process, ensuring they fully understand the options available to them and the associated risks and benefits. How can we respect the patient's autonomy while navigating the ethical complexities of treatment decisions? Should we push for what we believe is best for the patient based on medical evidence, or should we take extra care to ensure that their personal values and preferences are incorporated into the final decision?

In the end, these clinical scenarios pose fundamental questions about how to balance advanced medical technology, cost, patient well-being, and ethical principles. Healthcare providers must make thoughtful decisions, striving to ensure that the treatment chosen aligns not only with medical best practices but also with the values and desires of the patient.[9,10]

Ethical implications of deactivating devices.

ETHICAL PRINCIPLES AND THE ROLE OF EUTHANASIA LAWS

Decisions regarding the deactivation of pacemaker devices at the end of life are based on fundamental bioethical principles such as autonomy, beneficence, non-maleficence, and justice. However, these principles may intersect with laws regulating euthanasia, complicating decisions about withdrawing life-sustaining devices.

When we refer to the principle of autonomy and euthanasia, patient autonomy is paramount in decisions regarding the deactivation or withdrawal of cardiac stimulation therapies, as patients have the right to accept or refuse any treatment, including life-sustaining therapies such as pacemakers and implantable cardioverter defibrillators (ICDs). Euthanasia laws, when applicable, often influence these decisions. In countries such as the Netherlands, Belgium, and Luxembourg, where euthanasia is legally permitted under strict guidelines, device deactivation is considered similar to the withdrawal of other life-sustaining treatments. These laws provide a secure framework for the limitation of life-support treatments.[9,10,11,12,13]

The principles of beneficence and non-maleficence are particularly relevant when deactivating devices in terminal patients. Continuing to use devices that no longer contribute to the patient's well-being may be deemed unethical, as it could unnecessarily prolong suffering. In countries where euthanasia is legal, physicians are permitted to deactivate life-sustaining treatments to relieve suffering. This is carried out within a legal framework that emphasizes direct patient consent, family authorization, or advance directives, as well as confirmation of a terminal diagnosis. In contrast, in countries where euthanasia is illegal, deactivating devices may still be considered ethically acceptable if the primary aim is to alleviate unnecessary suffering without directly causing death.[8,9]

Is it ethically different to deactivate a pacemaker in a patient who is completely dependent on it to maintain their heart rhythm, compared to deactivating the anti-tachycardia therapies of an implantable cardioverter-defibrillator (ICD) in a patient with secondary prevention, given that both involve the withdrawal of a life-sustaining therapy? Deactivating a pacemaker in a pacemaker-dependent patient results in an immediate outcome: cessation of cardiac rhythm and, consequently, the patient's death. This raises ethical concerns regarding the physician's responsibility in making a decision that directly leads to a terminal outcome. Conversely, deactivating anti-tachycardia therapies in an ICD does not result in immediate death but allows a future malignant arrhythmia to cause a fatal outcome. In both cases, the fundamental act is the withdrawal of a life-sustaining therapy. However, the immediacy of the outcome in the case of the pacemaker introduces greater emotional and ethical weight for healthcare professionals and families, whereas the deactivation of ICD therapies may be perceived as more "natural," as death occurs later as a result of the underlying disease. The ethical dilemma lies in whether this temporal and perceptual difference justifies a distinct approach in terms of informed consent, the emotional burden on the medical team, and societal acceptance of the procedure. Should the immediacy of the outcome be considered an ethically relevant factor, or should the principle of respect for patient autonomy prevail in both scenarios?

CULTURAL AND RELIGIOUS PERSPECTIVES

Cultural and religious beliefs play a significant role in shaping practices related to the deactivation of cardiac devices.

The Catholic Church generally permits the withdrawal of life-sustaining treatments when they serve to alleviate suffering, particularly in terminal conditions, but prohibits euthanasia. In Catholic healthcare settings, the decision to deactivate devices is more acceptable for ICDs, which are often associated with painful shocks, than for pacemakers, which may be viewed as more directly extending life.[14]

Islamic teachings prioritize the preservation of life but also allow the discontinuation of futile treatments when death is imminent. While some Islamic scholars may approve the deactivation of devices such as ICDs if they cause harm, cultural norms around end-of-life decisions vary widely between different Islamic communities.[15]

About Western Legal Frameworks, in countries like the United Kingdom, where euthanasia is illegal, deactivating life-sustaining devices is considered ethically justifiable as long as it aligns with the goals of palliative care, although active euthanasia remains strictly prohibited.[16]

International Guidelines on Deactivation of Cardiac Devices

The recommendations outlined in cardiac pacing guidelines regarding the deactivation of devices in end-of-life situations. :

ESC GUIDDELINES 2021: These guidelines recommend proactive and early discussions about device deactivation, emphasizing shared decision-making to align treatment with the patient's goals. The goal is to ensure that the use of the device is consistent with the patient's preferences and does not unnecessarily prolong suffering.[17]

HRS/APHRS/LAHRS GUIDELINES 2023: The 2023 guidelines provide detailed recommendations for managing pacemaker devices in terminal patients, advising that deactivation be considered when a device no longer serves a therapeutic function and is merely prolonging the dying process.[7]

AHA STATEMENTS 2019: These statements affirm that physicians must respect patient autonomy and end-of-life decisions in accordance with palliative care principles. Deactivating devices is considered ethically appropriate when it aligns with the patient's wishes and care objectives.[18]

Practical Recommendations for Managing Device Deactivation

To address the complex ethical and cultural challenges surrounding the deactivation of cardiac devices, we suggest:

LONGITUDINAL CARDIAC STIMULATION PLAN:
The need for cardiac pacing varies throughout the lives of our patients. At the time of implantation, discussions with the patient should include the different life scenarios they may encounter, especially during the end-of-life period, where diseases or clinical conditions unrelated to the cardiac pathology that prompted the implantation of the device are causing a deterioration in quality of life, and the cardiac device is prolonging this situation. Exploring the patient's wishes and documenting them regarding device deactivation is an approach that upholds the principle of autonomy and relieves the family and healthcare professionals from making decisions that could have been anticipated.

MULTIDISCIPLINARY CONSENSUS:
When considering the deactivation of a cardiac pacing device, we must involve ethical committees, palliative care teams, and legal advisors in healthcare matters to ensure that the decision is ethically supported, culturally respectful, and free from legal implications that could conflict with the laws of the country where it is applied.

TRAINING OF HEALTHCARE STAFF:
Educating healthcare professionals in bioethics, raising awareness about culture and religion, and promoting knowledge of the current legal framework would enable the person responsible for the patient to recognize the situations we are discussing and coordinate the different professionals involved in making these complex decisions.[18,19]

Conclusion

The ethical challenges surrounding cardiac pacemaker therapies, from device selection to deactivation, are multifaceted. Transparent decision-making, adherence to ethical principles such as autonomy and justice, and respect for cultural and religious values are essential for providing equitable, patient-centered care. Ongoing education and institutional oversight are necessary to ensure that clinical decisions are guided by patient needs and well-being rather than external interests., Finally, end-of-life care requires a careful balance of legal, ethical, and cultural perspectives, ensuring that device deactivation aligns with both the patient's wishes and best medical practices.

Conflicts of interest statement:

The authors have no conflicts of interest to declare.

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