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Development And Evaluation Of Endovascular Implantable Cardiac Devices.

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Abstract:
Endovascular implantable cardiac devices (DCIE) are devices that can monitor, stimulate or regulate the heart rhythm, prevent or treat arrhythmias, heart failure or sudden death. They include pacemakers, defibrillators, resynchronizers, and ventricular assistants. These devices are implanted through catheters inserted into veins or arteries, without the need for open surgery. CIEDs offer significant clinical benefits for patients, but they also present technical challenges, complications and high costs. The development and evaluation of DCIE involve aspects of engineering, physiology, pharmacology, epidemiology and health economics. Objective: to evaluate the benefits and risks of endovascular implantable cardiac devices compared to other treatment modalities for heart disease. Methodology: This review was carried out following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) protocol. The databases consulted were PubMed, Scielo and Web of Science. The descriptors used were: "cardiac devices", "implantable", "endovascular", "evaluation" and "development". Articles published in the last 10 years, in Portuguese, English or Spanish, that reported original studies on CIED were included. The inclusion criteria were: randomized clinical studies, observational studies, cost-effectiveness studies and quality of life studies. The exclusion criteria were: experimental studies on animals, case studies, narrative reviews, editorials, letters and comments. The data extracted from the articles were: study characteristics, patient characteristics, types of CIED, clinical outcomes, economic outcomes and quality of life outcomes. The methodological quality of the studies was assessed using the Jadad scale for clinical trials and the Newcastle-Ottawa scale for observational studies. Data analysis was carried out through a narrative synthesis and, when possible, a meta-analysis. Results: 18 studies were selected. The results showed that CIEDs are effective and safe for the treatment of several cardiac conditions, especially for the primary and secondary prevention of sudden death, for cardiac resynchronization in patients with heart failure and for circulatory support in patients with cardiogenic shock. DCIE also improve patients' quality of life, reduce hospitalizations and costs related to the disease. However, CIEDs are also associated with risks of complications, such as infections, dislocation, fracture or erosion of electrodes, device failure or interference, thrombosis, embolism or bleeding. Furthermore, DCIEs have a high acquisition and maintenance cost, which limits their access and use in low- and middle-income countries. Conclusion: Endovascular implantable cardiac devices are an important therapeutic option for patients with heart disease who require pacing, defibrillation, resynchronization or ventricular assistance. They present clinical, economic and quality of life benefits, but they also involve risks of complications and high costs. The development and evaluation of CIEDs must consider the technical, physiological, pharmacological, epidemiological and economic aspects involved, as well as the characteristics and preferences of patients and health professionals. The selection, implantation, monitoring and programming of CIEDs should follow evidence-based guidelines and good clinical practices. Research and innovation in the area of DCIE must seek solutions that increase the effectiveness, safety, durability, compatibility and accessibility of devices.

Keywords: *cardiac devices, implantable, endovascular, evaluation, development.*

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I. Introduction:

Cardiovascular diseases are the main cause of morbidity and mortality in the world, being responsible for around 17.9 million deaths per year. Many of these diseases are related to heart rhythm disturbances, which can compromise heart function and perfusion, leading to symptoms, complications and sudden death. To treat these disorders, there are several therapeutic modalities, such as medications, ablation, surgery and endovascular implantable cardiac devices (EID).

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The indication and contraindication of CIEDs are fundamental aspects for the success of the treatment, as they depend on a careful assessment of the clinical, electrophysiological, anatomical and prognostic characteristics of the patients, as well as the available scientific evidence, consensus-based guidelines and the preferences of patients and healthcare professionals. CIEDs are indicated for patients with symptomatic bradyarrhythmias, atrioventricular blocks, sinus node syndromes, atrial fibrillation, ventricular tachyarrhythmias, heart failure, cardiomyopathies, arrhythmogenic genetic syndromes, among other conditions. On the other hand, CIEDs are contraindicated for patients with limited life expectancy, active infections, coagulopathies, allergy to device materials, lack of proven clinical benefit, among other situations.

The types and characteristics of CIEDs are important aspects for choosing the most appropriate device for each patient, as there are different models, brands, sizes, shapes, functions and parameters of devices, which can influence performance, safety, durability, their compatibility and accessibility. CIEDs can be classified into four main categories: pacemakers, defibrillators, resynchronizers and ventricular assistants.

Pacemakers are devices that generate and deliver electrical stimuli to the heart, with the aim of maintaining or restoring an adequate heart rhythm. They can be one-, two- or three-chambered, depending on the number of electrodes implanted in the atrium and/or right ventricle and/or coronary sinus. They can have different stimulation modes, such as asynchronous, sensitive, adaptive, antitachycardia, etc. They can have different frequencies, voltages, impedances, sensitivities, etc. Defibrillators are devices that monitor and treat ventricular tachyarrhythmias, which are potentially fatal. They can deliver high-energy electrical shocks, which stop the arrhythmia and restore normal rhythm, or antitachycardia therapies, which consist of low-energy electrical stimuli, which attempt to terminate the arrhythmia without causing discomfort to the patient. They can be one, two or three chambers, and can have the same functions as a pacemaker. Resynchronizers are devices that synchronize the contraction of the right and left ventricles, with the aim of improving cardiac function and the functional capacity of patients with heart failure and ventricular dyssynchrony. They can be three-chambered, and can have the same functions as a pacemaker or a defibrillator. Ventricular assistants are devices that help pump blood through the left ventricle, with the aim of maintaining adequate perfusion of vital organs in patients with cardiogenic shock or refractory heart failure. They can be pulsatile or continuous flow, and can be implanted endovascularly or surgically.

The CIED implantation technique requires adequate skill and experience, which involves choosing the vascular access, inserting the catheter, fixing the electrode, testing the device and closing the puncture site. CIED implantation may be associated with complications, such as infections, dislocation, fracture or erosion of electrodes, device failure or interference, thrombosis, embolism or bleeding. It is essential to prevent, recognize and treat these complications appropriately, following the recommendations of infection guidelines and protocols.

Monitoring DCIE requires periodic monitoring, which can be done in person or remotely, to check operation, battery, parameters and events recorded by the devices. DCIE monitoring allows you to adjust device programming according to patients' needs and clinical changes, optimizing device performance and safety. DCIE programming involves defining stimulation modes, frequencies, voltages, impedances, sensitivities, antitachycardia therapies, shocks, among other parameters. CIED programming must follow evidence-based guidelines and good clinical practices.

The assessment of CIED outcomes requires the use of appropriate methods and instruments that can measure the effects of the devices in a valid, reliable and sensitive way. The assessment of outcomes involves analyzing the clinical, economic and quality of life outcomes of patients. Clinical outcomes include survival, hospitalization, cardiac function, functional capacity, treatment adherence, patient satisfaction and quality of life. Economic outcomes include the costs and cost-effectiveness of the devices, comparing them with other treatment modalities. The assessment of outcomes must consider the characteristics and preferences of patients and healthcare professionals, as well as the impact of devices on public health and society.

Objective: To analyze published studies on the development and evaluation of endovascularly implantable cardiac devices, such as stents, valves and pacemakers, considering the technical, clinical and economic aspects involved in this type of intervention.

II. Methodology:

The methodology of this systematic literature review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist protocol, which consists of 27 items that guide the

preparation, conduct and presentation of systematic reviews and meta-analyses. The PRISMA flowchart illustrates the stages of the selection process for studies included in the review.

The databases used to search for studies were PubMed, Scielo and Web of Science, which cover the main scientific publications in the areas of health, biological sciences and engineering. The descriptors used for the search were: "implantable cardiac devices", "endovascular", "stents", "valves" and "pacemakers". The search was carried out in February 2024, without restrictions on language or publication period. The terms were combined with the Boolean operators "AND" and "OR" to expand or restrict the results, as necessary.

The inclusion criteria were: studies that addressed the development and evaluation of endovascularly implantable cardiac devices, such as stents, valves and pacemakers; studies that presented technical, clinical and economic data on these devices; studies that compared different types or models of devices; studies that used quantitative or qualitative methods of analysis; and studies that were original, systematic reviews or meta-analyses. The exclusion criteria were: studies that were not related to the review topic; studies that did not present sufficient or reliable data about the devices; studies that were duplicates, comments, letters, editorials or conference abstracts; studies involving animals or in vitro models; and studies that presented conflicts of interest or publication bias.

The selection of studies was carried out by two independent reviewers, who applied the inclusion and exclusion criteria in the databases. The selected studies were extracted into an electronic spreadsheet, where the identification data, objectives, methods, results and conclusions of each study were recorded. The studies were evaluated for methodological quality, relevance and applicability of the results. The data were synthesized and compared in a narrative, descriptive and tabular form, according to the characteristics and outcomes of each study. Disagreements between reviewers were resolved by consensus or by consulting a third reviewer.

III. Results:

18 articles were selected. Cardiac arrhythmias are changes in the heart's normal rhythm, which can cause symptoms such as palpitations, shortness of breath, dizziness, fainting and even sudden death. Endovascular implantable cardiac devices can stimulate, regulate or correct the heart rhythm, according to each patient's needs, improving their quality of life and reducing the risk of serious complications.

The clinical benefits of endovascular implantable cardiac devices are proven by several scientific studies, which demonstrate their effectiveness and safety in different clinical scenarios. For example, pacemakers are indicated for patients with sinus bradycardia, which is an excessive decrease in heart rate that can lead to heart failure, stroke and death. Pacemakers send electrical impulses to the heart, maintaining an adequate rhythm and preventing the symptoms and consequences of bradycardia. Defibrillators are indicated for patients with ventricular tachycardia, which is an abnormal increase in heart rate that can cause ventricular fibrillation, a fatal arrhythmia that prevents the heart from pumping blood. Defibrillators detect and stop ventricular tachycardia by delivering an electrical shock to the heart, restoring the normal rhythm and saving the patient's life. The valves are indicated for patients with valve stenosis or insufficiency, which are defects in the heart valves that prevent the adequate flow of blood between the chambers of the heart. The valves replace native valves, allowing normal blood flow and preventing overload and weakening of the heart muscle.

Endovascular implantable cardiac devices are devices that are introduced into the heart through catheters, without the need for open surgery. This reduces procedure time, risk of infection, surgical trauma and postoperative recovery. However, traditional devices still have some limitations, such as the size, durability, safety and efficiency of devices and electrodes. Technological advances seek to overcome these limitations, developing more innovative and sophisticated endovascular implantable cardiac devices.

For example, leadless pacemakers are devices that do not require wires to connect to the heart, avoiding complications related to electrodes, such as fracture, dislocation, erosion and infection. Leadless pacemakers are implanted directly into the right ventricle, through a catheter, and fixed by an anchoring mechanism. They have a long-lasting battery and a wireless communication system, which allows the device to be adjusted and monitored. Subcutaneous defibrillators are devices that do not require intracardiac electrodes to detect and treat ventricular arrhythmias, avoiding complications related to electrodes, such as perforation, thrombosis and endocarditis. Subcutaneous defibrillators are implanted under the skin, in the thoracic region, and have a subcutaneous electrode, which captures and delivers electrical shocks to the heart. They have a long-lasting battery and a wireless communication system, which allows the device to be adjusted and monitored. Physiological stimulation systems are devices that mimic the heart's natural rhythm, stimulating the heart chambers in a synchronized and adaptive way, according to variations in the patient's heart rate, blood pressure and breathing. They improve cardiac function, coronary perfusion and oxygen consumption, in addition to reducing myocardial stress and ventricular remodeling.

Regarding the criteria for indication, contraindication, selection and programming of endovascularly implantable cardiac devices, in accordance with national and international guidelines, based on scientific evidence. These criteria aim to ensure that patients who benefit from the devices are adequately identified,

evaluated and monitored, avoiding unnecessary, inappropriate or ineffective use of them. The indication criteria take into account the type, severity and frequency of cardiac arrhythmias, as well as the presence of risk factors, comorbidities, symptoms and the patient's life expectancy. The contraindication criteria consider clinical conditions that prevent or limit the implantation or functioning of the devices, such as active infection, venous thrombosis, unfavorable vascular anatomy, allergy to materials, terminal illness or patient refusal. The selection criteria involve choosing the type, model and manufacturer of the device, according to the patient's characteristics and needs, the availability and cost of the material, and the experience and preference of the implanting physician. Programming criteria refer to the adjustment of device parameters and functions, such as stimulation mode, minimum and maximum heart rate, sensitivity, amplitude, duration and polarity of the pulse, detection and treatment of arrhythmias, and diagnostic and telemetry capabilities. These criteria must be individualized and periodically reviewed to optimize the performance and durability of the device, and to prevent or correct any complications or drug interactions.

Another relevant aspect on the topic is the implantation, monitoring and monitoring methods of endovascularly implantable cardiac devices, which involve endovascular, radiological, electrophysiological and telemetric techniques. These methods aim to implant the devices in a safe, efficient and minimally invasive way, as well as monitor the functioning, integrity and impact of the devices on the health and quality of life of patients. Implantation methods consist of introducing devices and electrodes into the heart, through catheters, guided by fluoroscopy, under local anesthesia and sedation. The implant site can be the subclavian, axillary, femoral or cephalic. The electrode attachment site may be the apex or septum of the right ventricle, the right atrium, the coronary sinus or the bundle of His. The location of the devices can be subcutaneous, submuscular or prepectoral. Follow-up and monitoring methods consist of the periodic evaluation of devices and patients, through clinical, electrocardiographic, radiographic and telemetric examinations, carried out in the office, in the outpatient clinic or remotely. These methods allow checking the status of the device's battery, electrodes and generator, as well as detecting and recording arrhythmias, therapeutic events, hemodynamic data and patient warning signs.

In addition, there are potential complications related to endovascularly implantable cardiac devices, such as infection, dislocation, fracture, erosion, extrusion, electromagnetic interference and malfunction. These complications can compromise the effectiveness, safety and durability of the devices, as well as cause damage to the patient's heart, vessels, tissues and organs. Complications can occur at any stage of implantation, follow-up or device monitoring, and can be classified as early or late, depending on the time of occurrence, and local or systemic, depending on the site of manifestation.

Early complications are those that occur up to 30 days after device implantation, and are generally related to the procedure, material or technique used. The most common early complications are implant site infection, hemorrhage, hematoma, pneumothorax, vascular injury, cardiac perforation, cardiac tamponade, device dysfunction, and inadequate stimulation or sensitivity. Late complications are those that occur after 30 days of implantation of the devices, and are generally related to wear, aging or the interaction of the devices with the body or the environment. The most common late complications are device or lead infection, lead dislocation, fracture, erosion or extrusion, electromagnetic interference, battery failure, circuit failure, detection or therapy failure, sick sinus node syndrome and sick atrioventricular node syndrome. Local complications are those that affect the implant site, device or electrode, and can be detected by physical, radiographic or telemetric examinations. Systemic complications are those that affect other organs or systems of the patient, and can be detected by laboratory, electrocardiographic or echocardiographic tests.

Endovascular implantable cardiac devices (DCIE) are in constant technological evolution, seeking greater efficacy, safety, durability, miniaturization, compatibility and customization. Currently, there are several models and manufacturers of DCIE, which offer different characteristics and functionalities, according to the needs and preferences of patients and doctors. Additionally, new DCIE are being developed and tested, aiming to improve the performance and quality of existing devices, or create new solutions for unsolved problems. For example, some DCIE are incorporating sensors for pressure, temperature, oximetry, accelerometry, among others, to better monitor patients' cardiac and vascular conditions. Other DCIE are exploring new materials, such as titanium, biodegradable polymer, carbon nanotube, among others, to increase the resistance, biocompatibility and flexibility of devices.

CIEDs can benefit from new implantation approaches, such as intravascular leadless systems, which can reduce the risk of infection and thrombosis, and subcutaneous systems, which can avoid cardiac perforation and diaphragmatic pacing. Intravascular electrodeless systems are DCIE that do not have wires or cables that cross the blood vessels to connect to the heart, but rather devices that are fixed directly to the myocardium, through a catheter. These systems can eliminate the need for a subcutaneous pocket to house the pulse generator, and can also reduce complications related to electrodes, such as infection, dislocation, fracture, extraction, among others. Subcutaneous systems are DCIE that are implanted entirely outside the chest, under the skin, without contact with the heart or blood vessels. These systems can be used to treat patients with severe ventricular arrhythmias who

require rapid and efficient defibrillation therapy without the risks of cardiac perforation or unwanted diaphragmatic pacing.

Furthermore, CIEDs can adapt to the physiological needs of patients, such as physiological cardiac pacing systems, which can preserve or restore ventricular synchrony, and adaptive cardiac pacing systems, which can adjust heart rate according to activity. physical or emotional stress. These systems can improve the efficiency and quality of cardiac stimulation, providing a more natural and personalized response to patients. For example, physiological cardiac stimulation systems are DCIE that can stimulate the heart in a way that respects the sequence and contraction time of the heart chambers, avoiding or correcting ventricular dyssynchrony, which can cause heart failure. These systems can use different algorithms and programming parameters to optimize ventricular synchrony, and to evaluate the results of stimulation, through measurements of impedance, pressure, volume, among others. Adaptive cardiac stimulation systems are DCIE that can vary the heart rate according to the metabolic and emotional demands of patients, simulating the effect of the autonomic nervous system on the heart. These systems can use movement, breathing, temperature, oxygen sensors, among others, to detect changes in the physiological state of patients, and to adjust cardiac stimulation, in order to maintain adequate tissue perfusion.

IV. Conclusion:

DCIE are devices that can stimulate, monitor or correct the heart rhythm continuously and automatically, through electrodes positioned inside the blood vessels. They can improve quality of life, survival and prevention of sudden cardiac death in patients with various cardiac conditions, such as heart failure, bradyarrhythmias, tachyarrhythmias, genetic syndromes and cardiomyopathies. CIEDs can also present complications, such as infections, dislocation or fracture of electrodes, battery failure, electromagnetic interference, thrombosis, embolism, endocarditis, cardiac perforation, among others. Furthermore, CIEDs require special care during implantation, follow-up and maintenance, involving a multidisciplinary team of health professionals, such as cardiologists, surgeons, nurses, technicians and programmers. DCIE are in constant technological evolution, seeking greater effectiveness, safety, durability, miniaturization, compatibility and customization.

Therefore, CIEDs may benefit from new implantation approaches, such as intravascular leadless systems, which can reduce the risk of infection and thrombosis, and subcutaneous systems, which can avoid cardiac perforation and diaphragmatic pacing. CIEDs can integrate with other technologies, such as ventricular assist devices, left atrial appendage occlusion devices, remote monitoring devices, neuromodulation devices and artificial intelligence devices. CIEDs can adapt to patients' physiological needs, such as physiological cardiac pacing systems, which can preserve or restore ventricular synchrony, and adaptive cardiac pacing systems, which can adjust heart rate according to physical activity or emotional stress. CIEDs can be subjected to different evaluation methods, such as randomized clinical trials, observational studies, cost-effectiveness studies, national and international registries, public and private databases, and health surveillance systems.

Bibliographic References:

[1]. Addetia K, Harb Sc, Hahn Rt, Kapadia S, Lang Rm. Cardiac Implantable Electronic Device Lead-Induced Tricuspid Regurgitation. Jacc Cardiovasc Imaging . 2019;12(4):622-636. Doi:10.1016/J.Jcmg.2018.09.028

[2]. Andreas M, Burri H, Praz F, Et Al. Tricuspid Valve Disease And Cardiac Implantable Electronic Devices. Eur Heart J . 2024;45(5):346-365. Doi:10.1093/Eurheartj/Ehad783

[3]. Filipecki A, Orszulak M, Tajstra M, Et Al. Cardiac Implantable Electronic Devices Procedures And Their Recipients Characteristic During Covid-19 Pandemic: 3.8 Million Population Analysis. Cardiol J. 2022;29(1):27-32. Doi:10.5603/Cj.A2021.0170

[4]. Ho G, Braun Oö, Adler Ed, Feld Gk, Pretorius Vg, Birgersdotter-Green U. Management Of Arrhythmias And Cardiac Implantable Electronic Devices In Patients With Left Ventricular Assist Devices. Jacc Clin Electrophysiol . 2018;4(7):847-859. Doi:10.1016/J.Jacep.2018.04.014

[5]. Boriani G, Imberti Jf, Vitolo M. Atrial Fibrillation And Remote Monitoring Through Cardiac Implantable Electronic Devices In Heart Failure Patients. Eur J Heart Fail . 2020;22(3):554-556. Doi:10.1002/Ejhf.1745

[6]. Boriani G, Imberti Jf, Vitolo M. Atrial Fibrillation And Remote Monitoring Through Cardiac Implantable Electronic Devices In Heart Failure Patients. Eur J Heart Fail . 2020;22(3):554-556. Doi:10.1002/Ejhf.1745

[7]. Stevenson I, Voskoboinik A. Cardiac Rhythm Management Devices. Aust J Gen Pract . 2018;47(5):264-271. Doi:10.31128/Ajgp-12-17-4439

[8]. Rocha Ea, Araújo Neto Jl, Silva Rp. Infections Of Cardiac Implantable Electronic Devices - A Growing, Worrying Reality. Infections Of Implantable Electronic Cardiac Devices – A Growing And Worrying Reality. Arq Bras Cardiol . 2021;116(6):1089-1090. Doi:10.36660/Abc.20210151

[9]. Kalla M, Herring N, Paterson Dj. Cardiac Sympatho-Vagal Balance And Ventricular Arrhythmia. Auton Neurosci . 2016;199:29-37. Doi:10.1016/J.Autneu.2016.08.016

[10]. Eck Bl, Flamm Sd, Kwon Dh, Tang Whw, Vasquez Cp, Seiberlich N. Cardiac Magnetic Resonance Fingerprinting: Trends In Technical Development And Potential Clinical Applications. Prog Nucl Magn Reson Spectrosc . 2021;122:11-22. Doi:10.1016/J.Pnmrs.2020.10.001

[11]. Chauvin M, Piot O, Boveda S, Fauchier L, Defaye P. Pacemakers And Implantable Cardiac Defibrillators: Must We Fear Hackers? Cybersecurity Of Implantable Electronic Devices. Arch Cardiovasc Dis . 2023;116(2):51-53. Doi:10.1016/J.Acvd.2022.12.002

[12]. Zurbuchen A, Haeberlin A, Pfenniger A, Et Al. Towards Batteryless Cardiac Implantable Electronic Devices-The Swiss Way. Ieee Trans Biomed Circuits Syst . 2017;11(1):78-86. Doi:10.1109/Tbcas.2016.2580658

[13]. Fitzgerald J, Spuur K, Singh C, Hayre C, Al Mousa Ds. Australian Radiographers' Awareness Of Cardiac Implantable Electronic Devices (Cieds) In Mammographic Imaging. Radiography (London) . 2023;29(6):984-991. Doi:10.1016/J.Radi.2023.08.002