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LEADLESS PACEMAKER IN PATIENTS WITH CHRONIC KIDNEY DISEASE AND HEMODIALYSIS: A SCOPING REVIEW

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ABSTRACT

Introduction: Chronic kidney disease (CKD) is a global health condition affecting approximately 10% of the adult population and is associated with high morbidity and mortality. Patients with CKD are at an increased risk of developing cardiovascular diseases and arrhythmias, often requiring pacemaker implantation. The leadless pacemaker has been studied in various populations and offers advantages over traditional devices. However, the efficacy and safety of using leadless pacemakers in this population remain uncertain. Objective: This study aims to map the existing literature on the use of leadless pacemakers in patients with chronic kidney disease (CKD) undergoing hemodialysis, addressing aspects of efficacy, safety, and factors related to their adoption in clinical practice. **Methodology:** A scoping review was conducted following the PRISMA protocol. Searches were performed in the PubMed, Embase, Scopus, Cochrane Library, and CINAHL databases, covering studies that addressed leadless pacemakers, chronic kidney disease, and hemodialysis. Articles in English, Portuguese, and Spanish were included, with no time restrictions. **Results:** A total of 230 articles were found during the initial search. After the exclusion of duplicates, 165 studies remained and were analyzed based on their titles and abstracts. After the analysis, 25 articles were considered eligible for full-text reading and the application of eligibility criteria. After reading, 15 studies were included in this review. The types of studies found were: 7 (46.6%) case reports, 6 (40%) observational studies, 1 (6.6%) editorial comment, and 1 (6.6%) review article. Among the studies, 7 (46.6%) concluded that the leadless pacemaker is associated with improved clinical outcomes when compared to the transvenous pacemaker in patients with chronic kidney disease and undergoing hemodialysis due to the failure of vascular accesses and the higher risk of infection in this population. One (6.6%) study demonstrated an association between the leadless pacemaker and a higher rate of perioperative and early post-implantation complications when compared to the conventional pacemaker. **Conclusion:** The results of this scoping review suggest that the leadless pacemaker is an effective alternative with a higher safety profile in the medium and long term compared to conventional devices in patients with chronic kidney disease and undergoing hemodialysis. However, the literature remains conflicting regarding safety during the perioperative and early post-implantation periods, and further studies are needed for a better understanding of the topic.

Keywords: Leadless Pacemaker, Chronic kidney disease, Hemodialysis, Effectiveness, Security.

PRESENTATION

Chronic kidney disease (CKD) is a global health condition affecting approximately 10% of the adult population and is associated with high morbidity and mortality.[1] CKD is characterized by the progressive decline in renal function, which can lead to renal failure, requiring treatment through hemodialysis.[2] Furthermore, patients with CKD are at increased risk of developing cardiovascular diseases and cardiac arrhythmias.[3]

Pacemaker therapy is a proven treatment for patients with arrhythmias.[4] The conventional pacemaker is an electronic device capable of stimulating the heart to contract in a synchronized manner, ensuring adequate blood pumping by introducing cardiac electrodes via intravenous access, powered by an implanted generator in the chest.[5] It is a functional device, widely used in clinical practice, but there are concerns regarding potential complications related to its implantation.[6]

In this regard, the leadless pacemaker was developed with improvements in battery design, reduction in component size, and elimination of the need for intravenous electrodes to provide the rhythm.[7] This new device has been studied in various populations and presents advantages over traditional devices, such as a lower risk of infection, shorter implantation time, and reduced aesthetic impact.[8] Furthermore, the leadless technology may offer specific benefits for patients with chronic kidney disease (CKD) undergoing hemodialysis, as venous access is preserved and the risk of infection is reduced.[9]

However, the efficacy and safety of using leadless pacemakers in this population remain uncertain, as well as the factors that may influence their adoption in clinical practice.

Therefore, the present study aims to map the existing literature on the use of leadless pacemakers in patients with chronic kidney disease (CKD) on hemodialysis, addressing aspects of efficacy, safety, and factors related to their adoption in clinical practice.

METHODOLOGY

A scoping review was conducted following the steps suggested by Arksey and O'Malley[10] and Levac, Colquhoun, and O'Brien[11], with adaptations as necessary to meet the specific objectives of this study. The steps included: identification of the research question, identification of relevant studies, selection of studies, data extraction, and analysis and synthesis of the results.

2.1. Search Strategy

2.1.1. Databases Consulted

The systematic search was conducted in the following databases: MEDLINE (via PubMed), Embase, Scopus, Cochrane Library, and CINAHL. Additionally, manual searches were performed in the reference lists of the selected studies and related systematic reviews to identify any additional relevant studies.

2.1.2. Search terms and combinations

The search terms were selected based on the main concepts of the research question, including leadless pacemaker, chronic kidney disease, and hemodialysis. Specific terms and

synonyms were used, as well as MeSH (Medical Subject Headings) and Emtree terms, as appropriate for each database. The search strategies were adapted for each database and combined using the Boolean operators "AND" and "OR."

2.2. Inclusion and Exclusion Criteria

2.2.1. Study Type

Observational studies (cohort, case-control, and cross-sectional), controlled clinical trials, case reports, and case series that addressed the use of leadless pacemakers in patients with CKD and undergoing hemodialysis were included. Systematic reviews, meta-analyses, and qualitative studies were excluded, but their reference lists were checked to identify additional studies.

2.2.2. Target Population

Studies involving adult patients (≥18 years) with chronic kidney disease undergoing hemodialysis who require pacemaker therapy were included.

2.2.3. Intervention

The intervention of interest is the implantation of a leadless pacemaker for the treatment of cardiac arrhythmias in patients with CKD and hemodialysis.

2.2.4. Comparison

Comparative studies should compare leadless pacemakers with conventional pacemakers with leads or other therapies for cardiac arrhythmias.

2.2.5. Outcomes

The outcomes of interest included, but were not limited to: effectiveness in maintaining regular heart rhythm, adverse effects, complications, quality of life and patient satisfaction, and factors influencing the use of leadless pacemakers in this population.

2.3. Study Selection Process

2.3.1. Initial Screening of Titles and Abstracts

Two reviewers independently performed the initial screening of the titles and abstracts of the studies identified through the search strategy. Potentially relevant studies were selected for full-text analysis. Disagreements between reviewers were resolved by consensus or, when necessary, with the participation of a third reviewer.

2.3.2. Full-Text Assessment

The full texts of the studies selected in the previous step were independently evaluated by two reviewers based on the pre-established inclusion and exclusion criteria. Disagreements were resolved by consensus or with the participation of a third reviewer.

2.4. Data Extraction

A standardized data extraction form was developed and tested by the reviewers before the data extraction process began. The following data were extracted from the selected studies: author(s), year of publication, study location, study design, sample size, population characteristics, details of the intervention and comparison, outcomes evaluated, and results.

2.5. Analysis and Synthesis of Results

The results of the included studies were synthesized in a narrative review, grouped according to the outcomes of interest and organized into relevant themes related to the research question. Tables and graphs were presented, as necessary, to facilitate the understanding and interpretation of the results.

2.6. Identification of Gaps and Recommendations for Future Research

Based on the analysis and synthesis of the results, gaps in the literature and areas where further research is needed were identified. These gaps included issues related to the efficacy and safety of leadless pacemakers in specific subgroups of patients with CKD and hemodialysis, long-term outcomes, or issues related to the implementation and acceptance of this technology by healthcare professionals and patients.

RESULTS AND DISCUSSION

A total of 230 articles were found during the initial search. After duplicates were removed, 165 studies remained and were analyzed based on their titles and abstracts. After this analysis, 25 articles were deemed eligible for full-text review and application of eligibility criteria. Following the full-text review, 15 studies were included in this review. The study types identified were: 7 (46.6%) case reports, 6 (40%) observational studies, 1 (6.6%) editorial comment, and 1 (6.6%) review article.

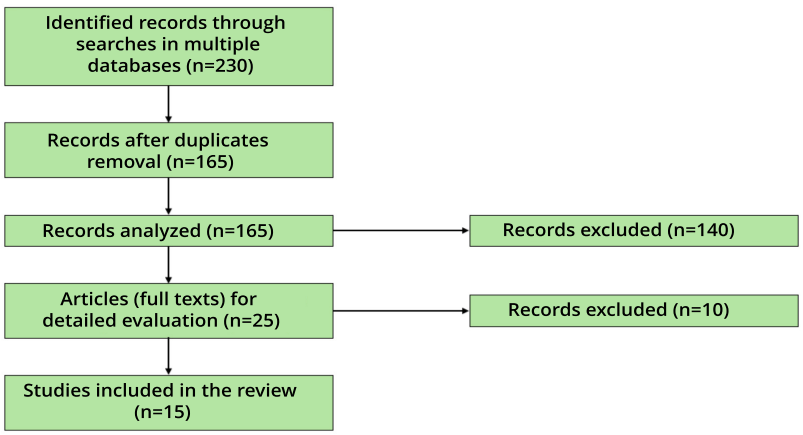

Figure 1. Study screening flowchart according to PRISMA-ScR.

Source: created by the authors (2024).

The technology of leadless pacemakers has emerged as a promising alternative for patients with CKD, particularly those undergoing hemodialysis. This review highlights both the benefits and challenges of this approach in a highly vulnerable population.

Leadless pacemakers offer several significant advantages over traditional transvenous pacemakers, particularly for patients with CKD undergoing hemodialysis. One of the main benefits is the preservation of vascular access, which is crucial for hemodialysis patients who often require central venous access for dialysis therapy. Afendoulis et al.[12] highlight the effectiveness of implanting a leadless pacemaker in a patient with no vascular access, emphasizing the ability of this technology to avoid strain on the central vessels, as detailed by Maradey, Jao, and Vachharajani.[13]

Moreover, leadless pacemakers tend to have a reduced profile of infectious complications. The study by Alshami et al.[14] showed that patients with end-stage renal disease using leadless pacemakers have a lower rate of infectious complications compared to those using traditional single-chamber pacemakers. This benefit is crucial for patients with chronic kidney disease, who are more prone to infections due to vascular access and immunosuppression.

However, despite the advancements, there are challenges associated with leadless pacemakers. Issues such as intermittent loss of capture and related complications, such as pericardial effusion, have been reported. Chong, Mar, and Hussein[15] reported episodes of capture loss in a patient undergoing dialysis therapy, while Hazwani et al.[16] documented pericardial effusion after leadless pacemaker implantation. These complications highlight the need for rigorous monitoring and appropriate postoperative management.

In addition, the study by Khan et al.[17] suggests that, despite the advantages, the implantation of leadless pacemakers in patients with CKD may be associated with procedure-related complications and adverse hospital outcomes. These findings highlight the need for well-defined implantation and follow-up protocols to mitigate risks.

Another aspect to consider is the interaction between leadless pacemakers and other technologies. Frazer et al.[18] investigated the interactions between leadless pacemakers, especially in patients who may have multiple implanted electronic devices, such as defibrillators or other leadless pacemakers. The study highlighted that the presence of more than one leadless device may lead to electromagnetic interference and challenges in synchronization between devices. These interactions can result in issues such as pacemaker malfunction, changes in capture, and even signal overlap, which can compromise the clinical effectiveness of the devices and patient safety. Therefore, a deeper understanding of these interactions and the implementation of strategies to minimize risks are essential, ensuring safe and effective integration of leadless pacemakers with other medical technologies.

This study has limitations. First, many of the included studies have a small number of patients, which may limit the generalization of the findings. Additionally, most of the included studies are observational in nature, which prevents a more granular assessment that establishes causal relationships. These limitations highlight the need for future research on the topic, with large-scale randomized clinical trials and extended follow-up periods, which would allow for a more accurate determination of the effectiveness and safety outcomes associated with the use of leadless pacemakers in patients with CKD.

Table 1 - Characteristics of the Articles

Authors	Country	Study type	Participants	Main objective	Key results	Conclusion
Alshami et al., 2023 [14]	USA	Retrospective	Not specified	Compare the incidence of infectious complications between leadless pacemakers and single-chamber pacemakers in patients with chronic kidney disease.	Leadless pacemakers showed a lower rate of uma menor taxa de infectious complications infecciosas em compared to single-chamber pacemakers.	Leadless pacemakers are preferable for reducing infections in patients with end-stage renal disease.
Boczar et al., 2024 [19]	Poland	Descriptive	1	Evaluate the effectiveness of implanting a leadless pacemaker with active fixation after the extraction of an infected device.	The implantation with active fixation was successfully performed after the extraction of an infected device, with no additional complications occurring.	Electrode-less pacemakers with active fixation can be an effective solution after device infections.
Chong, Mar e Husseim 2021 [15]	Not informed	Descriptive	1	Report intermittent capture loss in a hemodialysis patient after the implantation of a Micra pacemaker.	Intermittent capture loss was observed with the Micra pacemaker.	It is essential to have rigorous monitoring to manage capture loss in patients on hemodialysis.
Da Costa et al., 2017 [20]	Not informed	Review	Not specified	Discuss the advantages of leadless pacemakers as an alternative to transvenous devices.	Leadless pacemakers provide a valuable alternative to transvenous devices, especially in patients with venous access restrictions.	Leadless pacemakers are a promising alternative for patients with vascular access difficulties.

Authors	Country	Study type	Participants	Main objetive	Key results	Conclusion
Frazer, et al., 2023[18]	Not informed	Descriptive	Not specified	Investigate the interaction between leadless pacemakers and other implanted electronic devices.	It was identified that the presence of multiple leadless pacemakers can lead to electromagnetic interference and synchronization issues.	It is crucial to monitor and manage the interactions between leadless devices to prevent interference and malfunctions.
Hazwani et al., 2024[16]	Not informed	Descriptive	1	Report the occurrence of pericardial effusion following the implantation of a Micra pacemaker with temporary pacing electrodes.	Pericardial effusion was observed following the implantation of the Micra pacemaker, with the presence of temporary pacing electrodes.	Careful management is necessary to avoid complications such as pericardial effusion following pacemaker implantation.

Authors	Country	Study type	Participants	Main objetive	Key results	Conclusion
Hsu et al., 2020[21]	USA	Analytical	Not specified	Evaluate the feasibility of contralateral dialysis access in patients with leadless devices compared to transvenous devices.	Leadless pacemakers allow contralateral dialysis access, preserving the integrity of central vessels, which is not possible with transvenous devices.	Leadless pacemakers facilitate the preservation of vascular access for hemodialysis.
Khan et al., 2024[17]	USA	Analytical	Not specified	Study the complications and hospital outcomes associated with the implantation of leadless pacemakers in patients with chronic kidney disease.	Procedural complications and adverse outcomes were observed in the implantation of leadless pacemakers in patients with chronic kidney disease.	Implantation protocols should be carefully defined to minimize risks in patients with chronic kidney disease.

Authors	Country	Study type	Participants	Main objetive	Key results	Conclusion
Kusztal e Nowak, 2018[22]	Not informed	Descriptive	Not specified	Examine strategies to overcome vascular access issues in patients with implanted cardiac devices.	It was recommended to adopt strategies to ensure adequate vascular access for the implantation of cardiac devices.	Effective strategies are needed to address vascular access issues in patients with implantable devices.
Longacre et al., 2023[23]	USA	Comparative	Not specified	Compare the results between the Micra AV leadless pacemaker and dual-chamber transvenous pacemakers in patients with chronic kidney disease.	The Micra AV leadless pacemaker showed comparable or superior results to dual-chamber transvenous pacemakers in patients with chronic kidney disease.	Leadless pacemakers are an effective option compared to transvenous devices in patients with chronic kidney disease.

AV: Atrioventricular; USA: United States of America.
Source: created by the authors (2024).

CONCLUSION

This scoping review highlights that leadless pacemakers have emerged as an effective and safe alternative for managing cardiac conduction disorders in patients with chronic kidney disease (CKD) on hemodialysis, especially when compared to conventional devices. Their benefits include the preservation of vascular access and a significant reduction in infectious complications, which are crucial aspects for this population. However, the literature reveals ongoing concerns, such as intermittent capture loss and complications like pericardial effusion, which require rigorous monitoring and specific management strategies. Furthermore, the potential interaction with other electronic devices underscores the need for a better understanding and evaluation of possible interference. While leadless pacemakers offer notable advantages, existing gaps regarding safety in the peri- and early postoperative period highlight the importance of further studies to improve the application of these devices in CKD patients. These future investigations are essential to solidify the safety and efficacy of leadless pacemakers in this specific patient group.

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