USE OF DAPAGLIFLOZIN (FORXIGA) IN THE TREATMENT OF HEART FAILURE: CURRENT EVIDENCE AND CLINICAL EFFICACY

USO DA DAPAGLIFOZINA (FORXIGA) NO TRATAMENTO DA INSUFICIÊNCIA CARDÍACA: EVIDÊNCIAS ATUAIS E EFICÁCIA CLÍNICA

USO DE DAPAGLIFLOZINA (FORXIGA) EN EL TRATAMIENTO DE LA INSUFICIENCIA CARDÍACA: EVIDENCIA ACTUAL Y EFICACIA CLÍNICA

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ABSTRACT

Heart failure remains one of the leading causes of cardiovascular morbidity and mortality worldwide, being associated with high hospitalization rates, progressive functional

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impairment, and significant socioeconomic burden. In this context, dapagliflozin, a sodium-glucose cotransporter-2 (SGLT2) inhibitor, has emerged as an important therapeutic strategy in the contemporary management of heart failure, demonstrating cardiovascular and cardiorenal benefits that extend beyond glycemic control. This study aimed to analyze current scientific evidence regarding the clinical efficacy of dapagliflozin in the treatment of heart failure, emphasizing its effects on cardiovascular mortality, hospitalizations, quality of life, functional capacity, and renal protection. This is an integrative literature review with a qualitative and descriptive approach, conducted through searches in PubMed, SciELO, and ScienceDirect databases using descriptors related to dapagliflozin, heart failure, and cardiovascular outcomes. Studies published between 2019 and 2023 were included, comprising randomized clinical trials, systematic reviews, meta-analyses, and international guidelines. The main findings demonstrated significant reductions in heart failure hospitalizations, cardiovascular mortality, and episodes of clinical worsening, in addition to improvements in quality of life and preservation of renal function across different phenotypes of the disease. The DAPA-HF and DELIVER trials were particularly highlighted as milestones in consolidating SGLT2 inhibitors as a fundamental therapeutic component in heart failure management. It is concluded that dapagliflozin represents an important advancement in the treatment of heart failure, promoting consistent clinical benefits and contributing to a more integrated and multidimensional therapeutic approach aimed at optimizing cardiovascular and cardiorenal outcomes.

Keywords: Heart Failure. Dapagliflozin. Forxiga. SGLT2 Inhibitors. Cardiovascular Outcomes. Cardiorenal Protection.

RESUMO

A insuficiência cardíaca permanece como uma das principais causas de morbimortalidade cardiovascular no mundo, associando-se a elevadas taxas de hospitalização, piora funcional progressiva e importante impacto socioeconômico. Nesse contexto, a dapagliflozina, inibidor do cotransportador sódio-glicose tipo 2 (SGLT2), emergiu como estratégia terapêutica relevante no manejo contemporâneo da insuficiência cardíaca, demonstrando benefícios cardiovasculares e cardiorrenais que extrapolam o controle glicêmico. O presente estudo teve como objetivo analisar as evidências científicas atuais acerca da eficácia clínica da dapagliflozina no tratamento da insuficiência cardíaca, enfatizando seus efeitos sobre mortalidade cardiovascular, hospitalizações, qualidade de vida, capacidade funcional e proteção renal. Trata-se de uma revisão integrativa da literatura, de abordagem qualitativa e caráter descritivo, realizada por meio de buscas nas bases PubMed, SciELO e ScienceDirect, utilizando descritores relacionados à dapagliflozina, insuficiência cardíaca e desfechos cardiovasculares. Foram incluídos estudos publicados entre 2019 e 2023, incluindo ensaios clínicos randomizados, revisões sistemáticas, meta-análises e diretrizes internacionais. Os principais achados evidenciaram redução significativa de hospitalizações por insuficiência cardíaca, mortalidade cardiovascular e episódios de descompensação clínica, além de melhora da qualidade de vida e preservação da função renal em diferentes fenótipos da doença. Destacaram-se especialmente os estudos DAPA-HF e DELIVER, considerados marcos na consolidação dos inibidores de SGLT2 como componente terapêutico fundamental na insuficiência cardíaca. Conclui-se que a dapagliflozina representa avanço importante no tratamento da insuficiência cardíaca, promovendo benefícios clínicos consistentes e contribuindo para uma abordagem terapêutica mais integrada, multidimensional e voltada à otimização dos desfechos cardiovasculares e cardiorrenais.

Palavras-chave: Insuficiência Cardíaca. Dapagliflozina. Forxiga. Inibidores de SGLT2. Desfechos Cardiovasculares. Proteção Cardiorrenal.

RESUMEN

La insuficiencia cardíaca sigue siendo una de las principales causas de morbilidad y mortalidad cardiovascular a nivel mundial, asociada a altas tasas de hospitalización, deterioro funcional progresivo e impacto socioeconómico significativo. En este contexto, la dapagliflozina, un inhibidor del cotransportador de sodio-glucosa tipo 2 (SGLT2), ha surgido como una estrategia terapéutica relevante en el manejo contemporáneo de la insuficiencia cardíaca, demostrando beneficios cardiovasculares y cardiorrenales que van más allá del control glucémico. Este estudio tuvo como objetivo analizar la evidencia científica actual sobre la eficacia clínica de la dapagliflozina en el tratamiento de la insuficiencia cardíaca, haciendo hincapié en sus efectos sobre la mortalidad cardiovascular, las hospitalizaciones, la calidad de vida, la capacidad funcional y la protección renal. Se trata de una revisión bibliográfica integradora, con un enfoque cualitativo y descriptivo, realizada mediante búsquedas en las bases de datos PubMed, SciELO y ScienceDirect, utilizando descriptores relacionados con la dapagliflozina, la insuficiencia cardíaca y los resultados cardiovasculares. Se incluyeron estudios publicados entre 2019 y 2023, incluyendo ensayos clínicos aleatorizados, revisiones sistemáticas, metaanálisis y guías internacionales. Los principales hallazgos mostraron una reducción significativa en las hospitalizaciones por insuficiencia cardíaca, la mortalidad cardiovascular y los episodios de descompensación clínica, así como una mejor calidad de vida y la preservación de la función renal en diferentes fenotipos de la enfermedad. Los estudios DAPA-HF y DELIVER fueron particularmente relevantes, considerados hitos en la consolidación de los inhibidores de SGLT2 como un componente terapéutico fundamental en la insuficiencia cardíaca. Se concluye que la dapagliflozina representa un avance importante en el tratamiento de la insuficiencia cardíaca, promoviendo beneficios clínicos consistentes y contribuyendo a un enfoque terapéutico más integral y multidimensional, centrado en la optimización de los resultados cardiovasculares y cardiorrenales.

Palabras clave: Insuficiencia Cardíaca. Dapagliflozina. Forxiga. Inhibidores de SGLT2. Resultados Cardiovasculares. Protección Cardiorrenal.

1 INTRODUCTION

Heart failure (HF) remains one of the main causes of cardiovascular morbidity and mortality on a global scale, configuring itself as an important public health problem due to the high frequency of recurrent hospitalizations, progressive functional limitation and substantial socioeconomic impact. Characterized by the inability of the heart to adequately meet the metabolic and hemodynamic demands of the body, the syndrome is associated with complex clinical manifestations, including dyspnea, fatigue, and intolerance to physical exertion. Despite the therapeutic advances observed in recent decades, HF still presents an unfavorable clinical evolution in a significant portion of patients, especially in the presence of reduced ejection fraction, renal impairment, and multiple associated comorbidities, evidencing persistent prognostic limitations even in the face of conventional pharmacological strategies (McMurray et al., 2019).

In this context, type 2 diabetes mellitus stands out as an important factor associated with the progression of heart failure and a significant increase in cardiovascular risk. The coexistence between metabolic dysfunction, chronic inflammation, hemodynamic alterations, and cardiorenal injury contributes to greater clinical complexity and worse outcome of these patients. In view of this pathophysiological interrelation, there has been a growing interest in therapeutic approaches capable of acting simultaneously on the cardiovascular, metabolic, and renal axes. Initially developed as hypoglycemic agents, sodium-glucose cotransporter type 2 (SGLT2) inhibitors have begun to demonstrate clinical effects that go beyond glycemic control, especially in the context of heart failure. Among them, dapagliflozin, commercially known as Forxiga®, has received increasing prominence due to its ability to modulate mechanisms related to natriuresis, reduction of volume overload, improvement of cardiorenal dynamics, and possible attenuation of cardiac remodeling, reflecting in favorable clinical outcomes regardless of the presence of diabetes mellitus (PETRIE et al., 2020).

The consolidation of dapagliflozin in the contemporary management of heart failure occurred mainly after the publication of the DAPA-HF study, considered a therapeutic milestone by demonstrating a significant reduction in the combined risk of worsening heart failure and cardiovascular death in patients with reduced ejection fraction. In addition to the decrease in relevant clinical events, a consistent impact on symptoms and functional outcome was observed, reinforcing the potential of dapagliflozin as a complementary therapy to traditional approaches already established in the treatment of HF (MCMURRAY et al., 2019). Subsequently, the findings of the DELIVER study expanded the clinical relevance of this drug by showing favorable results also in individuals with slightly reduced or preserved

ejection fraction, a scenario historically marked by limited therapeutic options and less robust pharmacological evidence (SOLOMON et al., 2022).

In addition to the effects on mortality and clinical decompensations, recent investigations have demonstrated relevant repercussions of dapagliflozin on the quality of life, functional capacity, and symptomatic perception of patients with heart failure. Evaluations based on the Kansas City Cardiomyopathy Questionnaire (KCCQ) have shown clinically significant improvement in different domains related to cardiovascular health status, both in patients with reduced and preserved ejection fraction (KOSIBOROD et al., 2020; KOSIBOROD et al., 2023). At the same time, studies involving renal outcomes suggest an additional protective effect on renal function, a particularly relevant aspect in view of the recognized bidirectional interaction between heart failure and chronic kidney disease, often associated with worse clinical outcome and greater therapeutic complexity (JHUND et al., 2020).

In view of the increasing incorporation of SGLT2 inhibitors in international guidelines for the management of heart failure, it is essential to critically understand the contemporary evidence related to the clinical efficacy of dapagliflozin and its impact on the different phenotypic profiles of the disease. Recent updates from the European Society of Cardiology (ESC) have started to recommend this therapeutic class as an essential component in the treatment of heart failure, recognizing its consistency in reducing adverse cardiovascular events and optimizing the clinical evolution of patients (MCDONAGH et al., 2023). In this sense, the present study aims to review the current scientific evidence on the use of dapagliflozin in the treatment of heart failure, emphasizing its clinical efficacy, its therapeutic effects, and its relevance in cardiovascular and cardiorenal outcomes.

2 METHODOLOGY

The present study consists of an integrative literature review, of a descriptive nature and qualitative approach, developed with the purpose of critically analyzing the contemporary scientific evidence related to the use of dapagliflozin (Forxiga®) in the treatment of heart failure, emphasizing its clinical efficacy, prognostic repercussions, and impact on cardiovascular, functional, and cardiorenal outcomes in different phenotypes of the disease.

The bibliographic survey strategy was conducted through systematized searches in internationally recognized scientific databases, PubMed, SciELO and ScienceDirect, selected due to their wide relevance in the indexing of biomedical, cardiovascular and pharmacotherapeutic studies of high methodological rigor. To construct the search strategy,

descriptors in Portuguese and English associated with Boolean operators "AND" and "OR" were used, including the terms: "dapagliflozin", "Forxiga", "heart failure", "SGLT2 inhibitors", "reduced ejection fraction", "mildly reduced ejection fraction", "preserved ejection fraction" and "cardiovascular outcomes". The combined use of these descriptors sought to contemplate the growing phenotypic complexity of contemporary heart failure, ranging from patients with reduced ejection fraction to those with slightly reduced or preserved ejection fraction.

Scientific articles published between 2019 and 2023, available in full in Portuguese and English, that directly addressed the use of dapagliflozin in patients with heart failure, were included. The selection prioritized randomized clinical trials, multicenter studies, secondary analyses of large cardiovascular trials, systematic reviews, meta-analyses, and international guidelines related to sodium-glucose cotransporter type 2 (SGLT2) inhibitors and the contemporary management of heart failure. Among the main studies included, the DAPA-HF and DELIVER trials stand out, considered methodological milestones in the consolidation of SGLT2 inhibitors as a central therapeutic component in heart failure, particularly due to the robustness of their clinical designs, population breadth, and relevance of the cardiovascular outcomes evaluated. In addition, analyses related to quality of life, functional evolution, renal protection and therapeutic response in different clinical profiles of the syndrome were incorporated.

Duplicate studies, incomplete publications, studies without a direct relationship with the proposed theme, experimental studies without relevant clinical applicability, isolated case reports, and articles that did not present consistent clinical outcomes related to the therapeutic efficacy of dapagliflozin in heart failure were excluded. Studies with low methodological relevance or without adequate correlation with the central objectives of this review were also disregarded.

After the selection stage, eligible studies were submitted to critical analysis and comparative integration of evidence, considering aspects related to methodological design, population profile, heterogeneity of heart failure phenotypes evaluated, nature of clinical endpoints, and consistency of the therapeutic results observed. The analytical synthesis focused especially on major cardiovascular outcomes, including cardiovascular mortality, hospitalizations for heart failure, and episodes of clinical decompensation, as well as functional parameters, quality of life, and cardiorenal repercussions, components progressively valued in contemporary studies on heart failure. Thus, we sought to construct an integrated and critically contextualized interpretation of the recent literature, allowing us

to understand the role of dapagliflozin in the redefinition of modern therapeutic strategies applied to heart failure.

3 RESULTS AND DISCUSSION

The integrated analysis of the selected studies demonstrates that dapagliflozin has established itself as one of the main therapeutic innovations in the contemporary management of heart failure. The clinical trials analyzed show consistent benefits in different phenotypes of the syndrome, promoting a favorable impact not only on major cardiovascular outcomes, but also on functional parameters, quality of life, and cardiorenal protection. These findings contributed to significantly modify the traditional therapeutic approach to heart failure, which has historically focused predominantly on neurohormonal modulation.

The DAPA-HF study represented a relevant milestone in this process by demonstrating that dapagliflozin significantly reduced the combined risk of worsening heart failure and cardiovascular death in patients with reduced ejection fraction, regardless of the presence of diabetes mellitus (MCMURRAY et al., 2019). In addition to the reduction in hospitalizations and cardiovascular mortality, consistent clinical improvement was observed even in patients undergoing optimized pharmacological therapy. This suggests a complementary effect to the therapies traditionally used in the management of heart failure. Subsequent analyses derived from DAPA-HF demonstrated that the benefits remained consistent regardless of the background therapies employed, including beta-blockers, renin-angiotensin system antagonists, and mineralocorticoid receptor antagonists (DOCHERTY et al., 2020). These results strengthened the consolidation of SGLT2 inhibitors as a structural component of modern heart failure therapy.

Another aspect of high clinical relevance refers to the efficacy observed regardless of the glycemic status of the patients. Although initially developed as an antidiabetic agent, dapagliflozin has demonstrated similar benefits in individuals with and without type 2 diabetes mellitus, significantly expanding its clinical applicability in the cardiovascular context (PETRIE et al., 2020). This effect appears to involve mechanisms partially independent of glycemic control. Among the main mechanisms proposed are osmotic natriuresis, reduction of cardiac preload and afterload, improvement of myocardial metabolic efficiency, attenuation of systemic congestion, and preservation of renal function. Together, these effects suggest integrated action on multiple pathophysiological axes of heart failure.

Historically, patients with heart failure and preserved or slightly reduced ejection fraction had limited therapeutic options and less expressive clinical results when compared to those with reduced ejection fraction. In this scenario, the DELIVER study represented an

important advance by demonstrating a significant reduction in the risk of worsening heart failure and cardiovascular death in patients with ejection fraction above 40%, including individuals with preserved ejection fraction (SOLOMON et al., 2022). In addition, subsequent analyses showed consistent benefits also in patients with previously reduced ejection fraction and later recovered, reinforcing the therapeutic scope of dapagliflozin in different clinical presentations of the syndrome (VARDENY et al., 2022). Despite the robustness of the findings, it should be considered that some of the studies have relatively limited follow-up time and selected populations, which may influence the extrapolation of the results to patients with greater clinical complexity observed in daily care practice.

In addition to the effects on mortality and clinical decompensation, a relevant impact of dapagliflozin on quality of life and functional capacity was observed. Studies based on the Kansas City Cardiomyopathy Questionnaire (KCCQ) have demonstrated significant improvement in symptoms, physical limitation, and global health perception in patients treated with the medication, both in heart failure with reduced and preserved ejection fraction (KOSIBOROD et al., 2020; KOSIBOROD et al., 2023). These findings have important clinical relevance, considering that heart failure is associated not only with high mortality, but also with progressive functional impairment and a substantial reduction in the quality of life of patients.

At the same time, the cardiorenal effects of dapagliflozin emerge as a central component in understanding its therapeutic efficacy. In DAPA-HF, patients with baseline renal impairment showed benefits similar to those observed in the general population, including reduction of cardiovascular events and slowing of loss of renal function over the course of clinical follow-up (JHUND et al., 2020). The preservation of renal function is of strategic relevance in heart failure, especially in view of the bidirectional interaction between cardiac dysfunction and chronic kidney disease. This association often contributes to a higher risk of recurrent hospitalizations, clinical progression, and mortality. Even so, the heterogeneity of the renal profiles evaluated in the studies and the lower representation of patients in advanced stages of chronic kidney disease remain aspects that require further investigation.

The results observed in the analyzed studies had a direct impact on the international guidelines for heart failure. Recent updates from the European Society of Cardiology have started to recommend SGLT2 inhibitors as an essential component of pharmacological therapy for heart failure, regardless of the presence of diabetes mellitus, consolidating dapagliflozin as one of the main therapeutic strategies in contemporary cardiology (MCDONAGH et al., 2023). However, challenges related to therapeutic implementation still

persist, including cost, access to treatment, medication adherence, and homogeneous incorporation of these recommendations in different health systems.

In addition, the systematic review and meta-analysis conducted by Ali et al. (2023) reinforced the magnitude of the clinical effects of dapagliflozin by demonstrating significant reduction in all-cause mortality, hospitalizations for heart failure, and cardiovascular death in a wide variety of patients with heart failure. The convergence between randomized controlled trials, secondary analyses, and meta-analyses strengthens the scientific consistency of the currently available evidence. Even so, the continuous production of data in more complex populations with prolonged follow-ups will be essential to expand the understanding of the effects of dapagliflozin in different clinical scenarios.

Thus, the findings analyzed in this review show that dapagliflozin transcends the role originally attributed to hypoglycemic agents, assuming a leading role in the contemporary management of heart failure. Its ability to act simultaneously on cardiovascular, functional, and cardiorenal outcomes reinforces the transition to a more integrated therapeutic model, aimed not only at reducing major clinical events, but also at modulating the pathophysiological complexity that characterizes modern heart failure.

4 CONCLUSION

The scientific evidence analyzed in this review demonstrates that dapagliflozin has established itself as an important therapeutic component in the contemporary management of heart failure, presenting consistent clinical benefits in different phenotypes of the disease, regardless of the presence of diabetes mellitus. The main randomized controlled trials, especially the DAPA-HF and DELIVER studies, have shown significant reductions in relevant cardiovascular outcomes, including worsening heart failure, recurrent hospitalizations, and cardiovascular mortality, as well as favorable repercussions on quality of life, functional capacity, and cardiorenal protection.

The available findings suggest that the therapeutic effects of dapagliflozin go beyond glycemic control, involving complex pathophysiological mechanisms related to natriuresis, reduction of hemodynamic overload, preservation of renal function, and modulation of cardiorenal dysfunction. This integrated action contributes to a more comprehensive therapeutic approach to heart failure, a condition characterized by high clinical complexity and important prognostic impact.

In addition, the incorporation of SGLT2 inhibitors into the main international guidelines reinforces the robustness of the currently available evidence and consolidates dapagliflozin as a fundamental strategy in the treatment of heart failure. However, despite the promising

results observed in contemporary studies, challenges remain related to applicability in clinically more complex populations, long-term follow-up, and therapeutic implementation in real clinical practice.

Thus, it is concluded that dapagliflozin represents a significant advance in the treatment of heart failure, promoting relevant cardiovascular, functional, and cardiorenal benefits. Its use shows the transition to a more integrated and multidimensional therapeutic model, aimed not only at reducing adverse clinical events, but also at improving the overall clinical evolution and quality of life of patients with heart failure.

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