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USE OF DAPAGLIFLOZIN (FORXIGA) IN THE MANAGEMENT OF OBESITY AND NON-ALCOHOLIC FATTY LIVER DISEASE IN PATIENTS WITH TYPE 2 DIABETES

USO DA DAPAGLIFLOZINA (FORXIGA) NO CONTROLE DA OBESIDADE E DA ESTEATOSE HEPÁTICA NÃO ALCOÓLICA EM PACIENTES COM DIABETES TIPO 2

USO DE DAPAGLIFLOZINA (FORXIGA) EN EL CONTROL DE LA OBESIDAD Y LA ENFERMEDAD DEL HÍGADO GRASO NO ALCOHÓLICO EN PACIENTES CON DIABETES TIPO 2

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ABSTRACT
This integrative review aimed to analyze scientific evidence published between 2020 and 2025 regarding the use of dapagliflozin (Forxiga®) in the management of obesity and non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes mellitus (T2DM). The search was conducted in PubMed, SciELO, ScienceDirect, and Consensus Academic Database, using controlled descriptors in Portuguese and English, and including clinical, experimental, and systematic review studies. The evidence analyzed indicates that dapagliflozin shows beneficial potential on glycemic and hepatic metabolism, leading to reductions in hepatic enzymes (ALT, AST, and GGT), improved insulin sensitivity, and decreased accumulation of body and liver fat. Complementary experimental studies demonstrated that the drug acts through the modulation of metabolic and inflammatory pathways, such as FXR/SHP and LXRα/SREBP-1c, reducing hepatic lipogenesis and enhancing fatty acid oxidation. Overall, the reviewed studies suggest that dapagliflozin is a safe and promising therapeutic option for the management of NAFLD in patients with T2DM, although long-term clinical trials with larger samples are still needed to validate its therapeutic potential.

Keywords: Dapagliflozin. Type 2 Diabetes Mellitus. Non-alcoholic Fatty Liver Disease. Obesity. Integrative Review.

RESUMO
Esta revisão integrativa teve como objetivo analisar as evidências científicas publicadas entre 2020 e 2025 sobre o uso da dapagliflozina (Forxiga®) no controle da obesidade e da doença hepática gordurosa não alcoólica (DHGNA) em pacientes com diabetes mellitus tipo 2 (DM2). A busca foi conduzida nas bases PubMed, SciELO, ScienceDirect e Consensus Academic Database, utilizando descritores controlados em português e inglês, com inclusão de estudos clínicos, experimentais e revisões sistemáticas. As evidências analisadas indicam que a dapagliflozina demonstra potencial terapêutico relevante, promovendo redução das enzimas hepáticas (ALT, AST e GGT), melhora da sensibilidade à insulina e diminuição do acúmulo de gordura corporal, especialmente no fígado. Estudos experimentais complementares apontam que o fármaco atua na modulação de vias metabólicas e inflamatórias, como FXR/SHP e LXRα/SREBP-1c, reduzindo a lipogênese hepática e estimulando a oxidação de ácidos graxos. De modo geral, as publicações sugerem que a dapagliflozina é segura e potencialmente eficaz no manejo integrado da DHGNA e do DM2, embora sejam necessários ensaios clínicos de longa duração e com maiores amostras para consolidar suas aplicações clínicas.

Palavras-chave: Dapagliflozina. Diabetes Mellitus Tipo 2. Doença Hepática Gordurosa não Alcoólica. Obesidade. Revisão Integrativa.

RESUMEN
Esta revisión integrativa tuvo como objetivo analizar la evidencia científica publicada entre 2020 y 2025 sobre el uso de dapagliflozina (Forxiga®) en el control de la obesidad y la enfermedad del hígado graso no alcohólico (EHGNA) en pacientes con diabetes mellitus tipo 2 (DM2). La búsqueda se realizó en las bases de datos PubMed, SciELO, ScienceDirect y Consensus Academic Database, utilizando descriptores controlados en portugués e inglés, e incluyó estudios clínicos, estudios experimentales y revisiones sistemáticas. La evidencia analizada indica que la dapagliflozina demuestra un potencial terapéutico relevante,

promoviendo una reducción de las enzimas hepáticas (ALT, AST y GGT), una mejora de la sensibilidad a la insulina y una disminución de la acumulación de grasa corporal, especialmente en el hígado. Estudios experimentales complementarios indican que el fármaco actúa modulando vías metabólicas e inflamatorias, como FXR/SHP y LXRα/SREBP-1c, reduciendo la lipogénesis hepática y estimulando la oxidación de ácidos grasos. En general, las publicaciones sugieren que la dapagliflozina es segura y potencialmente eficaz en el tratamiento integral de la EHNA y la DM2, si bien se requieren ensayos clínicos a largo plazo con muestras más amplias para consolidar sus aplicaciones clínicas.

Palabras clave: Dapagliflozina. Diabetes Mellitus Tipo 2. Enfermedad del Hígado Graso no Alcohólico. Obesidad. Revisión Integrativa.

1 INTRODUCTION

Obesity and type 2 diabetes mellitus (DM2) are among the main metabolic conditions with a high prevalence worldwide, being associated with insulin resistance, dyslipidemias, and chronic inflammatory processes. Such changes favor the development of **nonalcoholic fatty liver disease (NAFLD),** whose prevalence in individuals with DM2 can exceed 60%, representing a risk factor for cirrhosis and hepatocellular carcinoma (Mantovani et al., 2020). The evolution of NAFLD to **nonalcoholic steatohepatitis (NASH)** increases cardiovascular morbidity and mortality and imposes relevant clinical challenges to the treatment of these patients (Sumida et al., 2020).

The management of NAFLD associated with T2DM is multifactorial and traditionally involves lifestyle modifications, glycemic control, and the use of insulin sensitizers such as pioglitazone. However, this drug has important adverse effects, including **weight gain, fluid retention, and increased cardiovascular risk**, which limits its long-term use (Sumida et al., 2020). Given these limitations, **sodium-glucose cotransporter type 2 (SGLT2) inhibitors**, such as **dapagliflozin**, have emerged as a promising therapeutic alternative, by promoting **insulin-independent glycemic reduction**, weight loss, and systemic metabolic improvement (Cho et al., 2020).

Several clinical studies show that dapagliflozin significantly reduces serum levels of **alanine aminotransferase (ALT), aspartate aminotransferase (AST),** and **gamma-glutamyltransferase (GGT), in** addition to improving the insulin resistance index (HOMA-IR) and decreasing liver lipid content in patients with T2DM and NAFLD (Das et al., 2021; Gao et al., 2024). Additionally, a reduction in visceral and subcutaneous fat is observed, as well as an improvement in the lipid profile, reflecting positive effects on global metabolism (Han et al., 2021). These findings reinforce the hepatoprotective and metabolic potential of the drug.

Experimental evidence indicates that dapagliflozin exerts **anti-inflammatory, antioxidant, and antifibrotic action** on liver tissue by inhibiting lipogenesis and stimulating **mitochondrial β-oxidation**, mechanisms mediated by pathways such as **FXR/SHP** and **LXRα/SREBP-1c** (Qiao et al., 2022; Sun et al., 2025). Such effects contribute to the reduction of inflammation and fibrosis, with consequent improvement of liver function and insulin sensitivity. Thus, the drug has comprehensive therapeutic potential for complex metabolic disorders such as obesity, NAFLD, and T2DM.

Considering the increasing prevalence of obesity, T2DM, and NAFLD, it is essential to synthesize recent scientific evidence on the role of dapagliflozin in modulating these disorders. The integrated analysis of clinical and experimental studies can contribute to substantiate its use as a safe and effective therapeutic option. Thus, the present study aims **to review the scientific literature of the last five years on the use of dapagliflozin (Forxiga) in the control of obesity and nonalcoholic fatty liver disease in patients with type 2 diabetes**, highlighting its metabolic effects, physiological mechanisms, and clinical implications.

2 METHODOLOGY

2.1 TYPE OF STUDY

The present study is characterized as an **integrative literature review**, of a **descriptive and exploratory** nature, with a **qualitative** approach. Integrative review allows for gathering and critically analyzing research results on the same topic, favoring a comprehensive and systematized understanding of the phenomenon studied (Souza; Silva; Carvalho, 2010). This approach was chosen because it enables the integration of clinical and experimental studies on the effects of dapagliflozin (Forxiga®) on the control of obesity and nonalcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes mellitus (T2DM).

2.2 GUIDING QUESTION

The research question was structured based on the **PICO** (Population, Intervention, Comparison and Outcome) strategy, widely used in scientific reviews to formulate clinical questions. Thus, it was defined:

P (Population): patients with type 2 diabetes mellitus and/or obesity:

I (Intervention): use of dapagliflozin;

C (Comparison): conventional therapies or no specific treatment for NAFLD/NASH;

O (Outcome): reduction of liver fat, metabolic improvement, and control of body weight.

Thus, the guiding question was formulated**: *"What are the effects of dapagliflozin on obesity and nonalcoholic fatty liver disease in patients with type 2 diabetes?"***

2.3 SEARCH STRATEGIES AND SOURCES OF INFORMATION

The search for studies was carried out between **September and November 2025** in the **PubMed**, **SciELO,** ScienceDirect**,** and **Consensus Academic Databases**, selected for their relevance and scope in the biomedical area.

Controlled descriptors of the **DeCS** and **MeSH** vocabularies were used, combined with Boolean operators (AND/OR):

("Dapagliflozin" OR "Dapagliflozin") AND ("Obesity" OR "Obesity") AND ("Non-alcoholic fatty liver disease" OR "NAFLD") AND ("Type 2 Diabetes Mellitus").

The search strategy was applied in a standardized way in all databases, with refinement by period (2020–2025) and languages (Portuguese and English).

2.4 INCLUSION AND EXCLUSION CRITERIA

Articles that met the following criteria were included:

- Published between **January 1, 2020 and November 1, 2025**;
- Written in **Portuguese or English**;
- Original **studies** (clinical, observational, and experimental trials);
- Systematic reviews and meta-analyses addressing dapagliflozin in the context of obesity and NAFLD associated with T2DM.

The following were excluded:

- Case reports, letters to the editor and conference abstracts;
- Studies involving alcoholic liver disease or non-diabetic populations;
- Duplicate articles or articles without access to full text.

2.5 SELECTION AND ORGANIZATION OF STUDIES

The selection process followed the guidelines of **the PRISMA protocol (Preferred Reporting Items for Systematic Reviews and Meta-Analyses),** adapted to the integrative review format. Initially, **58 studies were identified**. After reading titles and abstracts, **30 were excluded** because they did not meet the eligibility criteria. Of the **28 articles fully evaluated**, **20 were included in the final sample**.

The relevant information was organized in a spreadsheet containing: author, year, type of study, sample, intervention, main results and conclusions. This systematization ensured the traceability and transparency of the data analyzed.

2.6 DATA PROCESSING AND ANALYSIS

The analysis of the studies was conducted in a **qualitative and descriptive** manner, focusing on the identification of **trends, convergences and divergences** between the results. The findings were grouped into thematic axes: metabolic effects, impact on body weight, liver function, and pathophysiological mechanisms.

The final synthesis was prepared through critical reading and integration of evidence, based on the principles of integrative review, respecting the criteria of methodological rigor, clarity and scientific relevance.

3 RESULTS AND DISCUSSION

3.1 CHARACTERIZATION OF THE INCLUDED STUDIES

20 articles published between 2020 and 2025 **were selected**, covering different methodological designs: randomized **clinical trials (n = 6), observational studies (n = 4), systematic reviews and meta-analyses (n = 3),** and **experimental trials in animal models (n = 4).** Most of the publications originated from Asian centers, especially Japan, China, and India, and indexed in databases such as **PubMed**, **ScienceDirect,** and **SciELO.**

The studies included **adults with type 2 diabetes mellitus (T2DM),** often with a concomitant diagnosis of **nonalcoholic fatty liver disease (NAFLD)** and **obesity**, treated with **dapagliflozin (10 mg/day)** for periods ranging from 8 to 24 weeks. This sample allowed the evaluation of the metabolic and hepatic effects of the drug in an integrated manner.

3.2 EFFECTS ON LIVER PARAMETERS

Most clinical studies have shown **significant improvement in liver enzymes (ALT, AST, and GGT)** after the use of dapagliflozin, indicating reduced hepatocellular inflammation and functional improvement of the liver (Das et al., 2021; Gao et al., 2024). Meta-analyses reinforce these findings, reporting mean reductions between 10 and 14 IU/L in transaminases (Mantovani et al., 2020; Lee et al., 2021).

In addition to biochemical effects, experimental studies have shown that dapagliflozin reduces **hepatic lipogenesis**, increases **mitochondrial β-oxidation,** and attenuates **liver fibrosis** by modulating **the FXR/SHP** and **LXRα/SREBP-1c** pathways (Qiao et al., 2022; Sun et al., 2025). These results suggest that the drug acts in a **multifactorial way**, both at the molecular and metabolic levels, with a positive impact on the progression of steatosis.

3.3 EFFECTS ON OBESITY AND GLUCOSE METABOLISM

The studies analyzed showed significant reductions in **body weight, visceral fat, and insulin resistance (HOMA-IR),** reflecting improved overall metabolic profile (Han et al., 2021; Das et al., 2021). In a clinical trial by Gao et al. (2024), after 20 weeks of using dapagliflozin, there was a decrease in **body mass index (BMI)** and improvement in inflammatory markers (IL-6 and hs-CRP), reinforcing the anti-inflammatory role of the drug.

A meta-analysis by Duan and Chen (2025) also showed mean reductions of **0.6% in HbA1c** and **1.1 standard deviations in ALT**, confirming the hepatoprotective potential of the drug. Thus, dapagliflozin demonstrates efficacy both in glycemic control and in **modulating hepatic and adipose inflammation**.

3.4 COMPARISON WITH OTHER THERAPIES

Comparative studies show that dapagliflozin has **similar efficacy to pioglitazone** in improving liver parameters, but with **a better safety profile and weight reduction** (Cho et al., 2020; Balgir; Singh, 2025). This advantage is particularly relevant in patients with T2DM and obesity, in whom weight gain can aggravate the clinical picture.

Some authors suggest that the **combination of SGLT2 inhibitors and GLP-1 agonists** may potentiate the hepatoprotective effect, although more controlled clinical studies are needed to confirm the safety of this strategy (Lin et al., 2024).

3.5 PATHOPHYSIOLOGICAL AND CLINICAL IMPLICATIONS

The reviewed results indicate that dapagliflozin acts on multiple pathophysiological mechanisms, reducing lipogenesis, oxidative stress, and liver inflammation, while improving insulin sensitivity and fatty acid oxidation (Sun et al., 2025; Qiao et al., 2022). These effects contribute to the **reestablishment of hepatic and systemic metabolic balance**, which justifies its potential use as **adjuvant therapy** in patients with T2DM and NAFLD.

The consistency of the findings between clinical and experimental studies reinforces the robustness of the evidence, pointing to dapagliflozin as a **safe, effective pharmacological intervention with broad metabolic benefit**.

3.6 SYNTHESIS OF THE MAIN FINDINGS

Overall, the integrated analysis of the studies included in this review demonstrates that **dapagliflozin** has broad and consistent effects on metabolic and hepatic parameters in

patients with **type 2 diabetes mellitus (T2DM)** and **nonalcoholic fatty liver disease (NAFLD).** Most clinical trials and meta-analyses have identified **significant reductions in liver enzymes ALT, AST, and GGT**, which indicates improvement in hepatocellular integrity and biochemical markers of liver inflammation (Mantovani et al., 2020; Das et al., 2021; Gao et al., 2024).

In addition, studies using imaging techniques have shown **a significant reduction in liver fat content**, both in humans and in experimental models, confirming the **hepatoprotective effect** of the drug (Qiao et al., 2022; Sun et al., 2025). These benefits were accompanied by **improved insulin resistance (HOMA-IR)** and **reduced total and visceral body fat**, outcomes observed in different populations and clinical settings (Han et al., 2021; Gao et al., 2024).

The findings also indicated **mean reductions of between 2 and 3 kg in body weight** and **decreases in glycated hemoglobin (HbA1c) by approximately 0.6%,** as reported in recent meta-analyses (Duan; Chen, 2025). In parallel, experimental studies have shown that dapagliflozin reduces **liver fibrosis** and **oxidative stress** by modulating metabolic and inflammatory pathways, such as **FXR/SHP** and **LXRα/SREBP-1c** (Qiao et al., 2022; Sun et al., 2025).

These results suggest that the drug not only contributes to glycemic control, but also **acts directly on the pathophysiological mechanisms of hepatic steatosis**, favoring the **oxidation of fatty acids** and inhibiting **de novo hepatic lipogenesis**. Thus, dapagliflozin can be considered a **pharmacological intervention with multisystem action**, with a positive impact on hepatic, adipose and glucose metabolism.

In a convergent way, the evidence from different methodological, clinical, observational, and experimental designs indicates **consistency in the beneficial effects of dapagliflozin**, reinforcing its potential clinical relevance as a **hepatoprotective agent and metabolic modulator** in patients with DM2 and NAFLD. However, the need for **long-term clinical trials** with **larger samples is highlighted** to consolidate the safety and magnitude of these effects in diverse populations.

3.7 FINAL CONSIDERATIONS OF THE DISCUSSION

The results of this review indicate that dapagliflozin represents a therapeutic option with a positive impact on **glycemic control, weight reduction, and improvement of liver function** in individuals with type 2 diabetes and NAFLD. The convergence of clinical and

preclinical findings strengthens the hypothesis that the drug acts through **complementary metabolic and anti-inflammatory mechanisms**.

However, there is **a paucity of longitudinal and population-based studies** evaluating the effects of dapagliflozin on **long-term clinical outcomes**, such as fibrosis progression and liver mortality. Therefore, it is recommended that multicenter trials be conducted for longer periods of time to consolidate their clinical applicability.

4 CONCLUSION

The present integrative review aimed **to analyze the scientific evidence published between 2020 and 2025** on the use of **dapagliflozin (Forxiga®) in the** control of **obesity** and **nonalcoholic fatty liver disease (NAFLD)** in **patients with type 2 diabetes mellitus (T2DM).**

The studies analyzed demonstrated that dapagliflozin has **relevant therapeutic potential**, promoting **improved glycemic control**, **weight reduction,** and **decreased liver fat**. There was also a **significant reduction in liver enzymes (ALT, AST, and GGT),** associated with **improved insulin sensitivity** and **attenuation of hepatic inflammatory processes**, which suggests **hepatoprotective and anti-inflammatory** action (Mantovani et al., 2020; Das et al., 2021; Gao et al., 2024).

Experimental evidence corroborates these findings, indicating that dapagliflozin **acts on the modulation of metabolic and inflammatory pathways**, such as **FXR/SHP** and **LXRα/SREBP-1c**, resulting in **reduced hepatic lipogenesis**, **greater fatty acid oxidation,** and **decreased liver fibrosis** (Qiao et al., 2022; Sun et al., 2025). This multisystem action contributes to the **reestablishment of the metabolic and functional balance of the liver**, which makes it a **promising pharmacological intervention in the** management of patients with T2DM and NAFLD.

Overall, the reviewed evidence indicates that dapagliflozin **is safe and potentially effective** in the integrated treatment of **metabolic and hepatic disorders** associated with type 2 diabetes. However, **methodological heterogeneity** among studies and the **scarcity of long-term clinical trials** limit the generalization of results and prevent definitive conclusions about their long-term efficacy.

It is recommended that **future research** evaluate the **prolonged effects of dapagliflozin** on the **progression of liver fibrosis**, **cardiovascular and renal events**, as well as **comparisons between different pharmacological classes**. The expansion of this

evidence may consolidate the role of dapagliflozin as an **adjuvant therapy of choice** in the treatment of individuals with **type 2 diabetes, obesity and NAFLD**, contributing to the **advancement of therapeutic practices and to the improvement of the quality of life of these patients**.

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