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Review Article

Non-Steroidal Anti-Inflammatory Drug Use and the Risk of Incident Heart Failure in Patients with Type 2 Diabetes Mellitus: A Systematic Review

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Abstract: Background: Patients with diabetes have a two to five times higher risk of experiencing heart function problems compared to the general population. In addition, it is known that the use of non-steroidal anti-inflammatory drugs (NSAIDs) is currently very widespread, which functions to manage chronic pain, even though it is known that the use of NSAIDs has side effects on the patient's cardiorenal function. This systematic review aims to evaluate the relationship between the use of NSAIDs and the risk of incident heart failure in patients with type 2 diabetes mellitus by following the PRISMA 2020 guidelines. Methods: This study conducted a comprehensive search strategy on several journal sources, including: PubMed, Scopus, PMC Europe, and Openalex, The selected journals had criteria including: journals in the last 10 years, The type of research selected was an observational study evaluating the incidence of heart failure in adult patients with Diabetes mellitus who used NSAIDs. Two reviewers independently screened the studies, extracted data, and assessed risk of bias using the Newcastle-Ottawa Scale. Results: Five study involving more than 3 million respondents was analyzed. It was concluded that short-term NSAID use was associated with increased risk of first-time hospitalization for heart failure. This risk was significantly higher in the elderly subgroup over 65 years of age and in patients with uncontrolled HbA1c levels. Conclusion: NSAID administration increases heart failure risk in patients with diabetes mellitus, particularly those over 65 and with poor glycemic control.

Keywords: Heart Failure; Nonsteroidal Anti-Inflammatory Drugs; PRISMA; Systematic Review; Type 2 Diabetes Mellitus.

1. Introduction

One of the rapidly growing global health challenges of the 21st century is diabetes mellitus. This condition is not simply a disorder of glucose metabolism. It has evolved into a complex syndrome. It is now characterized by insulin resistance, cellular-level systemic inflammation, and widespread vascular damage (Hsu et al., 2023; Giraldo-Gonzalez et al., 2025). According to global surveys, approximately hundreds of millions of people live with diabetes mellitus. This number is expected to increase each year due to lifestyle changes and aging (Hsu et al., 2023). One of the serious complications of diabetes is heart failure. It often appears as the first cardiovascular complication before the onset of other cardiovascular diseases, such as myocardial infarction or stroke (Hsu et al., 2023).

Type 2 diabetes mellitus and heart failure are strongly linked in terms of pathomechanism. Chronic hyperglycemia increases the formation of advanced glycation end-products (AGEs). These later bind to their receptors (RAGE), resulting in oxidative stress and myocardial dysfunction in cardiomyocytes (Giraldo-Gonzalez et al., 2025). This condition causes cardiac remodeling and interstitial fibrosis in cardiomyocytes. It also causes myocardial cell stiffness, which is closely related to HFpEF-type heart failure. This situation

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makes drugs that affect hemodynamic conditions, such as NSAIDs, very crucial. It is a significant clinical issue (Schjerning et al., 2020).

NSAIDs are one of the most widely used types of drugs in the world, obtained either through a doctor's prescription or over-the-counter purchase (Wongrakpanich et al., 2018). This drug inhibits cyclooxygenase enzymes (COX-1 and COX-2), which are involved in prostaglandin synthesis. The results of this inhibition effectively reduce pain and inflammation. Prostaglandins also play a role in maintaining cardiorenal homeostasis. Prostaglandins such as PGE2 and PGI2 in the kidney play a role as afferent arteriole vasodilators and as modulators of tubular sodium excretion. When prostaglandin production is inhibited by NSAID use, renal vasoconstriction and fluid retention are likely, triggering or worsening heart failure in patients (Lucas et al., 2019; Hörl, 2010).

Recent research has shown that patients with diabetes have lower cardiovascular clinical conditions, so that the consequences of even short-term use of NSAIDs can result in cardiac decompensation (Holt et al., 2023). According to research data from Denmark, approximately one in six patients with diabetes buys at least one type of NSAID each year, thus indicating a very broad exposure in a high-risk cardiovascular population. Although several variables increase cardiovascular risk, for example, related to the type of NSAID, duration of use, and patient characteristics such as blood sugar control and age (Holt et al., 2023).

GLP-1 receptor agonists and SGLT2 inhibitors are used in current diabetes mellitus therapy. SGLT2 use is significantly protective against cardiovascular conditions in patients with heart failure. However, using nephrotoxic and volume-affecting drugs like NSAIDs at the same time can impair the benefits of SGLT2 or increase the risk of acute kidney failure (Ferreira et al., 2025). This may ultimately worsen the patient's heart condition. Therefore, clinicians need comprehensive knowledge about the risk of heart failure from NSAID use in patients with diabetes mellitus. Such knowledge can guide safe therapy decisions (Ferreira et al., 2025; Hsu et al., 2023).

This systematic review was compiled by synthesizing the latest scientific evidence regarding the relationship between NSAID use and the risk of new-onset heart failure in patients with type 2 diabetes mellitus. Researchers analyzed data from various journals, including cohort and national-scale studies, to provide a comprehensive picture of the magnitude of risk, risk factors, and underlying pathophysiological mechanisms. Based on these findings, clinicians are urged to exercise increased caution when prescribing NSAIDs to individuals with diabetes, to monitor for potential cardiac complications, and to consider relatively safer analgesic alternatives where appropriate (Butler et al., 2023;Cosentino et al., 2023; McGettigan & Henry, 2022).

2. Research Method

Research Design

This study uses a systematic review method by following the rules outlined in the Cochrane Handbook for Systematic Reviews of Interventions and reporting in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) 2020 guidelines.

Literature Search Strategy

A comprehensive literature search was conducted in four major electronic databases: PubMed, Scopus, PMC Europe, and Openalex. Relevant Boolean operators and keywords targeted type 2 diabetes mellitus, non-steroidal anti-inflammatory drugs, and heart failure. Only English-language studies from the past 10 years were included to ensure relevance to current clinical practice.

The search strategy was: (type 2 diabetes OR type II diabetes OR type 2 diabetes mellitus OR T2DM) AND (NSAID OR non-steroidal anti-inflammatory drug OR nonsteroidal anti-inflammatory drug OR ibuprofen OR diclofenac OR naproxen OR indomethacin OR meloxicam OR celecoxib OR etoricoxib) AND (heart failure OR cardiac failure OR congestive heart failure OR "incident heart failure" OR new-onset heart failure).

Eligibility Criteria

Study selection utilized a predefined PICOS framework to ensure consistency and relevance of the results. The selected journals were subsequently evaluated using the PICOS framework to establish inclusion and exclusion criteria, thereby ensuring consistency and relevance of the results.

Table 1. Inclusion criteria and exclusion criteria using the PICOS framework.

Component	Inclusion Criteria	Exclusion Criteria
Population (P)	Patients aged (>18 years) suffering from DMT2 without a history of previous heart failure (new onset HF).	Patients with type 1 diabetes, the non-diabetic population, or patients with a previous history of heart failure.
Intervention/Exposure (I)	Use of all types of NSAIDs, both non-selective (Ibuprofen, naproxen, diclofenac) and selective COX-2 (Celecoxib, etoricoxib).	Co-administration of drugs without separate analysis is associated with NSAID use, exposure to which is not clearly defined.
Comparison (C)	Patients who are not using NSAIDs or using comparators in other classes, such as colchicine or paracetamol.	N/A
Result (O)	Patients diagnosed with new cases of heart failure, heart failure hospitalization, or associated risk ratio (HR/OR).	Patients with cardiovascular diagnoses without detailed discussion data related to heart failure, and patients with cases of exacerbation of heart failure.
Study Design (S)	Research with cohort research design (prospective/retrospective) and case-control/case-crossover research.	Research with a systematic review research design, editorials, case reports, randomized clinical trials (RCTs) that are not relevant, or research with experimental animals.

Data Extraction

Data were independently extracted by two reviewers using a standardized, pre-tested data extraction form. Discrepancies between reviewers were resolved through discussion. Extracted data included: 1) study characteristics such as author, year of publication, country, and study design; 2) respondent characteristics including sample size, age, and control of HbA1C levels; 3) treatment details including NSAID type, dose, and duration of use; and 4) clinical outcomes related to heart failure, including HR, OR, and 95% CI.

Risk of Bias Assessment

The Newcastle-Ottawa Scale (NOS) was used to assess the risk of bias in observational studies. This tool evaluates three main domains: subject selection (representativeness), comparability between groups (control for confounding factors), and assessment of outcome or exposure. The maximum total score is nine stars. Scores of 7–9 indicate high quality, 5–6 indicate moderate quality, and scores below 5 indicate low quality.

3. Results

Literature search results

Database searches identified 202 records: PubMed (n = 30), Scopus (n = 54), PMC Europe (n = 134), and OpenAlex (n = 52). After removing 19 duplicates and excluding 109 records using automation tools, 74 records remained for title and abstract screening. Of these, 58 were excluded. Full-text evaluation excluded 11 studies due to incorrect interventions (n = 2), incomplete outcome data (n = 2), or insufficient data (n = 7). In total, 5 studies were included in the qualitative synthesis as depicted in the PRISMA flow diagram (Figure 1).

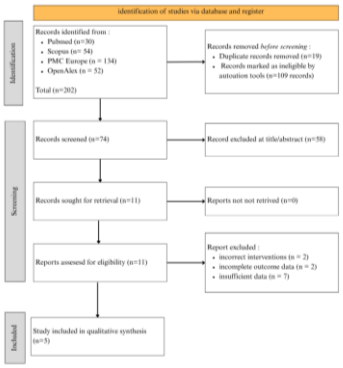

Figure 1. Prisma Flow Diagram

Risk of Bias Assessment

Assessment with the Newcastle-Ottawa Scale categorized all included studies as having good quality, with scores ranging from 7 to 9. These findings indicate high reliability in population selection and in controlling for confounding variables, including age, gender, and cardiovascular comorbidities.

Table 2. Risk of Bias Assesment with Newcastle-Otttawa scale tool.

Author and Year	Selection	Comparability	Outcome	Total Score	Quality
Lin et al., 2025	3/4	2/2	2/3	7/9	Good
Abi Khalil et al., 2018	3/4	2/2	3/3	8/9	Good
Jeon et al., 2025	4/4	2/2	3/3	9/9	Good
Bonnesen et al., 2023	3/4	2/2	3/3	8/9	Good
Holt et al., 2023	3/4	1/2	3/3	7/9	Good

Description of included trials

The literature search and screening process resulted in the identification of five primary studies that met the inclusion criteria and provided quantitative data on the risk of heart failure in diabetic patients using NSAIDs. These studies included a diverse range of populations, such as a cohort study conducted in Denmark and the TriNetx global database, which encompasses regions across the United States, Europe, and Asia.

Table 3. Summary of the characteristics of each study (2,8–11).

Author (Year)	Study Design	Population	Types of Drugs	Main Outcome (Heart Failure)	Risk Ratio (95% CI)
Holt et al. (2023)	Case-crossover	331,189 patients with T2DM (Denmark)	NSAIDs (Ibuprofen, Diclofenac, etc.)	First heart failure hospitalization	Ibuprofen : OR = 1.46 (95% CI: 1.26-1.69) Diclofenac : OR = 1.48 (95% CI : 1.10-2.00)
Bonnesen et al. (2023)	Cohort	103,308 DMT2 patients (Denmark)	Ibuprofen, Naproxen, Diclofenac	Congestive heart failure events	Ibuprofen : HR = 1.24 (95% CI: 1.00–1.53) Naproxen : HR=1.30 (95% CI: 0.49–3.49) Diclofenac : HR = 2.89 (95% CI: 1.65–5.04)
Lin et al. (2024)	Cohort (PSM)	2,946,579 obese patients ± with DMT2	GLP-1 RA + Aspirin	Heart Failure in DMT2 Patients	HR : 1.97 (95% CI 1.54–2.53)
Abi Khalil et al. (2018)	Retrospective Cohort	12,534 T2DM + HF patients (UK)	Aspirin (Low dose)	Composite of Death & HF Hospitalization	HR = 0.68 (95%CI: 0.45-1.03)
Jeon et al. (2025)	Cohort	DMT2 + Gout Patients (Korea)	Colchicine vs NSAIDs	Hospitalization for heart failure	HR= 1.01 (95%CI : 0.72-1.41)

From table 3, the most significant findings came from a case-crossover study conducted by Holt et al. (2023), which involved over 331,000 patients with diabetes in Denmark. This study design allows each patient to serve as their own control, thereby minimizing bias from genetic factors and sedentary behavior. The research revealed that short-term use of nonsteroidal anti-inflammatory drugs (NSAIDs) was associated with a 43% increase in first-time hospitalizations for heart failure (OR= 1,43; 95% CI =1,27-1,63) with a therapeutic window lasting 28 days (2).

Further analysis of specific drug types showed that the greatest risk was associated with the use of ibuprofen and diclofenac. Ibuprofen was associated with an odds ratio of 1.46 (95% CI =1.26-1.69). At the same time, diclofenac showed a slightly higher risk with an odds ratio of 1.48 (95% CI =1.10-2.00). However, no significant association was found in this study for the use of naproxen and celecoxib, although this may be due to the smaller number of users (small sample size) (2).

In addition, age is also an important risk factor . The risk of heart failure due to NSAID use was found to be highest in the age group above 65 years . In the subgroup of patients aged > 80 years, the OR for heart failure increased to 1.78 (95%CI :1,39-2,28). On the other hand, in patients under 65 years of age, the relationship became insignificant, thus leading to the conclusion that heart and blood vessel conditions due to aging are a prerequisite for the emergence of heart failure complications due to NSAID use (2).

Study by Bonnesen et al (2023) related to the interaction between blood sugar control and cardiovascular risk due to NSAID use. Diabetic patients with uncontrolled HbA1C levels (values above 48 mmol/mol or HbA1c>65% (53 mmol/mol) showed a greater level of vulnerability to NSAID side effects. In patients with controlled blood glucose levels, the relationship between NSAID use and heart failure became insignificant, so it was concluded that uncontrolled blood sugar levels can worsen myocardial dysfunction so that the heart becomes more sensitive to drug-induced fluid loads(8).

Research conducted by Lin et al (2024) explains that there is a complex and unexpected interaction between the use of aspirin and GLP-1 receptor agonist drugs (GLP-1 RA) in patients with obesity and diabetes. Although GLP-1 RA has been known to have cardioprotective effects, the addition of aspirin to the treatment regimen is actually associated with a significantly increased risk of heart failure compared with the use of GLP-1 RA alone HR 1.97(95% CI 1.54–2.53) (9).

In patients with diabetes who also suffer from gout, the choice of analgesic to treat attacks is often debated. A national cohort study conducted by Jeon et al (2025) in South Korea compared the use of colchicine with NSAIDs in a population of patients with DM. The results of this study showed that colchicine did not significantly reduce the risk of heart failure compared with NSAIDs. This indicates that both types of drugs may have comparable levels of cardiovascular risk when used for short durations in the management of diabetic patients with gout. However, NSAIDs are generally considered to have a greater risk for the kidneys and heart (11).

Discussions

Pathophysiology of NSAID-Induced Heart Failure in Diabetes

Results of a systematic review show strong evidence of a relationship between NSAID use in patients with type 2 diabetes and the patients' hemodynamic conditions (2). The underlying pathophysiological mechanisms are inhibition of the cyclooxygenase enzyme, renal regulation, and myocardial vulnerability in patients with diabetes.

The Role of Prostaglandins in Renal Homeostasis

Prostaglandins play a significant role in the kidneys, helping maintain blood flow and filtration. They are active especially when the sympathetic nervous system or the Renin-Angiotensin-Aldosterone System (RAAS) is active. Prostaglandins PGE2 and PGI2 (Prostacyclin) are produced by the kidneys as vasodilators in the afferent arterioles. PGE2 also inhibits sodium reabsorption in the renal tubules and water in the loop of Henle and collecting duct (6).

In diabetic patients who consume NSAIDs, COX-1 and COX-2 are inhibited, resulting in decreased prostaglandin levels (12). This results in vasoconstriction of the afferent arteriole, which can decrease the glomerular filtration rate (GFR) and cause significant sodium and water retention. In healthy individuals, fluid retention may appear as mild, subclinical edema (6). However, in diabetic patients who typically have left ventricular stiffness (diastolic dysfunction) or early diabetic nephropathy, a sudden increase in volume load can trigger a rapid response, leading to heart failure.

Peripheral Vasoconstriction and Afterload

In addition to their effects on the kidneys, prostaglandins play a role in blood vessels by helping maintain relaxed vascular tone. NSAID-induced inhibition of prostaglandins causes systemic vasoconstriction, resulting in increased blood pressure and systemic vascular resistance (afterload). Increased afterload causes the heart to work extra hard. In diabetic patients with myocardial conditions already experiencing oxidative stress and mitochondrial dysfunction, increased cardiac workload can lead to heart pump failure (6).

Diabetic Myocardial Dysfunction (Diabetic Cardiomyopathy)

It is important to understand that diabetic patients have a higher level of vulnerability than the non-diabetic population. The chronic hyperglycemic condition in T2DM causes structural changes in the heart due to the process of O-GlcNAcylation of cellular proteins and collagen buildup (fibrosis). This condition causes the heart to become stiff and less elastic, commonly known as diabetic cardiomyopathy (3). In this condition, the heart loses its ability to adapt to rapid changes in fluid volume. This is the basis for why even short-term use of NSAIDs, as in the study by Holt et al. (2023), is sufficient to result in hospitalization for heart failure in diabetic patients.

Significance of Glycemic Control and Age

The finding that the risk of heart failure due to NSAIDs is only significant in patients with high HbA1C levels indicates that good blood glucose control is not only important for preventing microvascular complications but can also act as a protector against the cardiotoxic effects of certain medications (9). Hyperglycemia appears to be a major cause of heart damage. myocardium, causing the heart to decompensate when exposed to triggers such as fluid retention due to NSAID use (2).

Advanced age (years) also appears to exacerbate the risk of heart failure due to age-related GFR decline and the possibility of subclinical ischemic heart disease. In older adults, the kidneys become highly dependent on prostaglandins to maintain perfusion, so COX inhibition due to NSAID use has a much more harmful impact than in younger (5).

The Paradox of Aspirin and GLP-1 RA

One of the most striking findings of this systematic review is the increased cardiovascular risk when aspirin is used concomitantly with GLP-1 RA. Theoretically, these two drugs have anti-inflammatory and antithrombotic properties that should be synergistic. However, research data indicate a significant increase in the risk of heart failure (9).

The underlying mechanism for this condition may involve "overcorrection" of platelet function due to disruption of the endothelial signaling pathway mediated by GLP-1. Low-dose aspirin is often used for cardioprotection; however, aspirin remains a COX-1 inhibitor that can affect the patient's renal hemodynamics to a certain extent, especially in patients with obesity and in diabetic patients who have a high metabolic load. This finding emphasizes that primary prevention with aspirin in diabetic patients must be tailored to the clinical condition (9).

Clinical Implications for Pain Management

Given the well-documented risks outlined in this review, pain management in patients with type 2 diabetes mellitus requires a more cautious and stratified approach.

Alternative Strategies

Given the risks summarized above, a more cautious and stratified approach to pain management in patients with type 2 diabetes mellitus is warranted.

Alternative strategies: Non-NSAID Analgesics: Paracetamol (acetaminophen) can be used as first-line pain relief for mild to moderate pain because it does not have a significant prostaglandin-inhibiting effect. Topical NSAIDs: Topical NSAID gels or patches can provide local pain relief with very low systemic absorption, resulting in a significantly reduced risk of cardiorenal side effects. Prudent Pain Management: For pain attacks, for example, in gout patients, colchicine can be an alternative option. However, clinicians should remain vigilant, as the risk of heart failure is equivalent to NSAID use in some studies. Short-term steroid use (glucocorticoids) may be another option, although close monitoring of blood sugar levels is necessary.

Limitations of Evidence

This systematic review has limitations that should inform further research. Most data sources come from journals with large-scale observational research designs. Although research methods such as case-crossover and propensity score matching have been used to minimize confounding factors, the risk of residual bias (Residual confounding) remains due to lifestyle factors and medication adherence that are not always perfectly recorded in administrative databases. In addition, the use of non-prescription NSAIDs (over the counter) is not fully represented. However, research in Denmark shows that non-prescription NSAID use only covers a small portion of the total systemic NSAID use in the country.

4. Conclusions

This systematic review demonstrates a strong and significant association between NSAID use and an increased risk of heart failure in patients with type 2 diabetes mellitus. Short-term NSAID use is associated with a 43% increased risk of first-time heart failure hospitalization, with the risk significantly higher in elderly patients and those with poor blood sugar control.

The primary mechanism of cardiac decompensation is triggered by prostaglandin inhibition, resulting in sodium retention, increased volume overload, and increased cardiac afterload in the already vulnerable myocardium of diabetic patients. In addition, adverse drug interactions between aspirin and GLP-1 RAs have been found, increasing the risk of heart failure. Therefore, a high level of caution is required when using multiple medications in this population.

In conclusion, clinicians should consider the use of NSAIDs in patients with type 2 diabetes mellitus. Consider safer alternative analgesics and ensure close cardiovascular monitoring. Increasing awareness of the cardiorenal risks of NSAID use is crucial for reducing morbidity and mortality from heart failure in the diabetic population worldwide.

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