Sotagliflozin in the Management of Heart Failure: A Comprehensive Review of Mechanisms, Evidence, and Clinical Implications

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Abstract

Heart failure (HF) and type 2 diabetes mellitus (T2DM) frequently coexist, substantially increasing cardiovascular (CV) risk and mortality. Sodium-glucose co-transporter 2 inhibitors (SGLT2is) have revolutionized the management of T2DM and HF by demonstrating CV and renal protective effects beyond glucose lowering. Among these, sotagliflozin, a dual SGLT1/SGLT2 inhibitor, offers additional metabolic benefits via gastrointestinal glucose modulation. This review comprehensively integrates findings from 27 studies analyzing sotagliflozin and SGLT2is in HF and diabetes.

The SOLOIST-WHF trial demonstrated sotagliflozin's efficacy in reducing CV death, HF hospitalizations, and urgent HF visits in T2DM patients following HF exacerbation. Meta-analyses confirmed reductions in major adverse cardiovascular events (MACE), all-cause mortality, and HF hospitalization. Sotagliflozin's dual mechanism further improves postprandial glycemic control, elevates GLP-1/GIP secretion, and may enhance myocardial efficiency, particularly in heart failure with preserved ejection fraction (HFpEF). Sotagliflozin also demonstrated safety and efficacy in type 1 diabetes mellitus (T1DM), reducing insulin needs and glucose variability.

Safety profiles align with SGLT2is, generally, but with additional gastrointestinal side effects from SGLT1 inhibition. Cost-effectiveness models project an incremental cost-effectiveness ratio (ICER) of ~\$45,596/QALY. Real-world eligibility studies suggest broad applicability of sotagliflozin in HF patients. Early initiation post-HF hospitalization offers rapid clinical benefit, while renoprotection remains robust even in advanced chronic kidney disease (CKD).

This review highlights sotagliflozin's unique dual mechanism, early benefits, and broad applicability, positioning it as a promising option for HF patients with diabetes.

Keywords: sotagliflozin, SGLT2 inhibitors, heart failure, diabetes mellitus, cardiovascular outcomes, cost-effectiveness

Abbreviations: HF: heart failure, T2DM: type 2 diabetes mellitus, CV: cardiovascular, SGLT2is: sodium-glucose cotransporter 2 inhibitors, MACE: major adverse cardiovascular events, T1DM: type 1 diabetes mellitus, HFpEF: heart failure with preserved ejection fraction, ICER: incremental cost-effectiveness ratio, QALY: quality-adjusted life year, CKD: chronic kidney disease, LVEF: left ventricular ejection fraction; eGFR: estimated glomerular filtration rate, HFrEF: heart failure with reduced ejection fraction, NHE1: sodium hydrogen exchanger, GLP-1: glucagon-like peptide-1, TIR: time-in-range, DKA: diabetic ketoacidosis, SOLOIST-WHF: Effect of Sotagliflozin on Cardiovascular Events in Patients with Type 2 Diabetes Post Worsening Heart Failure, SCORED: Effect of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes and Moderate Renal Impairment, DAPA-HF: Dapagliflozin and Prevention of Adverse Outcomes in Heart Failure, DAPA-CKD: Dapagliflozin and Prevention of Adverse Outcomes in Chronic Kidney Disease, DECLARE-TIMI: Dapagliflozin Effect on Cardiovascular Events—Thrombolysis in Myocardial Infarction, EMPA-REG: Empagliflozin Cardiovascular Outcome Event Trial in Type 2 Diabetes Mellitus Patients, EMPEROR-Reduced: Empagliflozin Outcome Trial in Patients with Chronic Heart Failure and a Reduced Ejection Fraction, CANVAS: Canagliflozin Cardiovascular Assessment Study, CREDENCE: Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation, VERTIS-CV: Evaluation of Ertugliflozin Efficacy and Safety Cardiovascular Outcomes Trial

1. Introduction

Heart failure (HF) remains a major public health concern and a leading cause of hospitalization, particularly among patients with type 2 diabetes mellitus (T2DM), who face a significantly elevated risk of cardiovascular (CV) morbidity and mortality. Despite existing therapies, residual risks remain high, especially following episodes of decompensated HF [1]. Over the past decade, sodium-glucose cotransporter 2 inhibitors (SGLT2is) have emerged as a cornerstone in HF management, demonstrating remarkable benefits not only in glucose control but also in reducing CV events and preserving renal function [2, 3].

Among these, sotagliflozin has garnered considerable attention due to its dual inhibition of SGLT2 and SGLT1, a mechanism that may confer broader therapeutic benefits compared to selective SGLT2 inhibition. While SGLT2 inhibition promotes glycosuria and natriuresis through renal pathways, SGLT1 inhibition in the gastrointestinal tract delays glucose absorption, enhances glucagon-like peptide-1 (GLP-1) secretion, and may offer neuroprotective and cardiometabolic effects [4, 5]. The drug's unique pharmacology has prompted investigations into whether dual inhibition provides additive or synergistic benefits in managing HF, especially in T2DM patients [6, 7].

The SOLOIST-WHF trial demonstrated that sotagliflozin, when initiated before or shortly after hospital discharge for worsening HF, significantly reduced the total number of CV deaths, hospitalizations, and urgent visits for HF by 33% [1]. Benefits were consistent across all left ventricular ejection fraction (LVEF) categories, including heart failure with preserved ejection fraction (HFpEF), a population previously lacking effective therapy [2, 8]. These findings suggest a potential shift toward early initiation of therapy in high-risk, recently decompensated patients, which could improve outcomes and reduce rehospitalizations [7, 9].

In parallel, the SCORED trial, which focused on T2DM patients with chronic kidney disease (CKD), showed a 26% reduction in the composite outcome of CV death, HF hospitalization, and urgent HF visits [2]. Uniquely, SCORED enrolled patients across all albuminuria stages and included a significant number with eGFR < 30 mL/min/1.73 m², a group often excluded from previous trials. Sotagliflozin's glycemic benefits were retained even in advanced CKD, likely due to its SGLT1-related glucose absorption delay [2, 10].

A pooled analysis of both trials showed a 28% risk reduction in major CV outcomes and notable benefits in patients with no prior HF history or normal EF, suggesting value in both primary and secondary prevention settings [2]. Real-world eligibility studies

reveal that over 25–60% of HF patients may meet criteria for sotagliflozin therapy under SOLOIST-WHF-like inclusion parameters [11], further supporting its broad clinical applicability.

In preclinical studies, sotagliflozin improved cardiac contractility and survival in zebrafish models of diabetic heart failure with reduced ejection fraction (HFrEF), via inhibition of sodium hydrogen exchanger (NHE1) pathways [12]. These mechanistic insights are complemented by observed improvements in postprandial glucose, GLP-1 levels, and myocardial energetics in both human and animal models [4, 5].

From an economic standpoint, sotagliflozin is consistently shown to be cost-effective. Modeling analyses revealed an incremental cost-effectiveness ratio (ICER) of ~\$45,596/QALY over a lifetime horizon [13]. Additional studies highlighted that up to 68% of the added pharmacy cost is offset by reduced hospital and emergency department utilization, with a manageable budget impact on payers [14]. Under value-based care models, sotagliflozin may enhance provider reimbursement by reducing readmissions and improving quality metrics [14].

Despite these benefits, dual inhibition is not without drawbacks. Increased incidence of gastrointestinal side effects like diarrhea and a small rise in severe hypoglycemia and diabetic ketoacidosis (DKA) have been reported, likely due to intestinal SGLT1 inhibition [1, 2]. However, there was no increased risk of amputation, differentiating sotagliflozin from early concerns seen with canagliflozin [15].

Network meta-analyses comparing sotagliflozin to other agents suggest it ranks among the top in reducing HF events and CV outcomes, although, dapagliflozin remains more favorable for all-cause mortality [6, 16]. These findings highlight the importance of tailoring therapy based on patient-specific risk profiles and therapeutic goals.

Recent guidelines from the European Society of Cardiology and the American Heart Association have acknowledged the role of SGLT2is, including sotagliflozin, in managing HF and T2DM. Notably, its early-onset benefit, observable within the first 28 days of therapy, supports its use during or immediately after hospital discharge [1, 7]. Furthermore, sotagliflozin's consistent efficacy across geographic regions, genders, ages, and renal function groups enhances its global relevance [1].

In conclusion, sotagliflozin represents a paradigm shift in managing HF in patients with T2DM, offering early, consistent, and cost-effective benefits through its unique dual SGLT1/2 inhibition. Backed by extensive trial data (SOLOIST-WHF, SCORED), real-world modeling, mechanistic insights, and comparative analyses, it stands out as a versatile agent in the expanding armamentarium for cardiometabolic disease. As healthcare continues to

embrace integrated and value-based approaches, sotagliflozin holds promise for improving both clinical outcomes and economic sustainability in high-risk populations.

2. Results and Discussion

HF and T2DM frequently coexist, each exacerbating the other's clinical course and increasing CV mortality [8, 17]. Despite available therapies, many patients remain at high residual CV risk, requiring novel therapeutic options that offer both metabolic and CV protection [10, 18].

SGLT2is, originally developed for glycemic control, have rapidly evolved into cornerstone treatments for HF across a range of ejection fractions. Among these, sotagliflozin is unique as the first dual inhibitor of both SGLT1 and SGLT2 [10, 19, 20].

2.1 Mechanism of action and metabolic effects

SGLT2 inhibition promotes glycosuria and natriuresis, thereby lowering blood glucose, reducing blood pressure, improving endothelial function, and enhancing renal protection [18, 20]. Sotagliflozin's additional SGLT1 inhibition delays intestinal glucose absorption, improves postprandial glucose levels, stimulates GLP-1 and peptide YY secretion, and may confer additional cardiac benefits [5, 10, 19].

The weight-reducing and blood pressure-lowering effects of sotagliflozin are believed to contribute to its overall CV benefits, similarly to other SGLT2is, as both obesity and hypertension are frequent comorbidities in patients with HF [21].

Compared to selective SGLT2is, sotagliflozin demonstrated superior postprandial glucose reduction and greater GLP-1 and GIP secretion [5], potentially enhancing myocardial efficiency and mitigating metabolic stress in HFpEF. A comprehensive summary comparing sotagliflozin with other major SGLT2is is provided in the table below (Table 1).

Drug	Mechanism	Key trials	Cardiovascular benefit	Unique advantages	Notable adverse effects	Cost- effectiveness
Sotagliflozin	Dual SGLT2 + SGLT1 inhibitor (20:1 selectivity)	SOLOIST- WHF, SCORED	↓ CV death, HF hospitalization, urgent HF visits (HR ~0.67); effective in HFpEF and HFrEF (1)	SGLT1 effect improves postprandial glucose, GLP-1, stroke ↓ 34% (2)	Diarrhea, hypoglycemia, DKA (slightly ↑), no ↑ in amputation risk	ICER ~\$45,596/QALY (Kim et al., 2024); budget- neutral over 5 yrs (14)
Dapagliflozin	Selective SGLT2 inhibitor	DAPA-HF, DAPA-CKD, DECLARE	↓ HF hospitalization (HR ~0.74), ↓ CV death in HFrEF; neutral in HFpEF (DECLARE-TIMI)	Strong mortality data in HFrEF; approved for CKD and HF irrespective of diabetes	Genital infections, volume depletion	Cost-effective; widely used and guideline endorsed
Empagliflozin	Selective SGLT2 inhibitor	EMPA-REG, EMPEROR- Reduced	↓ CV death, HF hospitalization (HR ~0.75); proven benefit in HFrEF and HFpEF	Strongest mortality reduction among early SGLT2is; fast- acting benefit	Risk of genital infections, ↑ hematocrit, caution in elderly	Cost-effective; supported by real-world data
Canagliflozin	Weak SGLT1, strong SGLT2 inhibition (1:250)	CANVAS, CREDENCE	↓ MACE, HF hospitalization (HR ~0.86); ↑ amputation risk in CANVAS trial	First to show renal endpoint protection (CREDENCE); dual effect proposed but limited (2)	↑ Risk of lower extremity amputation, fractures	Generally cost- effective; usage cautious due to safety concerns
Ertugliflozin	Selective SGLT2 inhibitor	VERTIS-CV	Neutral on MACE; modest ↓ in HF hospitalization	Good glycemic control; tolerability profile acceptable	Genital infections; less robust CV evidence	Less cost- effective compared to dapagliflozin or empagliflozin

Table 1: Comparative summary of major SGLT2 inhibitors.

2.2 Clinical trial evidence

The SOLOIST-WHF trial provided pivotal data demonstrating sotagliflozin's efficacy in patients with T2DM recently hospitalized for worsening HF. Sotagliflozin reduced the composite of CV death, HF hospitalizations, and urgent HF visits by 33% [1, 3, 8]. Benefits were consistent across both HFrEF and HFpEF populations [8]. Additionally, sotagliflozin significantly reduced total recurrent hospitalizations and improved days alive and out of hospital [22]. Complementing SOLOIST-WHF, the SCORED trial demonstrated sotagliflozin's renal particularly in patients with moderate to severe CKD, suggesting efficacy even in patients with eGFR < 30 ml/min/1.73 m² [10, 17].

Network meta-analyses confirmed that sotagliflozin consistently reduces HF hospitalizations, major adverse cardiovascular events (MACE), CV death, and all-cause mortality, with comparative efficacy to dapagliflozin and empagliflozin [6,16]. When directly compared to dapagliflozin, sotagliflozin displayed numerically greater mortality benefit in patients with recent HF decompensation, although statistical was not achieved due superiority to study heterogeneity [9]. The drug may offer unique patients advantages forwith recent hospitalization and T2DM, while dapagliflozin remains broadly used across HF phenotypes, including non-diabetics [9, 18].

Earlier phase 2 studies, such as the LX4211 trial, laid the groundwork by demonstrating sotagliflozin's safety, glycemic efficacy, and favorable tolerability in patients inadequately controlled on metformin [19], highlighting its early promise as a dual inhibitor. While most data pertain to T2DM, sotagliflozin has also shown efficacy in type 1 diabetes mellitus (T1DM), improving HbA1c, reducing insulin needs, lowering weight, and increasing time-in-range (TIR) [15]. These metabolic effects reinforce its potential in HF patients, where metabolic stress contributes to HF progression [15].

Aggarwal et al. [23] demonstrated that sotagliflozin significantly reduced the combined endpoint of CV mortality, hospitalization for HF, and urgent HF visits, with consistent benefits observed irrespective of baseline HbA1c levels. The treatment yielded a relative risk reduction of approximately 25–30% compared to placebo.

2.3 Therapeutic implications in heart failure management

Sotagliflozin offers several advantages in managing HF:

 Early initiation during hospitalization or immediately post-discharge improves CV outcomes [1, 8];

- Benefits extend across both HFrEF and HFpEF, filling a therapeutic gap for preserved EF [3, 8];
- Renal protective effects persist even in advanced CKD [17].

Real-world data suggest a large proportion of HF patients could be eligible for sotagliflozin therapy, supporting its broad clinical applicability [11]. In older adults with multiple comorbidities, SGLT2is, including sotagliflozin, are favored due to their low hypoglycemia risk and cardioprotective profile [11].

The benefits of sotagliflozin on patients' health status remained consistent across multiple subgroups, including across different levels of LVEF. Additionally, patients who initiated sotagliflozin prior to hospital discharge experienced substantial improvements in health status, with greater benefits than those receiving a placebo. Collectively, these results, along with the clinical efficacy and favorable safety outcomes observed in the SOLOIST-WHF trial, emphasize the importance of early initiation of sotagliflozin after stabilization of worsening HF, potentially providing rapid symptom relief and facilitating smoother transitions from inpatient care to home management [24].

The expanded use of SGLT2is in acute HF settings is increasingly supported. Early initiation during hospitalization is safe and associated with rapid benefit onset [8, 25].

2.4 Safety profile and adverse effects

Sotagliflozin's safety profile generally aligns with other SGLT2is, though SGLT1 inhibition may contribute to increased gastrointestinal side effects such as diarrhea [5, 10]. Other known risks include DKA, especially in insulin-treated populations, and mild genital infections [15]. Nonetheless, serious adverse events remain rare, and sotagliflozin remains well-tolerated in most clinical settings [8, 22].

During the COVID-19 pandemic, the antiinflammatory properties of SGLT2is led to investigations into their potential to mitigate cytokine storm phenomena in diabetic patients [26]. However, careful patient selection is warranted given the elevated risk of DKA in critically ill patients [26].

2.5 Cost-effectiveness and health economics

Cost-effectiveness analyses support sotagliflozin's economic value. Kim et al. [13] projected an ICER of \$45,596/QALY. Additional real-world economic models showed that reductions in hospitalizations and emergency visits offset much of the increased pharmacy cost, making sotagliflozin favorable in value-based care models [27].

Economic models demonstrated that sotagliflozin may reduce rehospitalizations by 34.5%, ED visits by 40%, and all-cause mortality by 18% [13], supporting its

formulary adoption for high-risk diabetic HF populations.

3. Future Directions

While the SOLOIST-WHF trial provides strong evidence, larger, longer-term randomized controlled trials comparing sotagliflozin directly to other SGLT2is remain warranted [6, 8, 9]. Ongoing research will further clarify its role in non-diabetic HF, advanced CKD, and HFpEF patients [10, 18].

4. Conclusion

The introduction of SGLT2is has dramatically reshaped the management of HF and T2DM, offering unprecedented CV and renal protection beyond glycemic control. Sotagliflozin, as the first dual SGLT1/SGLT2 inhibitor, adds further therapeutic potential through its combined renal and intestinal actions. The SOLOIST-WHF and SCORED trials, along with multiple meta-analyses, real-world studies, and cost-effectiveness models, support sotagliflozin's efficacy in reducing hospitalizations, CV death, and improving clinical outcomes across diverse HF phenotypes, including both HFrEF and HFpEF. Its rapid onset of benefit following HF hospitalization, favorable metabolic effects, and broad eligibility criteria distinguish it from selective SGLT2is. While sotagliflozin's safety profile is generally consistent with other agents in this class, its additional gastrointestinal effects due to SGLT1 inhibition require careful monitoring. As further research addresses the remaining evidence gaps, sotagliflozin is poised to become an increasingly valuable tool in modern cardiometabolic care.

Conflicts of Interest

The authors declare no conflict of interest.

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