Real-world Experience and Trends of Initiating Sodium-Glucose Cotransporter 2 Inhibitors among Hospitalized Patients with Acute Heart Failure

Saleh Sharif MD[1,2,3], Emran El Ukbi MD[1,3], Herschel Horowitz MD[1,3], Eran Kalmanovich MD[2,3], and Dror Cantrell MD[1,3]

[1]Department of Internal Medicine C, Shamir Medical Center (Assaf Harofeh), Zerifin, Israel
[2]Department of Cardiology Department, Shamir Medical Center (Assaf Harofeh), Zerifin, Israel
[3]Gray Faculty of Medical and Health Sciences, Tel Aviv University, Tel Aviv, Israel

ABSTRACT **Background:** Initiating oral antidiabetic therapy, such as sodium-glucose cotransporter 2 (SGLT2) inhibitors, is generally not recommended during hospitalization. However, guidelines since 2021 have supported their use in heart failure with reduced ejection fraction (HFrEF), and since 2023 in preserved ejection fraction (HFpEF).

Objectives: To assess the safety and outcomes of initiating SGLT2 inhibitors during hospitalization for acute heart failure (HF).

Methods: We conducted a historical cohort study of 307 patients admitted with acute HF between October 2018 and April 2022. Patients were grouped as chronic SGLT2i users, new initiators during hospitalization, or controls who did not receive SGLT2i.

Results: Among the 307 patients, 50.4% had HFrEF, 30.8% HFpEF, and 18.8% HF with mildly reduced ejection fraction. In-hospital mortality was 3.6% (11 patients); 2-year mortality was 37.7% (116 patients). New SGLT2i initiators had the lowest 2-year mortality (22.2%) compared to controls (43.9%) and chronic users (41.8%) (P = 0.008). They also had the lowest 1-year rehospitalization rates (18.3% vs. 35.5% vs. 32.8%; P = 0.025). Multivariable analysis identified older age and co-morbidities as independent predictors of mortality. SGLT2i initiation was associated with reduced rehospitalization. Adverse effects occurred in 15.6% of SGLT2i users, mainly acute kidney injury.

Conclusions: In-hospital SGLT2 inhibitor initiation in patients with HF appears safe and is associated with reduced post-discharge mortality and readmission rates.

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KEY WORDS: heart failure, mortality, readmission, sodium-glucose cotransporter 2 (SGLT2) inhibitors

Heart failure (HF) is a leading cause of morbidity and mortality worldwide, with a 28% one-year mortality rate following hospitalization for acute HF [1]. In Israel, HF is the most frequent cause of hospitalization among patients aged 65 years and older, accounting for approximately 26,000 hospitalizations annually [2].

Sodium-glucose cotransporter 2 inhibitors (SGLT2i) were first approved for the treatment of diabetes mellitus in 2013 [3]. Landmark trials have demonstrated their cardiovascular benefits, leading to their expanded use in heart failure treatment.

The EMPA-REG OUTCOME trial showed that empagliflozin reduced cardiovascular deaths and heart failure hospitalizations, and slowed kidney disease progression in patients with type 2 diabetes and high cardiovascular risk [4]. The SOLOIST-WHF trial found that sotagliflozin reduced cardiovascular deaths and heart failure events in recently hospitalized patients, with benefits observed regardless of ejection fraction and even when initiated pre-discharge [5]. The DICTATE-AHF trial suggested that dapagliflozin may improve diuretic efficiency in acute decompensated heart failure, although it did not achieve statistical significance for its primary outcome [6]. Together, these studies highlight the broad cardiovascular benefits of SGLT2 inhibitors in heart failure management.

As a result of these findings, practice guidelines began strongly recommending SGLT2i therapy for heart failure with reduced ejection fraction (HFrEF) in 2021 [7] and for heart failure with preserved ejection fraction (HFpEF) in 2023 [8]. These recommendations were subsequently adopted by the Israeli drug registry [9].

However, inpatient use of SGLT2i has raised safety concerns due to potential side effects, including transient renal impairment, an increased risk of urinary tract infections, euglycemic ketoacidosis, hypotension, and falls [10]. The 2020 American Diabetes Association (ADA) guidelines previously discouraged the use of SGLT2i and

other oral antidiabetic medications in hospitalized patients with heart failure [11]. However, the updated 2024 ADA guidelines now recommend initiating and continuing SGLT2i therapy in the inpatient setting [12].

Before the introduction of current HF guidelines, SGLT2i treatment was primarily used for diabetes mellitus, meaning that a subset of hospitalized HF patients had already been receiving chronic SGLT2i therapy. In this study, we evaluated the safety and efficacy of SGLT2i treatment during acute HF hospitalization.

PATIENTS AND METHODS

STUDY POPULATION AND DESIGN

This retrospective study analyzed heart failure patients admitted to the cardiology and internal medicine departments at Shamir Medical Center, a tertiary care university hospital in central Israel. The study included all patients with an ICD-9 discharge diagnosis of acute heart failure admitted between October 2018 and February 2022, excluding those hospitalized in 2020 to mitigate the potential impact of the coronavirus disease 2019 (COVID-19) pandemic on study results.

Patients were divided into three groups:

- Group A: SGLT2i therapy initiated during the index hospitalization
- Group B: Chronic SGLT2i therapy, defined as treatment with SGLT2i before and after hospitalization
- Group C (Control group): Patients not treated with SGLT2i

As outlined in the guideline changes, the control group comprised heart failure cases admitted before SGLT2i therapy became standard practice. Exclusion criteria included patients younger than 18 years, pregnant patients, and those with type 1 diabetes mellitus.

Mortality and rehospitalization outcomes were compared across these groups, accounting for demographic differences, co-morbidities, and available clinical and echocardiographic data. Drug-related side effects observed in this study were analyzed within the context of known SGLT2i-associated risks reported in the literature.

DATA COLLECTION

Data on all hospitalizations, including demographic characteristics such as age and sex, echocardiographic findings, laboratory values at admission, and in-hospital mortality, were retrieved from electronic health records via the hospital's patient registry. Mortality data were obtained from the Israeli Ministry of the Interior as of March 2024. Functional status was assessed using the Norton Scale [13]. Comparisons were made based on SGLT2i treatment groups.

STATISTICAL ANALYSIS

Qualitative data were expressed as numbers and percentages, while quantitative data distribution was assessed using a histogram and the Kolmogorov-Smirnov test. Normally distributed variables were reported as means with standard deviations, whereas non-normally distributed variables were presented as medians with interquartile ranges.

For comparisons between groups discrete and categorical variables were analyzed using the chi-square test or Fisher's exact test, as appropriate. Continuous variables were compared using the analysis of variance test or the Kruskal-Wallis test, depending on data distribution.

A Kaplan-Meier survival analysis was applied to assess mortality during the follow-up period, and differences between groups were compared using the log-rank test. A multivariable Cox regression model was used to investigate the association between patient groups and mortality while adjusting for potential confounders. Variables that differed significantly between groups and those known to be associated with mortality were included in the multivariable model.

The multivariable analysis included two blocks. In the first block, age and sex were forced into the regression model. In the second block, additional variables were entered and then a backward stepwise method was applied using a P-value > 0.1 as the criterion for variable removal.

The same methods were applied to assess first rehospitalizations. In addition, negative binomial regression was used to examine the association between treatment groups and the number of rehospitalizations per year for each patient.

All statistical tests were 2-sided, and a P-value < 0.05 was considered statistically significant. Statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics software, version 28 (SPSS, IBM Corp, Armonk, NY, USA).

ETHICS APPROVAL AND INFORMED CONSENT

The study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee at the Yitzhak Shamir (Assaf Harofeh) Medical Center, Zerifin, Israel (approval number 004923 ASF). Informed consent was not obtained from the patients because it was not requested for this retrospective study.

RESULTS

THE ENTIRE SAMPLE

Table 1 provides an overview of the demographic, clinical, and laboratory characteristics of the 307 patients included in the study. The cohort had a mean age of 72.7 ± 13.39 years, with 40.1% being female. Among these patients, 40.7% were admitted to the cardiology ward. The most prevalent co-morbidities included heart failure and related conditions such as coronary artery disease, diabetes mellitus, and hypertension. Functional capacity, assessed using the Norton scale, indicated that 70.7% of patients had preserved functional status. Echocardiographic assessments were performed in 73% of the cohort during hospitalization, revealing the distribution of heart failure phenotypes: 50.4% with HFrEF, 30.8% with HFpEF, and 18.8% with HFmrEF. The most prescribed medications included renin-angiotensin-aldosterone system inhibitors, statins, beta-blockers, furosemide, and metformin.

COMPARISON OF PATIENT OUTCOMES AND SENSITIVITY ANALYSIS

Table 2 compares outcomes among SGLT2i treatment subgroups (new initiation, chronic use, and control group). During the index hospitalization, 11 of 307 patients (3.6%) died, while 116 (37.78%) died within 2 years post-discharge. Overall, 27 patients (8.8%) were readmitted to the hospital within one month, and 89 (30%) within one year. Comparative analysis revealed that patients who initiated SGLT2i therapy during hospitalization had the lowest 2-year mortality rate compared to the control and chronic use groups (22.2% vs. 43.9% vs. 41.8%, respectively; $P = 0.008$) [Figure 1].

Similarly, the inpatient SGLT2i initiation group had the lowest one-year rehospitalization rate (18.3% vs. 35.5% vs. 32.8%; $P = 0.025$) [Figure 2].

A multivariable regression analysis was conducted to adjust for potential confounding factors, excluding variables without statistical significance [Table 1]. Factors associated with increased two-year mortality included chronic obstructive pulmonary disease (COPD) (hazard ratio [HR] 1.712, 95% confidence interval [95%CI], 1.003–2.923; $P = 0.049$), malignancies (HR 2.293; 95%CI 1.144–4.499; $P = 0.019$), atrial fibrillation (HR 1.626; 95%CI 1.048–2.522; $P = 0.03$), and a lower body mass index (HR 0.944; 95%CI 0.908–0.981; $P = 0.004$). In addition, a higher Norton score was associated with increased mortality (HR 0.872; 95%CI 0.821–0.927; $P < 0.001$).

A sub-analysis, including only patients with echocardiographic data, showed that higher ejection fractions (HR 0.975; 95%CI 0.956–0.995; $P = 0.016$) were associated with lower mortality, whereas severe valvular disease was linked to higher mortality (HR 2.995; 95%CI 1.722–5.209; $P < 0.001$).

A multivariable regression analysis using a backward selection method demonstrated that initiating SGLT2i therapy

Figure 1. Comparison between subgroups 2-year mortality

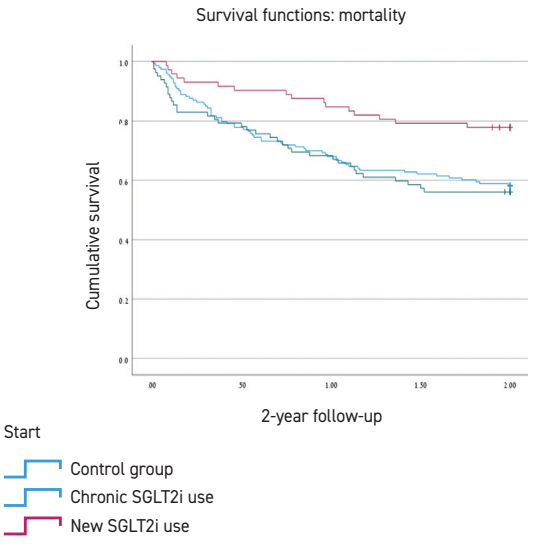

Figure 2. Comparison between subgroups 1-year rehospitalizations

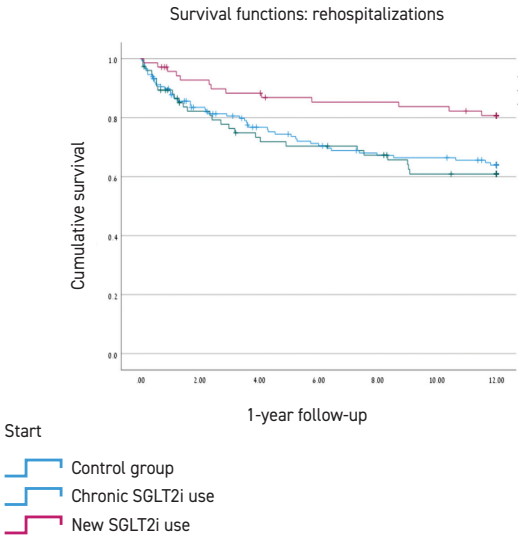

Table 1. Population characteristics

Variables	Overall	New use	Chronic use	Control	*P*-value
	307	72 (23.5%)	82 (26.7%)	153 (49.8%)	0.01
Age in years	72.7 ± 13.39	67.67 ± 14.3	71.05 ± 10.94	75.97 ± 13.27	0.001■■
Sex (female)	123 (40.1%)	17 (23.6%)	31 (37.8%)	75 (49%)	0.01■
Intensive cardiac care unit hospital	125 (40.7%)	58 (80.6%)	37 (45.1%)	30 (19.6%)	0.01■■
Body mass index	30.014 ± 6.48	28.6 ± 5.4	31.46 ± 7.4	29.9 ± 6.3	0.253
Norton score (18+)■	208 (70.7%)	53 (76.8%)	52 (69.3%)	103 (68.7%)	0.447
Co-morbidities					
Coronary artery disease	172 (56%)	40 (55.6%)	58 (70.7%)	74 (48.4%)	0.004■
Heart failure	212 (69.1%)	51 (70.8%)	69 (84.1%)	92 (61.1%)	0.001■■
Peripheral vascular disease	36 (11.7%)	11 (15.3%)	15 (18.3%)	10 (6.5%1)	0.016■■
Stroke	49 (16%)	10 (13.9%)	16 (19.5%)	23 (15%)	0.577
Dementia	19 (6.2%)	1 (1.4%)	4 (4.9%)	14 (9.2%)	0.067
COPD	53 (17.3%)	10 (13.9%)	20 (24.4%)	23 (15%)	0.134
Diabetes mellitus	197 (64.2%)	43 (59.7%)	72 (87.8%)	92 (53.6%)	0.001■■
Chronic kidney disease	69 (22.5%)	11 (15.3%)	22 (26.8%)	36 (23.5%)	0.209
Tumor	24 (7.8%)	6 (8.3%)	7 (8.5%)	11 (7.2%)	0.919
Hypertension	262 (85.3%)	55 (76.4%)	67 (81.7%)	140 (91.5%)	0.006■■
Atrial fibrillation	110 (35.8%)	20 (27.8%)	30 (36.6%)	60 (39.2%)	0.245
Chronic medications					
Metformin	117 (38.4%)	25 (35.2%)	49 (59.8%)	43 (28.3%)	0.001■■
Dpp4 inhibitors	32 (10.5%)	5 (7%)	10 (12.2%)	17 (11.2%)	0.54
Sulfonylureas	29 (9.5%)	13 (15.9%)	1 (1.4%)	15 (9.9%)	0.01■■
Thiazolidinedione	4 (1.3%)	2 (2.8%)	1 (1.2%)	1 (0.7%)	0.353
GLP1 agonists	15 (4.9%)	2 (2.8%)	8 (9.8%)	5 (3.3%)	0.084
Insulin	73 (23.9%)	10 (14.1%)	32 (39%)	31 (20.4%)	0.001■■
RAAS inhibitors	185 (60.7%)	42 (59.2%)	59 (72%)	84 (55.3%)	0.043■
Sacubitril/valsartan	16 (5.2%)	6 (8.5%)	8 (9.8%)	2 (1.3%)	0.003■■
Mineralocorticoids	66 (21.6%)	16 (22.5%)	22 (26.8%)	28 (18.4%)	0.322
Statins	201 (65.9%)	49 (69%)	62 (75.6%)	90 (59.2%)	0.034■
Ezetimibe	24 (7.9%)	7 (9.9%)	11 (13.4%)	6 (3.9%)	0.029■
Beta-blockers	228 (74.8%)	45 (63.4%)	71 (86.6%)	112 (73.7%)	0.004■
Furosemide	186 (61 %)	30 (42.3%)	62 (75.6%)	94 (61.8%)	0.001■■■
Antiarrhythmics	50 (16.4%)	15 (21.1%)	19 (23.2%)	16 (10.5%)	0.021■■
Echocardiography					
Echo during hosp.	224 (73%)	69 (95.8%)	64 (78%)	91 (61.4%)	0.001■■■
Sev valvular	48 (21.4%)	13 (18.8%)	15 (23.4%)	20 (22%)	0.801
HFpEF (50+%)	69 (30.8%)	8 (11.6%)	22 (34.4%)	39 (42.9%)	0.001■■
HFmEF (40–49%)	42 (18.8%)	8 (11.6%)	17 (26.6%)	17 (18.7%)	0.001■
HFrEF (< 40%)	113 (50.4%)	53 (76.8%)	25 (39.1%)	35 (38.5%)	0.001■■
Lab values					
Hemoglobin (g/l)	12.06 ± 2.0	12.68 ± 2	12.18 ± 2	11.7 ± 2.1	
A1c%	7.33 ± 1.65	7.29 ± 1.9	7.29 ± 1.3	7.42 ± 1.7	0.787
Creatinine (mg/dl)	1.2 ± 0.5	1.15 ± 0.4	1.3 ± 0.6	1.21 ± 0.47	0.298
Glomerular filtration rate (mmol/l)	63.86 ± 24.8	71.52 ± 24.5	61.7 ± 24	61.38 ± 24.79	0.011■■
< 30	37 (11.4%)	2 (2.8%)	6 (16.2%)	29 (17%)	0.249
30–44.99	71 (21.8%)	11 (15.3%)	19 (23.2%)	41 (24%)	0.249
45–59.99	56 (17.2%)	12 (16.7%)	15 (18.3%)	29 (17%)	0.249
60+	161 (49.5%)	47 (65.3%)	42 (51.2%)	72 (41.1%)	0.249
B-type natriuretic peptide (pg/ml)	6020 ± 6478	6064.44 ± 6546	6937 ± 7970	4965 ± 4149	0.818

COPD = chronic obstructive pulmonary disease, HFmEF = heart failure with mildly reduced ejection fraction, HFpEF = heart failure with preserved ejection fraction, HFrEF = heart failure with reduced ejection fraction, RAAS = renin-angiotensin-aldosterone system

■ Comparing new vs. chronic use

■ Comparing new vs. control

■ Comparing chronic vs. control

A Norton score of 18 or higher indicates a lower risk for pressure ulcers and is commonly used as a measure of frailty

Table 2. Outcomes

Variables	Overall	New use	Chronic use	Control	*P*-value
In-hospital mortality	11 (3.6%)	1 (1.4%)	6 (7.3%)	4 (2.6%)	0.139
2-year mortality from index hospitalization	116 (37.78%)	16 (22.2%)	36 (43.9%)	64 (41.8%)	0.008
1-month readmissions from index hospitalization	27 (8.8%)	3 (4.22%)	8 (10.5%)	16 (10.7%)	
1-year readmissions from index hospitalization	89 (30%)	13 (18.3%)	27 (35.5%)	49 (32.8%)	0.025

during hospitalization was associated with a lower rehospitalization rate (HR 0.49; 95%CI 0.259–0.929; $P = 0.029$). A negative binomial regression analysis further revealed that male sex (incidence rate ratio [IRR] 1.82; 95%CI 1.127–2.937; $P = 0.014$) and a preexisting diagnosis of HF (IRR 1.64; 95%CI 0.99–2.89; $P = 0.05$) were associated with higher hospitalization rates. Conversely, inpatient initiation of SGLT2i therapy was linked to a lower rehospitalization rate (IRR 0.38; 95%CI 0.212–0.714; $P = 0.002$).

Among all patients, 24 (15.6%) who received SGLT2i therapy during hospitalization experienced adverse effects. The most commonly reported complication was acute renal failure, affecting 12 patients. Urinary tract infections were the second most frequent adverse effect, occurring in six patients. In addition, there were three cases of diabetic ketoacidosis and one case of hypoglycemia.

DISCUSSION

In this cohort study, we evaluated the efficacy and safety of SGLT2i therapy during hospitalization for acute heart failure in both chronic and first-time users. The findings revealed that inpatient initiation of SGLT2i was associated with significantly lower 2-year mortality and 1-year rehospitalization rates compared to chronic users and patients not receiving SGLT2i therapy. These results align with the EMPA-REG and SOLOIST-WHF trials [4,5], which reported reductions in cardiovascular deaths with SGLT2i use. However, our study uniquely highlights these benefits in a real-world clinical setting, thereby enhancing the applicability of findings from controlled trials.

Patients who initiated SGLT2i during hospitalization were generally younger, had fewer co-morbidities, and were more frequently admitted to cardiology wards. In contrast, chronic SGLT2i users were typically older, had a greater burden of co-morbidities, such as diabetes mellitus and ischemic heart disease, and were more commonly hospitalized in internal medicine wards. The control group, which had the highest prevalence of HFpEF, also had more advanced age and co-morbidities, consistent with existing literature [14] on patients admitted to internal medicine wards. These findings reflect the evolving role of SGLT2i in heart failure management beyond diabetes, addressing its previous underutilization in this population [15].

Despite presenting with more severe clinical conditions, such as higher rates of HFrEF and ICCU admissions, patients who initiated SGLT2i during hospitalization experienced better outcomes. This result may be attributed to their younger age, lower co-morbidity burden, and specialized care they received. These findings underscore the importance of early SGLT2i initiation and specialized care in improving outcomes, particularly for high-risk patients.

A multistep sensitivity analysis identified frailty, COPD, and atrial fibrillation as significant predictors of increased mortality. Consistent with previous studies [16], these findings highlight the need for targeted interventions to improve outcomes in high-risk patients, further reinforcing the potential role of SGLT2i therapy in this subgroup. Similarly, older patients and those with more co-morbidities had higher 1-year rehospitalization rates, aligning with prior research [17,18], which identified age and co-morbidity burden as key predictors of rehospitalization. These results emphasize the need for closer monitoring and individualized care strategies.

Adverse effects were observed in only 15.6% of patients receiving SGLT2i therapy, with acute renal failure being the most common. However, these adverse events may also be linked to other risk factors, such as nephrotoxic medications and cardiogenic shock. These findings align with previous studies [19,20], confirming the safety of SGLT2i therapy during heart failure hospitalizations and reinforcing its utility in this clinical setting.

LIMITATIONS

This single-center retrospective study has limited generalizability and does not establish causality. Despite multivariate analyses, subgroup differences remained. We observed a trend toward SGLT2 inhibitor (SGLT2i) use in younger, nondiabetic HFrEF patients. Biases were addressed through matching and a multistep analytical approach.

Adverse effects during hospitalization were minimal but may have been underreported. Notably, side effects in the control group were not specifically assessed, as the study primarily focused on SGLT2i-related outcomes and safety. Some reported adverse events, such as acute kidney injury, may have been influenced by other factors, including sepsis and cardiogenic shock, making it difficult to attribute them solely to SGLT2i use.

The study period partially overlapped with the COVID-19 pandemic, which significantly impacted mortality and hospitalization rates. To mitigate this effect, data from 2020, the peak mortality period in Israel, was excluded.

Due to technical limitations restricting access to follow-up data, post-discharge side effects, and outpatient SGLT2i initiation could not be fully assessed. Consequently, long-term outcomes between inpatient initiation and outpatient continuation, as well as potential post-discharge adverse events, remain unknown.

These limitations, along with the complex clinical backgrounds of the patients, should be carefully considered when interpreting the study's findings.

CONCLUSIONS

SGLT2 inhibitors were found to be safe for patients hospitalized with acute HF. Their initiation was associated with reduced mortality and rehospitalization, including in nondiabetic patients.

Correspondence

Dr. S. Sharif
Dept. of Internal Medicine C, Shamir Medical Center (Assaf Harofeh), Zerifin 70300, Israel
Email: salehsharif6@gmail.com

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An ounce of mother is worth a pound of clergy.
Spanish proverb