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Original Article

Pilot Study Evidence on Cardiac Benefits of Empagliflozin, A Changing Landscapes in Heart Failure Treatment

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ABSTRACT

Background: Despite conventional cardiac agents, the prognosis of heart failure remains unmet to improve clinical presentations, and morbidity remains high. Growing evidence from multiple placebo-controlled studies on Sodium-Glucose Transporter Level Two inhibitors (SGLT2i) is evaluating cardiovascular benefits, transforming the landscape of Heart Failure treatment. The actual magnitude of SGLT2i in cardiovascular benefits is yet to be evaluated. **Aim:** To examine the feasibility of testing the efficacy of SGLT2i in Heart Failure patients irrespective of their diabetes status. **Materials and Methods:** This was a single-site prospective randomized interventional study. Data collected from patients were analyzed by paired and unpaired t-test statistical methods. **Results and Discussion:** Over 12 weeks, the interventional group receiving empagliflozin showed a significant reduction in systolic blood pressure (–3.72 mmHg, p=0.049) and a significant rise in diastolic blood pressure (+3.10 mmHg, *p*=0.047). While heart rate improved (–1.28 bpm), the change was not statistically significant (*p*=0.134). In contrast, the conventional group demonstrated only minimal, non-significant changes in SBP, DBP, and HR. Improvements in ejection fraction for both the Conventional (+0.40%) and Interventional (+3.58%) groups were statistically significant (*p*=0.005, *p*=0.000, respectively). **Conclusion:** Present pilot study findings indicate that interventional therapy with empagliflozin confers meaningful clinical and statistically significant advantages over conventional treatment, especially in enhancing key prognostic cardiac markers.

Keywords: Conventional Treatment, Empagliflozin, Heart Failure, SGLT2i.

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INTRODUCTION

Empagliflozin's (EMZ) are Sodium Glucose Transporter Level Two inhibitors (SGLT2i) which are orally administered hypoglycemic agents acts by promoting glucose excretion in the proximal tubule and collecting duct as illustrated in Figure 1. Phase III clinical Trial evidences on Type Two Diabetes Mellitus (T2DM) patients taking 10 mg, 25 mg once daily were shown an outcome of 1% reduction in HbA_{1C}, 3 mmHg reduction in their systolic and Diastolic Blood Pressure as well as 2-3 kg reduction in body weight with a treatment of 24-month duration (Steiner *et al*., 2016; Klug *et al*., 2023). This promising evidence laid the corner stone of SGLT2 inhibitors in Diabetes Mellitus as best drug of choice predominantly in diabetes patients with comorbidities like heart failure, kidney disease and other cardiac disorders while SGLT2inhibitors evolved in the market as third line drug of choice for T2DM.

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Worldwide, the burden of heart failure has increased to an estimated 23 million people, and approximately 50% of cases are HF with Reduced Ejection Fraction (HFrEF). Heart failure affects an estimated 6.5 million US adults and accounts for an estimated 1 million hospitalizations annually, of which approximately 50% are caused by HFrEF, with the balance caused by heart failure with midrange or preserved ejection fraction (Voors *et al*., 2022). Once developed, heart failure results in significant morbidity and mortality, with a 1-year mortality rate of 7.2% and a 1-year hospitalization rate of 31.9% in patients with chronic heart failure, and in patients hospitalized for acute heart failure, these rates increase to 17.4% and 43.9%. The rate of re hospitalization among patients with HFrEF is close to 29% within 60-90 days of discharge from hospital (Ambrosy *et al*., 2014).

Patients with Heart Failure and Preserved Ejection Fraction have experienced a high burden of clinical presentations and physical limitations to which the conventional treatments were unmet to improve the outcome (Nassif *et al*., 2021). The impaired Health status and deliberating clinical presentation of Heart Failure focuses on the need of novel cardiac agents despite the use of conventional therapies. The EMPA-REG OUTCOME trial showed that a SGLT2i, empagliflozin, reduced the risk of major Cardiovascular (CV) events by 14%, CV mortality by

38%, and hospitalization for HF by 35% in patients with T2D and established CV disease. These effects were evident early after treatment initiation and were consistent in those HF patients with and without Diabetes (Fitchett *et al.*, 2016).

SGLT2i target the cardio metabolic abnormalities through verity of mechanism and have shown to reduce the risk of cardiovascular morbidities and mortalities. The multidimensional effects of SGLT2i Heart Failure showed 14% relative reduction in morbidities through various mechanisms like effect on insulin resistance in cardiac metabolism improving the oxygen delivery, cardiac fuel energetics, mitochondrial function, regulated blood pressure and preload reduction (Damman *et al.*, 2020). All the above-mentioned cardiovascular benefits as illustrated in Figure 2 from SGLT2 inhibitors are working consistently in achieving best cardiovascular outcomes and become a promising drug of choice for Heart Failure. Despite reducing the morbidity of HF, it also significantly reducing the number of hospital visits, emergency visits and duration of hospitalizations among Heart failure patients (Cardoso *et al.*, 2021; Liu *et al.*, 2024).

This study sought to evaluate the cardiac benefits of SGLT2 inhibitors receiving patients compared with patients receiving conventional treatment of HF with a follow up of 12 weeks from baseline, and the end points were set to be improvement in systolic blood pressure, diastolic blood pressure, pulse rate, and ejection fraction.

MATERIALS AND METHODS

Study design and study settings

This single site pilot study was conducted at the Department of Cardiology, Adichunchanagiri Hospital and Research Centre (AH&RC), B.G. Nagara after obtaining the approval of Institutional Ethical Committee and we reported this article as per STROBE Checklist. It employed a prospective, randomized, interventional study design carried out over a period of one year, starting from the enrolment of the first participant and continuing until the completion of a 12-week follow-up for the last enrolled subject.

Eligibility criteria and Data collection

Participants were recruited based on clearly defined inclusion and exclusion criteria. Eligible participants included Heart Failure patients aged above 18 years who provided informed consent and were available for a minimum of 12-week follow-up. Additional inclusion criteria were a confirmed diagnosis of heart failure for at least six months with supporting echocardiographic evidence, Left Ventricular Ejection Fraction (LVEF) of less than 40%, or elevated NT-pro BNP levels in cases where LVEF was greater than 40%. Patients also needed to have established atherosclerotic cardiovascular disease with a history of Major Adverse Cardiac Events (MACE), qualifying them for Empagliflozin therapy, and had to be adherent to their current medications. Exclusion criteria included any myocardial infarction, coronary artery bypass graft surgery, other major cardiovascular procedures, or stroke within 90 days before the first study visit, as well as patients who had undergone heart transplantation or were on a transplant waiting list, those with an implanted Left Ventricular Assist Device (LVAD), individuals with gastrointestinal conditions that could impact drug absorption. Data collection tools included an informed consent form, structured baseline data collection forms encompassing demographics, screening results, and detailed medical histories, as well as follow-up records of hospitalizations, healthcare resource use, echocardiographic reports, vital signs (including blood pressure and pulse rate), and standardized assessments at the baseline and follow-up after 12 weeks.

Statistical analysis

All the collected data were entered into Microsoft Excel sheets, thoroughly verified, and analysed Statistical Package for the Social Sciences (SPSS) free version 25.0 developed by IBM (Armonk *et al.*, 2017). The categorical and continuous data were presented as frequency with percentages and mean with standard deviation respectively. And Student paired and unpaired t test were implied for comparing the within and between outcomes.

RESULTS

Demographic and Baseline Data

A total of 100 patients were listed as listed in Table 1, with n=50 patients assigned to the interventional group receiving empagliflozin and n=50 patients to the conventional treatment group. In the interventional group, 29 participants were male and 21 were female, while in the conventional group, the gender distribution was balanced with 25 males and 25 females. With respect to age, 18 subjects in the interventional group were younger than 50 years, and 32 were aged above 50 years, whereas in the conventional group the distribution was equal, with 25 participants each below and above 50 years of age.

The prevalence of diabetes was identical across both groups, with 26 patients being diabetic and 24 non-diabetics. Hypertension was universally present in all patients across both groups. According to the New York Heart Association (NYHA) functional classification, in the interventional group, 29 patients were in Class II, 13 in Class III, and 8 in Class IV, whereas in the conventional group, 33 patients were in Class II, 15 in Class III, and only 2 in Class IV. Ejection Fraction (EF) distribution revealed that in the interventional group, 17 patients had EF >40%, 23 patients had EF between 30-40%, and 10 patients had EF <30%. In the conventional group, 20 patients had EF >40%, 17 had EF between 30-40%, and 13 had EF <30%.

Regarding concomitant medications, anti-diabetic drugs were received by 26 patients in each group. Beta-blocker use was higher in the conventional group (100%) compared to 31 patients

in the interventional group. Digoxin was prescribed in 16 cases in the interventional group and 18 in the conventional group.

Change in Cardiac Parameters

The effect of treatment on cardiac parameters was assessed over 12 weeks for the intervention group; the effect was tabulated on Table 2 and Conventional group as listed in Table 3. In terms of Systolic Blood Pressure (SBP), patients in the interventional group demonstrated a greater reduction, with mean SBP decreasing from 135.52±24.73 mmHg at baseline to 131.80±14.92 mmHg at follow-up, corresponding to a mean reduction of 3.72 mmHg. In contrast, the conventional group showed only a modest decline from 131.92±18.50 mmHg to 130.64±12.18 mmHg, with a mean change of 1.28 mmHg.

For Diastolic Blood Pressure (DBP), the interventional group exhibited a slight rise, increasing from 81.20±11.41 mmHg to 84.30±7.61 mmHg, yielding a net increase of 3.10 mmHg, whereas the conventional group remained essentially unchanged, moving from 81.46±14.53 mmHg at baseline to 81.42±9.37 mmHg after follow-up, with a negligible reduction of 0.04 mmHg.

Improvement in Ejection Fraction (EF) was more pronounced in the interventional group, which showed an increase from 41.00±8.78% at baseline to 44.58±7.68% after 12 weeks, reflecting a mean gain of 3.58%. By comparison, the conventional group displayed only a very minimal improvement, with EF rising from 48.96±7.43% to 49.36±6.95%, a mean increase of just 0.4%.

With respect to Heart Rate (HR), the interventional group showed a small reduction, decreasing from 82.32±10.93 beats/min to 81.04±7.86 beats/min, a net change of 1.2 beats/min. Similarly, the conventional group also demonstrated a minor decline from 81.20±18.46 beats/min to 79.94±13.14 beats/min, amounting to a change of 1.26 beats/min and all the mean deference's were represented in Figure 3.

Statistical Analysis, paired sample correlation

The paired sample correlation analysis demonstrated a strong and statistically significant correlation between baseline and follow-up values in both groups for most cardiac parameters as presented on Table 4. In the conventional group, systolic blood pressure (r=0.898, $p<0.001$), diastolic blood pressure (r=0.808, $p<0.001$), ejection fraction (r=0.993, $p<0.001$) and heart rate (r=0.911, $p<0.001$) all showed strong correlations. Similarly, in the interventional group, systolic blood pressure (r=0.901, $p<0.001$) and heart rate (r=0.849, $p<0.001$) also displayed strong associations, while diastolic blood pressure showed a moderate correlation (r=0.417, $p=0.003$). Notably, ejection fraction in the interventional group also showed a highly significant correlation (r=0.811, $p<0.001$), suggesting consistent improvements with treatment.

Statistical Analysis, Student's *t*-test results

The independent Student's *t*-test results as on Table 5 highlight the comparative efficacy between the two groups. In the conventional group, none of the cardiac parameters showed statistically significant changes except ejection fraction ($p=0.005$), and others are as reflected by *p*-values well above the threshold (SBP: $p=0.334$, DBP: $p=0.975$, HR: $p=0.297$). In contrast, the interventional group receiving empagliflozin demonstrated statistically significant improvements. Specifically, systolic blood pressure showed a significant reduction (mean difference: 3.72 mmHg, t=2.021, $p=0.049$), and diastolic blood pressure also improved significantly (mean difference: 3.10 mmHg, t=2.037, $p=0.047$). Improvement in ejection fraction was very prominent (mean difference +3.58%, t=4.903, $p=0.000$) which was also significant statistically. Although Heart Rate improved by 1.28 bpm, $t=1.523$, the change did not reach statistical significance ($p=0.134$).

Overall, these findings indicate that empagliflozin therapy produced statistically significant improvements in blood

Table 1: Demographics and Baseline Data.

Parameter	Interventional Group	Conventional Group
No: of Subjects	50	50
Gender	Male 29 Female 21	Male 25 Female 25
Age	<50 18 >50 32	<50 25 >50 25
Diabetes Status	Diabetic 26 Non-Diabetic 24	Diabetic 26 Non-Diabetic 24
Hypertension	YES 50 NO 00	YES 50 NO 00
Dyslipidemia	YES 30 NO 20	YES 25 NO 25
NYHA Classification	CLASS II 29 CLASS III 13 CLASS IV 08	CLASS II 33 CLASS III 15 CLASS IV 02
Anti Diabetic	YES 26 NO 24	YES 26 NO 24
Beta Blockers	YES 31	YES 50
Digoxin	YES 16 NO 34	YES 18 NO 32
Diuretics	YES 46 NO 04	YES 38 NO 12
Anti platelets	YES 32 NO 18	YES 36 NO 14
Ejection Fraction	>40% 17 <40% and >30% 23 <30 10	>40% 20 <40% and >30% 17 <30% 13

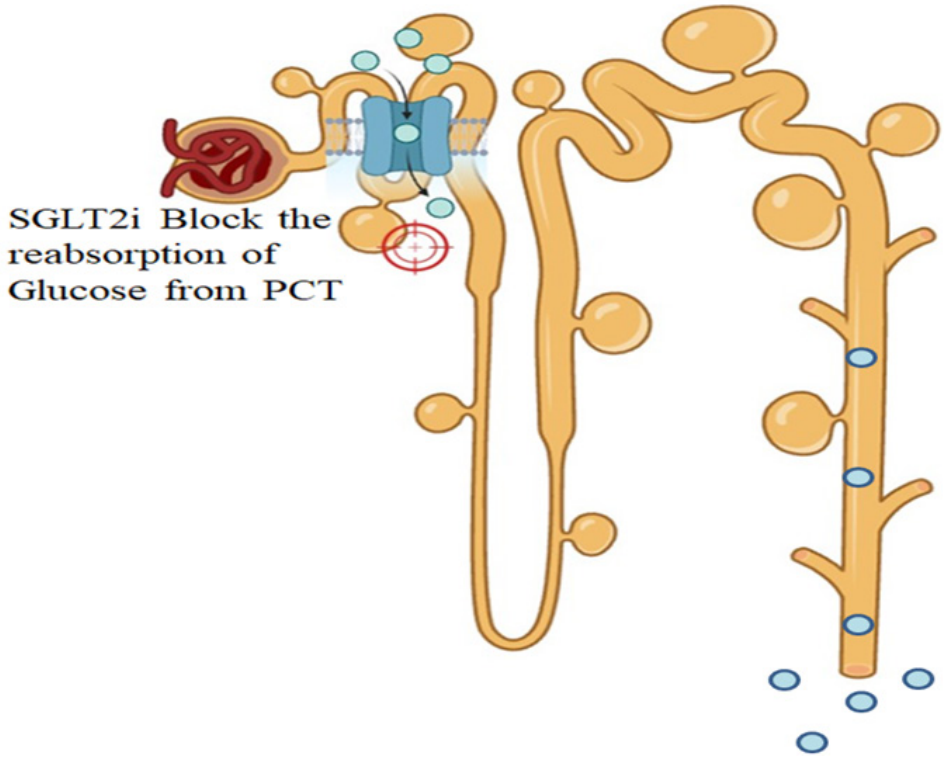

Figure 1: Mechanism of SGLT2i Diabetes Mellitus.

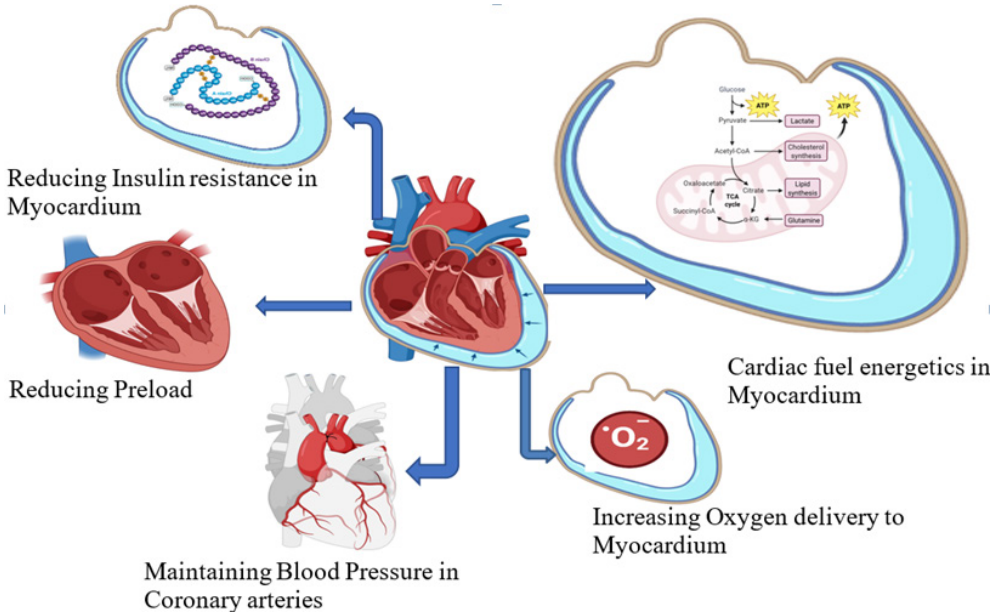

Figure 2: Multidimensional mechanism of SGLT2i on Heart.

Table 2: Effect of Interventional treatment on Cardiac Parameters.

Cardiac Parameter	Baseline (Mean±SD)	Follow up after 12 weeks (Mean±SD)	Change
Systolic Blood Pressure	135.52±24.73	131.80±14.92	3.72
Diastolic Blood Pressure	81.20±11.41	84.30±7.61	3.10
Ejection Fraction	41.00±8.78	44.58±7.68	3.58
Heart Rate	82.32±10.93	81.04±7.86	1.2

Table 3: Effect of Conventional Treatment on Cardiac Parameters.

Cardiac Parameter	Baseline (Mean±SD)	Follow up after 12 weeks (Mean±SD)	Change
Systolic Blood Pressure	131.92±18.50	130.64±12.18	1.28
Diastolic Blood Pressure	81.46±14.53	81.42±9.37	0.04
Ejection Fraction	48.96±7.43	49.36±6.95	0.4
Heart Rate	81.20±18.46	79.94±13.14	1.26

Table 4: Paired sample correlations.

Parameter	Conventional Group		Interventional Group	
	r-value	*p*-value	r-value	*p*-value
Systolic Blood Pressure	0.898	0.000*	0.901	0.000*
Diastolic Blood Pressure	0.808	0.000*	0.417	0.003*
Ejection Fraction	0.993	0.000*	0.811	0.000*
Heart Rate	0.911	0.000*	0.849	0.000*

*: Indicates significance at *p* value <0.05, 95% Confidence interval.

Table 5: Independent student *t* test for each variable.

Conventional Group			
Cardiac Parameter	Mean Difference	t (d_f=49)	*p*-value
Systolic Blood Pressure	1.28 mmHg	0.976	0.334
Diastolic Blood Pressure	0.04 mmHg	0.032	0.975
Ejection Fraction	0.40 %	-2.919	0.005*
Heart Rate	1.26 bpm	1.053	0.297
Interventional Group			
Cardiac Parameter	Mean Difference	t (d_f=49)	p-value
Systolic Blood Pressure	3.72 mmHg	2.021	0.049*
Diastolic Blood Pressure	3.10 mmHg	2.037	0.047*
Ejection Fraction	3.58%	4.903	0.000*
Heart Rate	1.28 bpm	1.523	0.134

*: Indicates significance at *p* value <0.05, 95% Confidence interval.

pressure control and Ejection fraction compared to conventional treatment, whereas changes in heart rate, although favourable, were not statistically significant within the study period.

DISCUSSION

This pilot study was designed to evaluate the cardiac benefits of SGLT2i by comparing the interventional group (*n*=50) receiving empagliflozin and conventional group (*n*=50) receiving conventional heart failure treatment. The demographic and baseline characters of both group shows approximately similar proportion of subjects in each group ensures the normal distribution of data. However, some differences can be ruled out in parameter like severity of disease which was expressed using NYHA classification *n*=08 in class IV of interventional group, whereas *n*=02 in conventional group.

The inferences of findings are consistent with and expand upon previous research. For instance (Packer *et al.*, 2020), in their double-blind trial, reported that empagliflozin reduced the risk of cardiovascular death and heart failure hospitalization in HFrEF patients, along with a slower decline in renal function findings mirrored in our study (Elm *et al.*, 2007).

The follow-up of cardiac parameters after an interventional period of 12 months among the group showed 3.75 mmHg decline in interventional group which is highly response that significantly in the Conventional group, while the diastolic blood pressure read about 3.10 mmHg in the interventional group and remains unchanged (0.04 mmHg) in Conventional group. Moreover, ejection fraction significantly improved with a mean change of 5.5% in interventional group and only minimal improvement of 0.4% observed in Conventional group. The Decrease in Heart rate across both groups doesn't show any clinically meaningful difference.

The Independent t test analysis of Cardiac variables among two groups also achieved statistically significant findings for Systolic Blood pressure (*p*=0.046), Diastolic Blood pressure (*p*=0.047) and Ejection fraction (*p*=0.000) confirm the superior

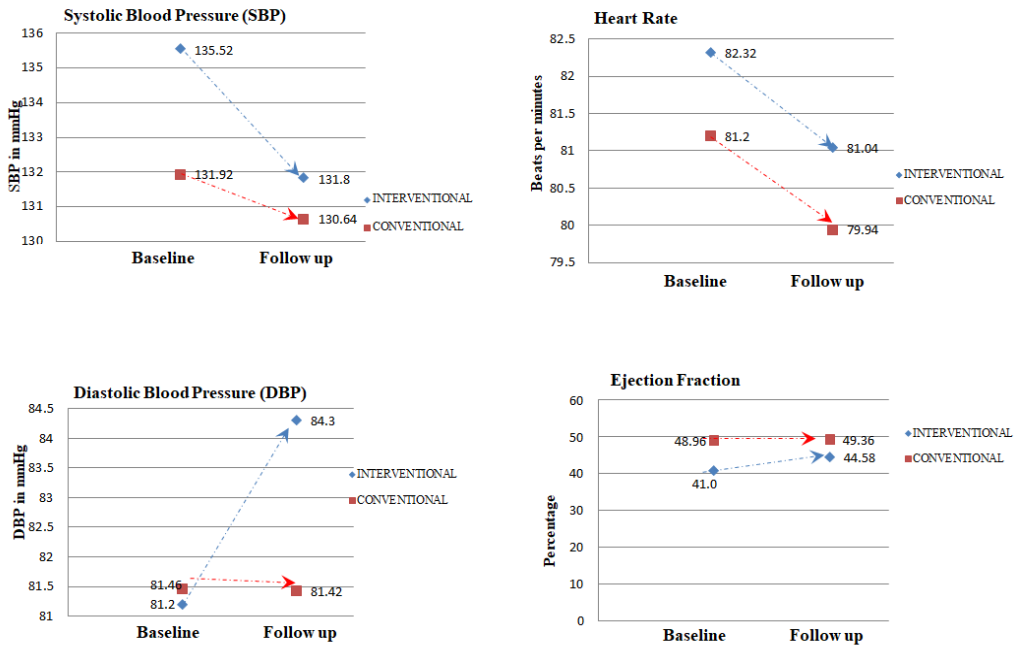

Figure 3: Comparison of Mean Change in various cardiac parameters.

effects of intervention. Similarly, Shahzeb *et al.*, concluded that empagliflozin benefits patients irrespective of the underlying etiology of heart failure, which supports our observation that both diabetic and non-diabetic patients responded positively to the intervention (Armonk *et al.*, 2017).

Moreover, Pierpaolo *et al.*, in the EMPA-REG OUTCOME trial observed early benefits within 12 weeks of empagliflozin initiation in patients with type 2 diabetes with or without heart failure (Pellicori *et al.*, 2020; Packer *et al.*, 2019). Our study likewise found significant hemodynamic and symptomatic improvements within the same time frame, which helped in determining optimal follow-up intervals for clinical evaluation.

The strength of our findings lies in their alignment with major clinical trials, yet they offer real-world insights through a focused, short-term observational framework. While the sample size was limited, the consistent and positive trends across multiple clinical endpoints highlight empagliflozin's potential as a cornerstone in heart failure management. These promising results lay the foundation for larger, long-term, randomized controlled trials to further validate and expand upon these benefits, especially in diverse populations and varying stages of heart failure. This study thus opens an important avenue for future research into optimizing early intervention strategies with SGLT2 inhibitors in heart failure.

CONCLUSION

This pilot study provides encouraging evidence that empagliflozin significantly improves cardiac function and hemodynamic parameters in patients with heart failure, including those with reduced ejection fraction. The interventional group showed marked improvements in systolic and diastolic blood pressure, heart rate, NYHA classification, and ejection fraction, along with early symptomatic relief observed within just 12 weeks. These findings were consistent across both diabetic and non-diabetic subgroups, underscoring the broad cardio protective role of empagliflozin beyond glycemic control.

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ABBREVIATIONS

AH&RC: Adichunchanagiri Hospital and Research Centre; **CV:** Cardiovascular; **DBP:** Diastolic Blood Pressure; **EF:** Ejection Fraction; **EMZ:** Empagliflozin; **HF:** Heart Failure; **HFrEF:** Heart Failure with Reduced Ejection Fraction; **HR:** Heart Rate; **IBM:** International Business Machines Corporation; **IEC:** Institutional Ethics Committee; **LVAD:** Left Ventricular Assist Device; **LVEF:** Left Ventricular Ejection Fraction; **MACE:** Major Adverse

Cardiac Events; **NYHA:** New York Heart Association; **SGLT2i:** Sodium-Glucose Transporter 2 Inhibitors; **SPSS:** Statistical Package for the Social Sciences; **STROBE:** Strengthening the Reporting of Observational Studies in Epidemiology; **SBP:** Systolic Blood Pressure; **T2DM:** Type 2 Diabetes Mellitus.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVALS

The study was conducted in accordance with the Ethical guidelines for biomedical research on human participants and Declaration of Helsinki, after obtaining approval from the Institution Ethics Committee (IEC) with IEC no: IEC/AH&RC/AC/23/2024.

AUTHOR CONTRIBUTIONS

- **Robin George:** Principal Investigator.
- **Irshad Pasha:** Biostatistics and Data management.
- **B J Mahendra Kumar:** Research Guidance.

Overall, the data indicates that empagliflozin produced more pronounced and clinically meaningful benefits across multiple cardiac parameters compared to standard therapy. The magnitude of improvement, particularly in ejection fraction, highlights the therapeutic potential of SGLT2 inhibition in heart failure management. These findings support the feasibility of further large-scale, long-duration randomized trials to validate and expand upon these results.

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