ABENHA MEDICAL JOURNAL bmj

Print ISSN 1110-208X.

Online ISSN 2357-0016

Original article

The Prognostic Value of SGLT2 Inhibitors in Patients Presenting with ST-Segment Elevation Myocardial Infarction with Preserved LV Systolic Function

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Received:
Accepted:

Abstract

Background: Acute STEMI presents a range of risks for recurrent myocardial infarction, chronic heart failure, and cardiovascular death. Early post-infarction treatment strategies aim to reduce adverse cardiac remodeling and prevent long-term complications like chronic HF and sudden cardiac death. SGLT2 inhibitors, such as Dapagliflozin, have shown potential in modulating ventricular remodeling, suggesting benefits in post-MI management. **Aim:** This study aimed to evaluate the effects of adding Dapagliflozin to standard post-MI care on morbidity and mortality in patients with acute STEMI and preserved LV systolic function, regardless of diabetic status. **Subjects and Methods:** Three hundred patients with acute STEMI were randomized into two groups (Group I and II, 150 each). Group I received Dapagliflozin 10 mg orally once, followed by a daily dose of 10 mg, in addition to standard post-MI therapies. Comprehensive assessments, including medical history, clinical examination, electrocardiogram, and echocardiography, were conducted for all participants. **Results:** The average age of participants was 54 ± 11 years, with 59% male. A significant proportion had diabetes (42%) and hypertension (46%), and 50% were smokers. Group I showed significantly lower rates of recurrent AMI (2% = vs. 12%, $P < 0.001$), heart failure hospitalizations (4% vs. 14%, $P = 0.002$), and major adverse cardiac events (6% vs. 27.3%, $P < 0.001$). However, there were no significant differences in mortality ($P = 0.498$) or stroke ($P = 0.498$). **Conclusion:** Early addition of Dapagliflozin to standard post-STEMI care significantly reduced heart failure hospitalizations and MACE but had no impact on mortality or stroke outcomes.

Keywords: ST-segment elevation myocardial infarction (STEMI); SGLT2 inhibitors; Heart failure (HF).

Introduction

ST-elevation myocardial infarction (STEMI) is a leading cause of morbidity and mortality, which is often associated with high mortality, while percutaneous coronary stenting (PCI) is the most effective intervention to limit cardiac ischemic injury and reduce the incidence of adverse cardiac events [1] .

Patients with acute STEMI represent a spectrum of risk for developing recurrent MI, chronic HF, life-threatening arrhythmia, and cardiovascular death [2].

Recently, these patients received a number of evidence-based therapies early post infarction to reduce the risk of adverse cardiac remodeling and development of chronic HF, sudden cardiac death, or end-stage heart disease [3].

Although tremendous progress has been made, there is nevertheless an impetus to discover further evidence-based strategies, as contemporary rates of adverse cardiovascular outcomes remain too high [4].

Sodium glucose cotransporter-2 (SGLT2) inhibitors improve cardio-renal outcomes in patients with type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD) and chronic heart failure with reduced ejection fraction (HFrEF) [5].

Early initiation and continuation of SGLT2 inhibition for acute MI is appealing with many proposed mechanistic effects that may alter the natural history, pre- disposition to ventricular remodeling, and progression to chronic HF and end-stage heart disease [6].

Patients and Methods

This study was a prospective, randomized clinical trial performed over a period of 18 months from November 2022 to April 2024 at the Department of Cardiology, Benha University Hospital.

A total of 300 patients with STEMI were selected by purposive sampling technique. The study patients were randomized in a 1:1 ratio into two groups (Group I and II) each 150 patients.

In group I: an initial dose of Dapagliflozin 10 mg is taken orally once at the first contact, and then Dapagliflozin (10 mg qd) is maintained from the second day in addition to standard of care therapies.

In group II (the control group): current standard of care therapies was given only.

Patients with 1st presentation with acute STEMI between 18 and 75 years old were included.

Acute STEMI was defined as ST-segment elevation ≥0.2 mV in at least 2 adjacent leads within 12 h of chest pain onset [7].

The following patients were excluded: patients with hemodynamic instability (systolic pressure <90 mmHg or any signs of insufficient organ perfusion, such as oliguria or wet and cold limbs, etc.), patients with complicated PCI (stent thrombosis, no reflow, pulmonary oedema), patients being treated with any SGLT-2i (Dapagliflozin, Canagliflozin, Empagliflozin) within the past 4 weeks, type 1 diabetes patients, allergic reactions to SGLT-2 inhibitors, previous history of HF, MI, valvular disease (moderate or more stenosis or regurgitation), congenital heart disease, impaired renal function (eGFR<30 ml/min/1.73 m^2) and significant co-morbidities e.g. malignant tumors.

All patients were subjected to history taking including age, gender, history of diabetes mellitus, hypertension, previous MI, SGLT-2i taking within the past 4 weeks and symptoms of heart failure.

Full clinical examination was done including heart rate, systolic blood pressure, diastolic blood pressure, signs of heart failure, hemodynamic instability, congenital or valvular heart diseases.

Blood samples were taken for CBC, serum creatinine and random blood glucose level.

Twelve-lead electrocardiogram was recorded in all patients to detect the presence of ST-segment elevation & cardiac rhythm abnormalities.

Comprehensive transthoracic echocardiographic examinations were performed at the first contact then after 6 months using a Philips, Epic 7C machine, with the 5.5 X transducer S5-1 probe with simultaneous ECG signal. Patients were examined in the left lateral decubitus position. All echocardiographic examinations were obtained and recorded offline.

LV end-diastolic and end-systolic volumes were used to calculate left ventricular ejection fraction (LVEF) using modified biplane Simpson's method in the apical four chamber and apical two chamber views. Ejection fraction is the fraction of the end – diastolic volume that is ejected with each beat; that is, stroke volume (SV) divided by end-diastolic volume. Stroke volume = end-diastolic volume – end systolic volume [8].

2D speckle tracking echocardiography was done using three consecutive end expiratory cardiac cycles at a frame rate of (50 – 70 frames / sec.) harmonic imaging was acquired in the apical four chamber, apical two chamber and apical long axis views. The 2D-STE analysis was performed offline on grey scale images of the LV obtained in these views. The endocardial border was manually traced in end-systole, and the software automatically tracked the myocardial region of interest. Once the regions of interest were optimized, the software generates automatically strain curves for different myocardial segments.

From the apical four chamber view, longitudinal strain (LS) was assessed through basal, mid, apical inferior septal wall, basal, mid and apical

antero-lateral wall segments. From the apical two chamber view LS was assessed through basal, mid, apical inferior wall, basal, mid, and apical anterior wall segments.

From the apical long axis view, LS was assessed through basal, mid, apical infero-lateral wall, basal, mid, and apical antero-septal segments. Global longitudinal strain has been calculated as the mean strain of all 17 segments [9].

Approval Code: MD 7-10-2022

Statistical analysis:

Patients were followed up for 6 months to monitor effect of adding Dapagliflozin to standard of care therapies on echocardiographic parameters, morbidity and mortality events.

All patients were managed by primary PCI strategy (Emergency coronary angiography and PCI of the IRA if indicated) in addition to evidence based medical therapy according to the latest ESC Guidelines for the management of acute coronary syndromes in patients presenting with ST-segment elevation. If patients have more than one vessel disease, PCI of residual lesions were done in another session within 45 days of discharge. Data management and statistical analysis were done using SPSS version 28 (IBM, Armonk, New York, United States). Quantitative data were assessed for normality using the Kolmogorov–Smirnov test and direct data visualization methods. According to normality, quantitative data were summarized as means and standard deviations. Categorical data were summarized as numbers and percentages.

Quantitative data were compared between the studied groups using the independent t-test. Categorical data were compared using the Chi-square or Fisher's exact test. Echocardiography data at baseline and six months were compared between groups using the two-way mixed model ANOVA and interaction between time and groups on

Multivariate logistic regression analyses were done to predict MACE. The odds ratios with 95% confidence intervals were calculated. All statistical tests were two-sided. P values less than 0.05 were considered significant [10].

Outcomes:

Clinical outcomes were observed and recorded. Outcome variables comprised of left ventricular remodeling (LVESV, LVEDV, EF and LV GLS), recurrent AMI, hospitalization for HF and death. Overall adverse outcomes were defined as consisting of the occurrence of any one of a set of multiple outcomes.

Results

The average age of participants was 54 ± 11 years. Males predominated,

comprising 59% (177 patients) of the population. A significant proportion of the participants had diabetes and hypertension, representing 42% (126 patients) and 46% (138 patients),

respectively. Furthermore, half of the participants (50%, 150 individuals) reported being smokers **(Table 1)**.

Patients were randomized into two groups; Group I: 150 patients received an initial dose of Dapagliflozin 10 mg orally once at the first contact, and then Dapagliflozin (10 mg qd) was maintained from the second day in addition to standard of care therapies; Group II (the control group): 150 patients who received the current standard of care therapy only.

At baseline, the LVEDV was slightly higher in Group II (101.2 ± 13.3) compared to Group I (98.4 ± 15.3), but this difference was not statistically significant (P = 0.098). At six months, a significant reduction in LVEDV was observed within both groups (P < 0.001 for both), with Groups I and II reaching 93.3 ± 12 and 96.3 ± 11, respectively. The difference between the groups at six months was significant (P = 0.027). No significant interaction was reported between time and groups on LVEDV (P = 0.718) **(Table 3)**.

At baseline, the LVESD was not significantly different between the groups (P = 0.228). At six months, there was a significant reduction in LVESD within each Group (P < 0.001 for both). At six months, Group I had a more pronounced reduction (33 ± 5.2) compared to Group II (38.6 ± 8), with the between-group difference being highly significant (P < 0.001). The interaction effect between time and groups was significant (P < 0.001) **(Table 3)**.

The studied groups were comparable regarding age (P = 0.397), sex (P = 0.291), diabetes mellitus (P = 1.0), hypertension (P = 0.487), and smoking (P = 0.488).

Group I showed significantly higher posterior MI (32% vs. 10%, P < 0.001) than Group II. No significant differences were observed between both groups regarding anterior MI (P = 0.475), inferior MI (P = 0.475), and number of vessels affected (P = 0.362) **(Table 2)**.

At baseline, EF was similar at the start (P = 0.556). At six months, significant improvement was noted in both groups (P < 0.001 for both), with Group I showing a more significant increase in EF (64.3 ± 6.6) compared to Group II (59.3 ± 8.7), leading to a significant between-group difference (P < 0.001). The interaction between time and groups on EF was significant (P < 0.001) **(Table 3)**.

At baseline, GLPSS was comparable between the groups (P = 0.292). At six months, there was a significant improvement in GLPSS within both groups (P < 0.001 for both), with Group I showing a more substantial improvement (-18.5 ± 1.7) compared to Group II (-16.4 ± 3.3). The between-group difference was significant (P < 0.001). The interaction between time and groups on GLPSS was significant (P < 0.001) **(Table 3)**.

Group I demonstrated significantly lower recurrent AMI (2% vs. 12%, P < 0.001), heart failure hospitalization (4% vs. 14%, P = 0.002), and MACE (6% vs. 27.3%, P < 0.001).

No significant differences were observed between the studied groups regarding mortality (p = 0.498) and stroke (P = 0.498) **(Table 3)**.

Multivariate logistic regression analysis was done to predict MACE. Patients with two-vessel disease had a 2.81 times higher risk (95% CI: 1.23 - 6.43, p = 0.014), while those with three-vessel disease exhibited an 11.4 times increased risk (95% CI: 3.33 - 39.11, p < 0.001) compared to single-vessel disease. Additionally, larger left ventricular end-diastolic volume (LVEDV) and end-systolic dimension (LVESD) were associated with higher risk, with odds ratios of 1.033 (95% CI: 1.009 - 1.056, p = 0.006) and 1.097 (95% CI: 1.05 - 1.146, p < 0.001), respectively. A decrease in ejection fraction (EF) also correlated with increased risk, with an OR of 0.81 (95% CI: 0.732 - 0.896, p < 0.001). Global longitudinal peak systolic strain (GLPSS) showed a protective effect with an OR of 0.706 (95% CI: 0.577 - 0.864, p = 0.001). The intervention of dapagliflozin was associated with reduced risk, showing an OR of 0.142 (95% CI: 0.064 - 0.318, p < 0.001) **(Table 4)**.

Table [1] Demographic characteristics of the whole patients

Demographics		
Age (years)	Mean ±SD	54 ±11
Sex		
Males	n (%)	177 (59)
Females	n (%)	123 (41)
Diabetes	n (%)	126 (42)
Hypertension	n (%)	138 (46)

*Significant P-value at P < 0.05; †Adjusted for age, gender, DM, HTN, and smoking; OR: Odds Ratio; CI: Confidence Interval.

Table [2] Diagnosis and number of vessels affected in the studied groups

		Group I (n = 150)	**Group II (n = 150)**	**P-value**
Anterior MI	n (%)	54 (36)	60 (40)	0.475
Inferior MI	n (%)	96 (64)	90 (60)	0.475
Posterior MI	n (%)	48 (32)	15 (10)	**<0.001***
Number of vessels affected				
Single vessel disease	n (%)	99 (66)	90 (60)	0.362
Double vessel disease	n (%)	42 (28)	45 (30)	
Triple vessel disease	n (%)	9 (6)	15 (10)	

Table [3] Echocardiography at baseline, follow-up, and Outcome in the studied groups

		Group I (n = 150)	**Group II (n = 150)**	**$P_{diff.}$**	**$P_{int.}$**
LVEDV					
Baseline	Mean ±SD	98.4 ±15.3	101.2 ±13.3	0.098	0.718
Six months	Mean ±SD	93.3 ±12	96.3 ±11	**0.027***	
P_{within}		**<0.001***	**<0.001***		
LVESD					
Baseline	Mean ±SD	42.6 ±7.6	43.7 ±8	0.228	**<0.001***
Six months	Mean ±SD	33 ±5.2	38.6 ±8	**<0.001***	
P_{within}		**<0.001***	**<0.001***		
EF					
Baseline	Mean ±SD	56.9 ±3.4	57.1 ±3.5	0.556	**<0.001***
Six months	Mean ±SD	64.3 ±6.6	59.3 ±8.7	**<0.001***	
P_{within}		**<0.001***	**<0.001***		
GLPSS					
Baseline	Mean ±SD	-15.4 ±1.7	-15.6 ±1.5	0.292	**<0.001***
Six months	Mean ±SD	-18.5 ±1.7	-16.4 ±3.3	**<0.001***	
P_{within}		**<0.001***	**<0.001***		
		Outcome			
Recurrent AMI	n (%)	3 (2)	18 (12)	**<0.001***	
HF Hospitalization	n (%)	6 (4)	21 (14)	**0.002***	
Mortality	n (%)	1 (0.7)	2 (1.3)	1	
Stroke	n (%)	0 (0)	2 (1.3)	0.498	
MACE	n (%)	9 (6)	41 (27.3)	**<0.001***	

Table [4] Multivariate logistic regression analysis to predict MACE

	OR (95% CI)†	**P-value**
Number of vessels (Ref: One vessel)		
Two vessels	2.811 (1.23 - 6.426)	**0.014***
Three vessels	11.405 (3.325 - 39.114)	**<0.001***
LVEDV	1.033 (1.009 - 1.056)	**0.006***
LVESD	1.097 (1.05 - 1.146)	**<0.001***
EF	0.81 (0.732 - 0.896)	**<0.001***
GLPSS	0.706 (0.577 - 0.864)	**0.001***
Dapagliflozin use (intervention)	0.142 (0.064 - 0.318)	**<.001***

*Significant P-value at P < 0.05; †Adjusted for age, gender, DM, HTN, and smoking; OR: Odds Ratio; CI: Confidence Interval.

Discussion

The main objective of our study was to evaluate the effect of adding Dapagliflozin to standard of care therapies on morbidity and mortality events in patients presenting with ST-segment elevation myocardial infarction with preserved LV systolic function regardless of their diabetic status. A total of 300 patients with STEMI were included and randomized in a 1:1 ratio into two groups

(intervention and control group) each 150 patients.

In our study, the mean age of participants was 54 years with a standard deviation of 11 years., while in a study conducted by Yi and colleagues (2022) [11] who assessed the effect of dapagliflozin on the prognosis of patients with acute myocardial infarction undergoing percutaneous coronary intervention, mean age was 62 years with a standard deviation of 14 years.

In our study, males were predominated, comprising 59% of the population, a finding consistent with Yi and colleagues (2022) [11] who found that 76.8% patients were male and 23.2% female.

In a study conducted by Mao and co-workers [12] who assessed effect of Dapagliflozin on risk of heart failure hospitalization in diabetic acute myocardial infarction patients, the proportion of men was higher in the DAPA group than in the DAPA-Free group ($p = 0.003$), but the mean age was considerably lower in the DAPA group ($p < 0.001$).

In DAPA-MI trial conducted by James and colleagues [13] who assessed role of Dapagliflozin in Myocardial Infarction without Diabetes or Heart Failure, mean age was 62 years with a standard deviation of 10 years. Males predominated, comprising 80% of the population, while females accounted for 20%.

In EMPACT-MI trial conducted by Hernandez and colleagues [14] who assessed role of Empagliflozin in patients hospitalized for acute myocardial infarction and was at risk for heart failure, the average age of participants was 63 years, with a standard deviation of 11 years. Males were the predominated sex, comprising 75% of the population, while females accounted for 25%.

In EMMY trial conducted by von Lewinski and co-workers [15] investigating role of Empagliflozin in recent acute myocardial infarction, the average age of participants was 57 years, with a standard deviation of 10 years and also Males were predominated, comprising 82% of the population, while females accounted for 18%.

In our study, a significant proportion of the participants had diabetes and hypertension, representing 42% and 46%, respectively. Furthermore, half of the participants (50%) reported being smokers.

In EMPACT-MI trial proportion of the participants' having diabetes was 32% and hypertension was 69%. [14]

In EMMY trial, proportion of the participants having diabetes and hypertension were 13% and 42%, respectively and 72% of the participants reported being smokers. [15]

In our study, both groups were comparable regarding age ($P = 0.397$), sex ($P = 0.291$), diabetes mellitus ($P = 1.0$), hypertension ($P = 0.487$), and smoking ($P = 0.488$). These findings were consistent with EMPACT-MI

trial where the previous risk factors were nearly equally distributed in both groups. [14]

The findings were also consistent with EMMY trial where age (P = 0.78), sex (P = 0.97), diabetes mellitus (P = 0.71), hypertension (P = 0.19), and smoking (P = 0.92) were similar between treatment groups. [15]

In the study conducted by Yi and co-workers [11], higher proportion of patients who received dapagliflozin had hypertension or diabetes.

In a study conducted by Mao and co-workers [12] hypertension (P = 0.9), and smoking (P = 1) were comparable in both groups.

Regarding the extent of coronary artery disease, most of our patients exhibited single vessel disease, accounting for 63% of the cases. Double vessel disease was also relatively common, seen in 29% of the participants. In contrast, triple vessel disease was less frequent, observed in only 8% of the cases. No significant differences were observed between both groups regarding number of vessels affected (P = 0.362).

In EMMY trial, proportion of patients with one vessel disease was 48%, two vessel disease 34% and three vessel disease 18%. Also, no significant differences were observed between both groups regarding number of vessels affected. [15]

In our study at baseline, the LVEDV was slightly higher in Dapagliflozin free Group (101.2 ± 13.3) compared to Dapagliflozin treated Group (98.4 ± 15.3), the LVESD was not significantly different between the groups (P = 0.228), EF was similar at the start (P = 0.556).

In the study conducted by Yi and other researchers [11], the LVEDD was slightly higher in Dapagliflozin treated group (5.3 ± 0.6) compared to Dapagliflozin free Group (5.1 ± 0.5) but LVEF was slightly lower (49% ± 10) compared to (53% ± 9).

In our study, EF was similar at the start (P = 0.556). At six months, significant improvement was noted in both groups (P < 0.001 for both), with DAPA Group showing a more significant increase in EF (64.3 ± 6.6) compared to DAPA free Group (59.3 ± 8.7).

These findings were consistent with Mao and colleagues [12] who found that EF was similar at the start (P = 0.771). At 1 year of follow up, the DAPA group had significantly higher left ventricular ejection fraction (LVEF) values than the DAPA-free group (P = 0.0214).

The findings were also similar to EMMY trial where Left-ventricular ejection fraction increased in both groups with the greater increase being in the empagliflozin than in the placebo group (P < 0.014) [15].

In our study, a significant reduction in LVEDV and LVESV was observed in each Group with DAPA Group had a more pronounced reduction compared to DAPA free Group (P = 0.027 for LVEDV and P < 0.001 for LVESV).

This finding was similar to EMMY trial where LVEDV and LVESV significantly improved in the empagliflozin group compared with the placebo group: LVESV (P=0.0003) and LVEDV (P=0.0015) were smaller in the empagliflozin group compared with the placebo group [15].

In our study, Dapagliflozin treated group demonstrated significantly lower recurrent AMI (2% vs. 12%, P < 0.001), heart failure hospitalization (4% vs. 14%, P = 0.002), and MACE (6% vs. 27.3%, P < 0.001). No significant differences were observed between the studied groups regarding mortality (p = 0.498) and stroke (P = 0.498).

In the study conducted by Yi and researchers [11], Dapagliflozin treated group demonstrated lower recurrent AMI (3.5% vs. 11.8%, P = 0.001), heart failure hospitalization (2.1% vs. 10.4%, P < 0.001), and MACE (8.5% vs. 18.3%, P = 0.018) but higher stroke (2.3% vs. 0%, P = 0.05). No significant differences were observed between the studied groups regarding mortality (p = 0.498).

In the study conducted by Mao and co-workers [12], the DAPA group also showed a lower HF hospitalization rate than the DAPA-Free group (6.9% vs. 16.5%; p < 0.001) but all-cause mortality was higher in the DAPA-Free group than in the DAPA group (P < 0.05).

In DAPA-MI trial dapagliflozin significantly improved cardiometabolic outcomes but no significant differences were observed between the studied groups regarding Major adverse cardiovascular events (3.4% vs. 3.6%, p > 0.05), cardiovascular death/hospitalization for HF/MI (4.1% vs. 4.3%, p > 0.05), or all-cause mortality: 2.0% vs. 1.7%, p > 0.05) [13].

The findings were consistent with EMPACT-MI trial where the risk for first HF hospitalization and total HF hospitalizations was significantly lower in the empagliflozin compared with the placebo group (3.6% versus 4.7%, P=0.031, for first HF hospitalization; 2.4% versus 3.6%, P=0.006, for total HF hospitalizations). Also, no significant difference was observed between the studied groups regarding mortality (5.2% vs. 5.5%, HR 0.96 (95% CI 0.78-1.19)) [14].

In EMMY trial, serious adverse event rates did not differ between the empagliflozin and the placebo groups. Seven participants were hospitalized for heart failure (three in the empagliflozin group, four in placebo group). Three deaths occurred during the study, all in the empagliflozin group [15].

Our study results extend the evidence base regarding the use of Dapagliflozin to post-MI populations for which data have not yet been available.

Conclusion

Among patients who were hospitalized with an acute STEMI, early initiation of Dapagliflozin given in addition to guideline-recommended post-MI treatment resulted in significantly lower heart failure hospitalization and

MACE compared to placebo, but no significant differences were observed between the studied groups regarding mortality.

Recommendation

Early initiation & maintenance of Dapagliflozin in patients with acute STEMI even with normal EF is recommended to improve outcome post MI. Large scale studies on different MI categories are recommended.

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To cite this article: Hany H. Ebaid, Maged Kh. Mahmoud, Khaled E. Elrabbat, Amr A. Elsayed, The Prognostic Value of SGLT2 Inhibitors in Patients Presenting with ST-Segment Elevation Myocardial Infarction with Preserved LV Systolic Function. BMFJ XXX, DOI: 10.21608/bmfj.2024.335914.2252