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Effects of Empagliflozin in Chronic Kidney Disease on Hemodialysis Patients

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Abstract

Background

Several risk factors in chronic kidney disease (CKD) patients cause mortality; cardiovascular risk is the most important one. So, new protective treatments have to be added to the management of CKD patients; the most important one is renin angiotensin aldosterone system inhibitors (RAASI), but the latest one is sodium glucose transporter 2 inhibitors (SGLT2i). Here in this study, we tried to approve cardiac and hematologic benefits of Empagliflozine using in end stage renal disease (ESRD) on renal replacement therapy (RRT) patients.

Methods

we started Empagliflozin 10 mg for 9 months in 17 hemodialysis patients. Echocardiography and serum hemoglobin to measure cardiac parameters (interventricular septum diameter {IVSD} and ejection fraction{EF%}) and serum hemoglobin (HG) levels were done at baseline and after 9 months. We included diabetic and non-diabetic patients in our study. Patients with urinary anomalies were excluded.

Statistical analysis was done to the results by IBM SPSS program to evaluate the benefits.

Results

We included 17 participants, 64.7 % of them were male and 35.3% were female. There ages range from 22 years old to 75. Results declared cardiac benefits, as interventricular septum diameter (IVSD) was reduced by mean of 0.08 cm (p.value 0.002), (Std.Deviation(0.088), and increased left ventricular ejection fraction (EF%) by mean of 2.7 % after treatment. (p.value 0.15), (Std.Deviation (7.48), and hematologic benefits, as hemoglobin increased by mean of 0.68 mg/dl (p.value 0.001), (Std.Deviation (0.67), with no important side effects.

Conclusion

We concluded that, using empagliflozin in hemodialysis patients, improved cardiac function and increased hemoglobin levels with statistically significance, and may improve prognosis and quality of life.

Keywords: Chronic Kidney Disease, Ejection Fraction, Hemoglobin, Interventricular Septum Diameter, Sodium Glucose

Key learning points

Currently, the safety and efficacy of initiating SGLT2i for people with an eGFR <20 ml/min per 1.73 m2, are not established. This study considered the first one, that expertise SGLT2I effects on cardiac and hematologic parameters in end stage renal disease (ESRD) patients, who are treated with hemodialysis, and suggested that, giving empagliflozin in CKD patients on hemodialysis, has positive results on hemoglobin levels, and cardiac structure parameters This study concluded that, using SGLT2I has also benefits in ESRD patients, that overwhelm the limitations of their use, and may improve the quality of life and prognosis.

1. Introduction

Chronic kidney disease (CKD) is a worldwide threat to public health and has a risk-multiplier effect on major noncommunicable diseases, including cardiovascular diseases. More than 322 million individuals are currently affected by CKD worldwide, and the number of patients with end-stage renal disease (ESRD) treated with renal replacement therapy (RRT) with dialysis or transplantation globally exceeds 2.6 million people.3 Independent of the

initial insult, progression to ESRD is relatively common in chronic nephropathies. Although genetic factors contribute to susceptibility and progression of renal disease, increased glomerular capillary flow and pressure consistently leading to increased urinary protein traffic have been claimed as independent factors of progression and poor renal outcomes in nondiabetic and diabetic kidney disease. Sodium glucose cotransporter protein subtype-2 (SGLT-2) in the renal proximal convoluted tubule is blocked by SGLT-2 inhibitors, thereby increasing renal excretion of glucose. There are increased risks for genital mycotic infections and, rarely, urinary tract infections; thus patients taking these should be cautioned. lthough many patients with chronic kidney disease (CKD) progress to end-stage renal disease (ESRD) and require renal replacement therapy (RRT), the majority die of nonrenal causes, particularly premature cardiovascular (CV) events. Early diagnosis of CKD is therefore important because it provides opportunities to delay progression of CKD and prevent CV complications. Management of CKD should be aimed a t slowing the rate of decline of kidney function and minimizing the effects of other complications. SGLT2 inhibitors induce osmotic diuresis and have natriuretic effects contributing to plasma volume contraction. They decrease systolic and diastolic BP by 4 to 6/1 to 2 mm Hg, respectively. They also decrease weight. SGLT2 inhibition is associated with an acute, dose-dependent reduction in eGFR by approximately 5 ml/min/1.73 m2 and approximately 30% to 40% reduction in albuminuria. These effects mirror preclinical observations suggesting that proximal tubular natriuresis activates renal tubuloglomerular feedback through increased macula densa sodium and chloride delivery, leading to afferent vasomodulation. Glycosuric effects are attenuated in patients with CKD (eGFR <60 ml/min/1.73 m2) but BP, eGFR, and albuminuria lowering effects are preserved. some guidelines now recommend that SGLT2 inhibitors with proven CV benefit be prioritized. in patients with type 2 diabetes with insufficient glycemic control and who have atherosclerotic CVD. Furthermore, the EMPA-REG OUTCOME study reported a 39% reduction in incident or worsening nephropathy that included doubling of serum creatinine (relative risk reduction, 44%) and renal-replacement therapy (relative risk reduction, 55%) in the empagliflozin group, while the CANVAS-Renal trial similarly reported an impressive 40% reduction in the composite renal outcome (defined as a sustained 40% reduction in the rate of eGFR decline, need for renal replacement therapy, or death from renal causes).1 In this study we tried to approve benefits of SGLT2I using in ESRD on hemodialysis patients on cardiovascular and hematologic effect and subsequently on prognosis.

2. Material and Methods

We started daily Empagliflozin 10 mg in 17 hemodialysis patients, who are on intermittent hemodialysis with twice weekly sessions, and constant Erythropoietin dose in the hemodialysis unit at Aleppo university hospital, to evaluate cardiac and hematologic benefits after 9 months of treatment. We choose the patients regardless of the cause of ESRD (Diabetes, FSGS, Analgesic nephropathy,), the age, the sex, the residual kidney function, and dialysis duration.m We excluded patients who have urinary anomalies. At baseline and after 9 months, we observationally did echocardiography to measure cardiac parameters (left ventricular ejection fraction {EF%} and Interventricular septum diameter {IVSD}), and hemoglobin levels to all participants in our study. Patients were prospectively monitored through 9 months to check benefits and possible side effects of the treatment. We analyzed the results, and did statistical study and analyzing charts by IBM SPSS program version 18. A P. value <0.05 was considered as statistically significant.

3. Results

We randomized 17 patients on hemodialysis treatment (two sessions weekly), 64.7 % of them were male and 35.3% were female. There ages ranges from 22 years old to 75.

			Month 0	Month 9	Month 0		Month 9	
	AGE	SEX	Hemoglobin	Hemoglobin	IVSD	EF%	IVSD	EF%
1	70	male	8	9	1.8	42	1.57	65
2	39	female	9	10	1.25	60	1.3	60
3	38	male	9.3	10	1.34	55	1.25	55
4	22	female	7.4	7.9	2.35	62	2.25	60
5	55	male	7.4	9.7	1.49	33	1.3	40
6	50	female	7.3	8.5	1.19	60	1.11	60
7	55	male	9	9.3	1.35	55	1.3	55
8	50	male	7.5	7.8	1.94	67	1.8	65
9	55	male	11.7	12	1.7	65	1.5	67
10	75	male	13.6	13.2	1.5	25	1.47	35
11	50	male	12	12.3	1.22	61	1.24	64
12	50	male	10	9.5	1.1	35	1.1	35

13	45	male	10	11	0.97	55	0.9	60
14	60	female	9.5	10	1.3	50	1.34	53
15	24	female	7.5	9	1.1	73	1.1	73
16	65	male	7.4	8.5	1.2	55	1.2	55
17	35	male	11	11.5	1.3	60	1.2	60

Table 1: Patient's Characters and Treatment Outcomes

The causes of chronic kidney disease in participants were: diabetes (23.5%), GN (29.4%), HTN (29.4%), and analgesic nephropathy (23.5%).

	MEAN	NUMBER	Standard deviation
Hemoglobin before treatment	9.27	17	1.91
Hemoglobin after treatment	9.95	17	1.56
Ejection fraction before treatment	53.7	17	12.93
Ejection fraction after treatment	56.41	17	8.9
IVSD before treatment	1.42	17	0.34
IVSD after treatment	1.34	17	0.31

Table 2: Shows the Mean and Standard Deviation of Variables Values Before and After Treatment

		Paired Differences					Sig. (2-tailed) p.value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		
					Lower	Upper	
Pair 1	Hemoglobin before treatment -Hemoglobin after treatment	-0.6824	0.6748	0.1637	-1.0293-	-0.3354-	0.001
Pair 2	Ejection fraction before treatment - Ejection fraction after treatment	-2.70588	7.48970	1.81652	-6.55673-	1.14497	0.156
Pair 3	IVSD before treatment - IVSD after treatment	0.08059	0.08856	0.02148	0.03505	0.12612	0.002

Table 3: Shows the Mean, Standard Deviation, and the P. Value of Paired Differences of Variables Before and After Treatment

• After treatment with Empagliflozin 10 mg daily for 9 months, we noticed a significant improvement in the hemoglobin levels, as it increased by mean of 0.68 mg/dl (p.value 0.001), (Std.Deviation (0.67), with statistically significance, as the mean value before treatment was (9.27) mg/dl with standard deviation (1.91), While The mean value after treatment increased to (9.95) mg/dl with standard deviation (1.56). Fig1

• In addition, The Ejection fraction of left ventricle increased by mean of 2.7 % after treatment. (p.value 0.15), (Std. Deviation (7.48)), with no statistically significance, as the mean value before treatment was (53.7%) with Std. Deviation (12.93), while it was after treatment (56.4%) with Std. Deviation (8.90). Fig2

• Also, the study approved an important reduction in the mean value of IVSD (interventricular septum diameter), as it reduced by mean of 0.08 cm (p.value 0.002), (Std. Deviation(0.088)), with statistically significance, as The mean value before treatment was (1.42cm), with Std. Deviation (0.34), while it was (1.34cm) with Std. Deviation (0.31) after treatment. Fig3

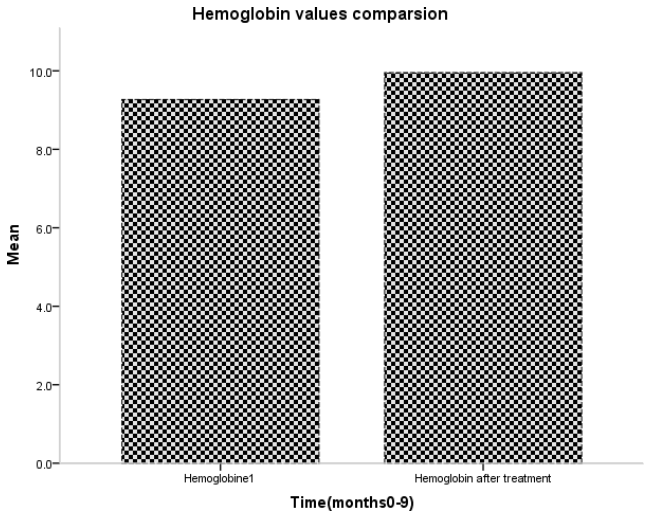

Figure 1: Shows a Comparison Between Mean Hemoglobin Values Before and After Treatment

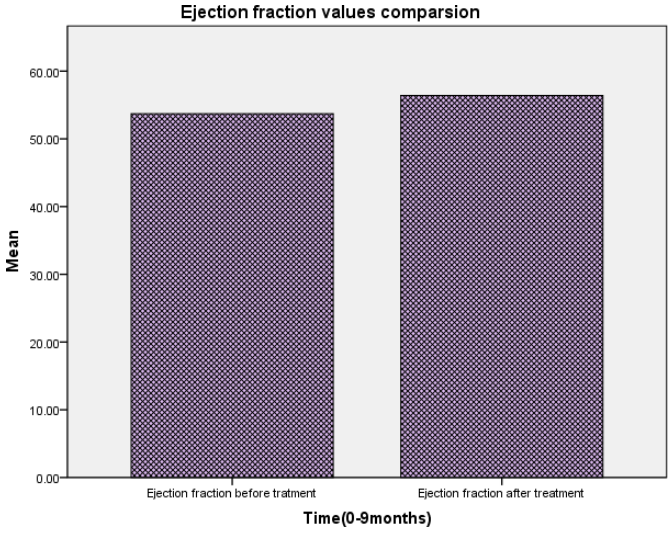

Figure 2: Shows A Comparison Between Mean Values of EF% Before and After Treatment

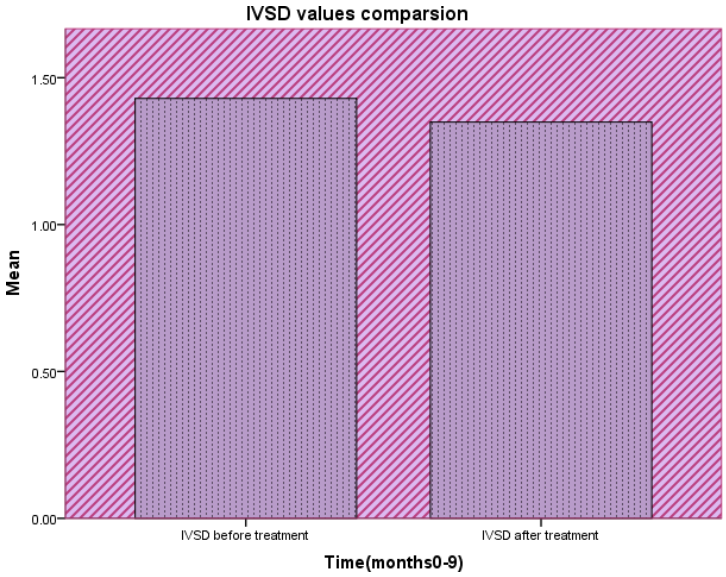

Figure 3: Shows Mean of IVSD Values Before and After Treatment

4. Discussion

Sodium glucose cotransporter protein subtype-2 (SGLT-2) in the renal proximal convoluted tubule is blocked by SGLT-2 inhibitors, thereby increasing renal excretion of glucose. There are increased risks for genital mycotic infections and, rarely, urinary tract infections; thus patients taking these should be cautioned. n the EMPA-REG OUTCOME trial, patients with T2DM and GFR greater than 90 to 45 ml/min/1.73 m2 were recruited. Empagliflozin was seen to reduce the risk for CV mortality, all-cause mortality, and hospitalization for congestive heart failure with favorable effects on weight, systolic blood pressure (BP), and serum uric acid. This is consistent with previous reports of SGLT-2 inhibitors on reducing CV and all-cause mortality. EMPA-REG OUTCOME also reported a reduction in doubling of serum creatinine and renal replacement therapy (RRT) while reducing progression to macroalbuminuria; however, the perceived renal benefits cannot be fully explained by the moderate reduction in HbA1c, BP, or serum uric acid. It has been postulated that SGLT-2 inhibitors decrease proximal tubular reabsorption of sodium that increases distal sodium delivery to the macula densa that in turns activates tubuloglomerular feedback, resulting in afferent vasodilatation and a reduction of hyperfiltration. There is a reduction in intraglomerular pressure, BP, blood glucose, and blood volume. In addition, the increase in ketone body metabolism is thought to induce an energy-efficient oxygen consumption state at the mitochondrial level that reduces hypoxic stress in the kidney, reducing renal progression of DN.1 In our study, we found similar results as worldwide studies approved, about improving cardiac structure (improved diastolic function and reduced interventricular septum diameter, but there were no significant effect on left ventricular ejection fraction, in addition giving empagliflozin in CKD patients on RRT had also positive results on hemoglobin levels (increased hemoglobin by 0.68g/dl after 9 months), But The important difference in our study is that, our cohort was ESRD patients on renal replacement therapy. these results mean that, improvement in cardiac structure, function, and hemoglobin levels, was achieved until in more advanced CKD patients with lower eGFR value, so we recommend to do larger trials to advance evidence and approve the benefits Main limitations were, The small number of patients, and Patients no adherence to treatment. We advise to use Sglt2i in ESRD patients in special cases (such as heart failure with reduced ejection fraction, left ventricular hypertrophy LVH, and as additional therapy for anemia).

5. Conclusion

Our study is the first one, that studied the effects of Empagliflozin on cardiac structure, and hemoglobin levels on hemodialysis patients. Here, we approved that, using Empagliflozin had cardiac and hematologic benefits, as the majority of patients had higher hemoglobin levels, and less interventricular septum diameter(IVSD) on echocardiography after treatment with Empagliflozin, with no important side effects that limit the using of these drugs. These are promised results to be added to the medical literature.

Statements and declarations:

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Not applicable. Competing interests

Competing interests and funding:

The authors declare that there are no competing interest regarding the publication of this paper.

Author's contributions

Dr.Sami albitar did the general review, patients treatment and monitoring.

Dr.Mohamad Kattan participated in patients treatment and did the information collection and writing.

Ethical Approval and Accordance

This study was approved by university of Aleppo committee, in accordance with the declaration of Helsinki 1975 as received in 2016.

Consent to Participate

Informed consent was taken from all participants.

Consent to publish

Not Applicable in This Manuscript Data Availability

All datasets generated or analyzed during this study are included in this published article.

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