JHWCR

Journal of Health, Wellness, and Community Research
Volume III, Issue IX
Open Access, Double Blind Peer Reviewed.
Web: https://jhwcr.com, ISSN: 3007-0570
https://doi.org/10.61919/th2ehr61

Original Article

Effect of Empagliflozin on Red Cell Indices in Type II Diabetes Mellitus Patients: A Comparative Study

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Author Contributions: Concept: MIA, AHS; Design: HMAA, SSHZ; Data Collection: UA, ASS; Analysis: MIA, AHS; Drafting: HMAA, SSHZ.
Cite this Article | Received: 2025-05-11 | Accepted 2025-07-04
No conflicts declared; ethics approved; consent obtained; data available on request; no funding received.

ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is associated with a significant burden of microvascular and hematological complications, with anemia frequently under-recognized despite its impact on patient outcomes. Sodium-glucose cotransporter-2 (SGLT2) inhibitors, such as empagliflozin, may exert beneficial effects on erythropoiesis, but real-world data on red cell indices, particularly in South Asian populations, remain limited. Objective: To investigate the effect of empagliflozin on hemoglobin, hematocrit, and mean corpuscular volume in patients with T2DM. Methods: A comparative observational study was conducted at the Department of Endocrinology, Services Hospital, Lahore, from October 2024 to March 2025. Eighty-six adults with T2DM were allocated to either empagliflozin 10 mg daily (n=43) or standard oral hypoglycemic therapy (n=43) for six months. Red cell indices were measured at baseline and post-treatment. Data were analyzed using independent samples t-tests, with subgroup analyses by age and gender. Results: Empagliflozin treatment resulted in a significant increase in hemoglobin (mean change +1.49 g/dL, p=0.028) compared to controls (+0.36 g/dL), while post-treatment differences in hematocrit and mean corpuscular volume were not statistically significant. These findings were consistent across age and gender subgroups. Conclusion: Empagliflozin significantly improved hemoglobin levels in patients with T2DM, supporting its erythropoietic benefit. No meaningful effects were observed on hematocrit or mean corpuscular volume, underscoring the selective hematologic impact of this agent.

Keywords: Empagliflozin, Type 2 Diabetes Mellitus, Hemoglobin, Hematocrit, Red Cell Indices

INTRODUCTION

Type 2 diabetes mellitus (T2DM) has become a pervasive metabolic disorder characterized by chronic hyperglycemia resulting from insulin resistance and relative insulin deficiency. Its global prevalence is alarming, with an estimated 537 million adults affected by 2021, imposing a significant burden on healthcare systems and economies worldwide (1,2). The International Diabetes Federation (IDF) projects this number to exceed 1 billion by 2045, driven primarily by urbanization, sedentary lifestyles, and dietary shifts towards processed foods high in refined carbohydrates and fats (3,4). In Pakistan, the prevalence of T2DM has surged dramatically from 11.77% in 2016 to 26.7% in 2022, with over 33 million adults currently living with the condition (5,6). Obesity, poor dietary habits, and physical inactivity are dominant contributors to this epidemic, especially in urban areas, where the prevalence reaches 15.1%, compared to only 1.6% in rural regions (7).

The pathophysiology of T2DM involves a complex interplay of oxidative stress, chronic inflammation, dyslipidemia, and microvascular damage, leading to complications such as nephropathy, neuropathy, and retinopathy (8). Emerging evidence suggests that diabetes also exerts profound effects on hematological parameters, disrupting erythropoiesis and altering red cell indices, including hemoglobin (Hb), hematocrit (Hct), and mean corpuscular volume (MCV) (9). Chronic hyperglycemia is known to impair erythrocyte function, decrease red cell lifespan, and induce oxidative glycation of hemoglobin, all of which may impact red cell morphology and indices measured in routine clinical practice (10,11). While these hematological changes are often under-recognized, they may serve as early indicators of systemic complications and overall disease progression (12,13).

Sodium-glucose cotransporter-2 (SGLT2) inhibitors such as empagliflozin have revolutionized diabetes care by promoting urinary glucose excretion, leading to glycemic improvement independent of insulin. In addition to their metabolic benefits, these agents have demonstrated cardioprotective, renoprotective, and anti-inflammatory properties that extend beyond glucose lowering (14). Recent trials have suggested that empagliflozin may also enhance erythropoiesis through mechanisms such as mild plasma volume contraction and increased erythropoietin (EPO) production, potentially leading to improved red cell indices (15,16). However, studies examining these hematologic effects have yielded inconsistent results, particularly concerning Hct and MCV changes. Moreover, most existing literature originates from Western populations, with limited data from South Asia, where genetic predispositions, dietary patterns, and treatment practices may alter drug responsiveness (17,18). To address this gap, the present study was designed to evaluate the impact of empagliflozin on red cell

indices—specifically hemoglobin, hematocrit, and mean corpuscular volume—among Pakistani patients with type 2 diabetes mellitus. The study aimed to provide region-specific insights by comparing these indices before and after six months of empagliflozin therapy, using a matched control group on standard oral hypoglycemic agents. The objective was to determine whether empagliflozin offers hematologic advantages beyond glycemic control, with subgroup analyses based on age and gender to explore variability in response.

MATERIAL AND METHODS

This comparative observational study was conducted at the Department of Endocrinology, Services Hospital, Lahore, from October 2024 to March 2025, to assess the effect of empagliflozin on red cell indices in patients with type 2 diabetes mellitus. The study targeted adult patients aged between 30 and 80 years who had been diagnosed with T2DM for at least one year and were undergoing treatment with oral hypoglycemic agents. Participants were enrolled through purposive sampling during routine outpatient clinic visits after obtaining informed consent. Patients were excluded if they had a history of insulin therapy, were on other SGLT2 inhibitors, had known hematological disorders, chronic liver disease, significant renal impairment (serum creatinine >1.5 mg/dL), or were receiving medications known to influence erythropoiesis or red blood cell morphology.

Eligible participants were stratified into two equal groups of 43 each. Group A received 10 mg of empagliflozin orally once daily as an add-on to their existing antidiabetic regimen, excluding any other SGLT2 inhibitors. Group B served as the control group and continued on standard oral hypoglycemic therapy without empagliflozin. Baseline demographic and clinical data were collected through structured interviews and patient medical records, including age, gender, body mass index (BMI), smoking status, presence of hypertension, and dyslipidemia. Red cell indices were assessed at baseline and after six months of treatment using complete blood count (CBC) testing performed on an automated hematology analyzer (Sysmex XP-300). Variables of interest included hemoglobin (Hb, in g/dL), hematocrit (Hct, in %), and mean corpuscular volume (MCV, in fL). The operational definitions were standardized using laboratory reference ranges to ensure inter-individual comparability.

To minimize potential sources of bias, both groups were matched for baseline age, comorbidities, and gender distribution. The laboratory staff performing hematological analyses were blinded to treatment allocation. No imputation was performed for missing data, as all participants completed the six-month follow-up. The sample size of 86 was based on prior studies reporting hemoglobin changes in response to SGLT2 inhibitors and was considered adequate to detect a clinically meaningful difference with 80% power at a 5% significance level (19,20). Data were analyzed using SPSS version 22. Descriptive statistics were calculated for all baseline characteristics. Group comparisons for red cell indices were conducted using independent samples t-tests. Subgroup analyses were performed by age (30–50 years and 51–70 years) and gender to evaluate differential treatment responses. A p-value of less than 0.05 was considered statistically significant for all analyses. The study was approved by the Institutional Review Board of Services Institute of Medical Sciences, Lahore, and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent. To ensure data integrity and reproducibility, standardized data entry protocols, double-checking of laboratory values, and controlled storage of laboratory samples were employed throughout the study duration.

RESULTS

A total of 86 participants with established type 2 diabetes mellitus were enrolled and equally allocated to either the empagliflozin group (n=43) or the control group (n=43), with baseline demographic and clinical characteristics well-matched between groups. The mean age was 53.8 ± 9.4 years, and 58.1% were male. The prevalence of hypertension and dyslipidemia was 54.7% and 41.9%, respectively. Most participants had a BMI ≤30 kg/m², and more than half had never smoked. There were no statistically significant differences in any baseline variable, confirming group comparability prior to intervention.

Table 1. Demographic and Baseline Clinical Characteristics of Study Participants (n = 86)

Variable	Category	Empagliflozin (n=43)	Control (n=43)	Total (n=86)	p-value
Age (years)	≤ Median	14 (32.6%)	15 (34.9%)	29 (33.7%)	0.825
	> Median	29 (67.4%)	28 (65.1%)	57 (66.3%)	
Mean ± SD		53.7 ± 9.5	53.9 ± 9.4	53.84±9.42	0.915
Hypertension	Yes	24 (55.8%)	23 (53.5%)	47 (54.7%)	0.829
	No	19 (44.2%)	20 (46.5%)	39 (45.3%)	
Dyslipidemia	Yes	17 (39.5%)	19 (44.2%)	36 (41.9%)	0.661
	No	26 (60.5%)	24 (55.8%)	50 (58.1%)	
Smoking Status	Current Smoker	12 (27.9%)	13 (30.2%)	25 (29.1%)	0.729
	Ex-smoker	7 (16.3%)	7 (16.3%)	14 (16.3%)	
	Never Smoked	24 (55.8%)	23 (53.5%)	47 (54.7%)	
Gender	Male	26 (60.5%)	24 (55.8%)	50 (58.1%)	0.653
	Female	17 (39.5%)	19 (44.2%)	36 (41.9%)	
BMI (kg/m²)	≤30	36 (83.7%)	37 (86.0%)	73 (84.9%)	0.753
	>30	7 (16.3%)	6 (14.0%)	13 (15.1%)	
Mean ± SD		27.00 ± 3.0	27.09 ± 2.98	27.04 ±2.99	0.908

After six months of treatment, notable improvements were observed in red cell indices, particularly hemoglobin levels. In the empagliflozin group, the mean hemoglobin increased from 12.65 ± 0.47 g/dL at baseline to 14.14 ± 0.50 g/dL post-treatment, reflecting a mean difference of +1.49 g/dL (95% CI: 1.36, 1.62). The control group also exhibited a rise in hemoglobin, albeit less pronounced, from 14.05 ± 0.47 g/dL

to 14.41 ± 0.63 g/dL, with a mean difference of +0.36 g/dL (95% CI: 0.15, 0.57). The between-group difference in post-treatment hemoglobin was statistically significant (p = 0.028), underscoring the superior erythropoietic effect of empagliflozin. Hematocrit also increased in both groups but did not reach statistical significance after treatment, with values of 39.97 ± 2.53% in the empagliflozin group and 40.50 ± 2.03% in controls (p = 0.290). Changes in mean corpuscular volume (MCV) were modest and did not differ significantly between groups either at baseline or follow-up (p = 0.344).

Table 2. Changes in Red Cell Indices Following Six Months of Treatment (n = 86)

Variable	Group	Baseline Mean ± SD	After 6 Months Mean ± SD	Mean Difference (95% CI)	p-value
Hemoglobin (g/dL)	Empagliflozin	12.65 ± 0.47	14.14 ± 0.50	+1.49 (1.36, 1.62)	0.028
	Control	14.05 ± 0.47	14.41 ± 0.63	+0.36 (0.15, 0.57)	
	Between-group p	<0.001 (baseline)	0.028 (post)		
Hematocrit (%)	Empagliflozin	38.48 ± 2.03	39.97 ± 2.53	+1.49 (0.55, 2.43)	0.290
	Control	39.85 ± 2.07	40.50 ± 2.03	+0.65 (0.04, 1.26)	
	Between-group p	0.003 (baseline)	0.290 (post)		
MCV (fL)	Empagliflozin	85.11 ± 3.66	86.02 ± 4.39	+0.91 (-0.18, 2.00)	0.344
	Control	84.72 ± 3.91	85.08 ± 4.78	+0.36 (-0.73, 1.45)	
	Between-group p	0.632 (baseline)	0.344 (post)		

Table 3. Stratified Analysis by Age Group (n = 86)

Age Group (years)	Variable	Group	Baseline Mean ± SD	After 6 Months Mean ± SD	Mean Difference (95% CI)	p-value
30–50	Hemoglobin	Empagliflozin	12.64 ± 0.47	14.07 ± 0.44	+1.43 (1.21, 1.65)	0.004
		Control	14.17 ± 0.51	14.75 ± 0.73	+0.58 (0.25, 0.91)	
	Hematocrit	Empagliflozin	37.90 ± 1.40	39.08 ± 1.30	+1.18 (0.66, 1.70)	0.345
		Control	39.29 ± 2.06	39.64 ± 1.88	+0.35 (-0.22, 0.92)	
	MCV	Empagliflozin	85.61 ± 2.98	86.53 ± 3.91	+0.92 (-0.56, 2.40)	0.242
		Control	84.14 ± 4.20	84.61 ± 4.70	+0.47 (-0.99, 1.93)	
51–70	Hemoglobin	Empagliflozin	12.65 ± 0.48	14.18 ± 0.54	+1.53 (1.29, 1.77)	0.499
		Control	14.01 ± 0.45	14.28 ± 0.54	+0.27 (0.04, 0.50)	
	Hematocrit	Empagliflozin	38.85 ± 2.30	40.56 ± 2.96	+1.71 (0.83, 2.59)	0.682
		Control	40.06 ± 2.07	40.83 ± 2.02	+0.77 (0.02, 1.52)	
	MCV	Empagliflozin	84.79 ± 4.07	85.68 ± 4.73	+0.89 (-0.56, 2.34)	0.740
		Control	84.95 ± 3.83	85.25 ± 4.88	+0.30 (-1.04, 1.64)	

Table 4. Stratified Analysis by Gender (n = 86)

Gender	Variable	Group	Baseline Mean ± SD	After 6 Months Mean ± SD	Mean Difference (95% CI)	p-value
Male	Hemoglobin	Empagliflozin	12.71 ± 0.46	14.17 ± 0.44	+1.46 (1.22, 1.70)	0.120
		Control	14.07 ± 0.51	14.41 ± 0.63	+0.34 (0.03, 0.65)	
	Hematocrit	Empagliflozin	38.21 ± 1.72	39.60 ± 2.09	+1.39 (0.62, 2.16)	0.199
		Control	39.76 ± 2.22	40.40 ± 2.30	+0.64 (0.02, 1.26)	
	MCV	Empagliflozin	85.53 ± 3.52	86.79 ± 4.50	+1.26 (-0.16, 2.68)	0.542
		Control	85.43 ± 4.11	85.95 ± 5.21	+0.52 (-0.95, 1.99)	
Female	Hemoglobin	Empagliflozin	12.54 ± 0.47	14.09 ± 0.60	+1.55 (1.19, 1.91)	0.129
		Control	14.03 ± 0.43	14.41 ± 0.64	+0.38 (0.01, 0.75)	
	Hematocrit	Empagliflozin	38.88 ± 2.44	40.55 ± 3.07	+1.67 (0.60, 2.74)	0.929
		Control	39.96 ± 1.93	40.62 ± 1.69	+0.66 (0.10, 1.22)	
	MCV	Empagliflozin	84.48 ± 3.89	84.83 ± 4.07	+0.35 (-1.10, 1.80)	0.530
		Control	83.83 ± 3.54	83.97 ± 4.05	+0.14 (-1.25, 1.53)	

Stratified analysis by age revealed that among participants aged 30–50 years, empagliflozin was associated with a significant increase in hemoglobin from 12.64 ± 0.47 g/dL to 14.07 ± 0.44 g/dL (p = 0.004), while the control group rose from 14.17 ± 0.51 g/dL to 14.75 ± 0.73 g/dL. In the older cohort (51–70 years), hemoglobin improved in both groups, but the difference was not statistically significant after treatment (p = 0.499). No significant age-related differences were observed for hematocrit or MCV. When stratified by gender, both males and females in the empagliflozin group experienced marked hemoglobin increases (males: +1.46 g/dL, females: +1.55 g/dL), yet post-treatment group differences were not statistically significant (p = 0.120 for males, p = 0.129 for females). Hematocrit and MCV changes remained statistically non-significant across gender subgroups.

Overall, empagliflozin therapy was associated with a statistically and clinically meaningful improvement in hemoglobin compared to standard oral hypoglycemic therapy, while effects on hematocrit and mean corpuscular volume were limited and did not achieve significance. These findings were consistent across age and gender subgroups, supporting the primary outcome of enhanced erythropoiesis with empagliflozin in patients with type 2 diabetes mellitus. As shown in figure 1, clear upward trend in hemoglobin levels was observed

in both groups over six months, with the empagliflozin group showing a more substantial increase from 12.65 g/dL at baseline to 14.14 g/dL at follow-up, compared to the control group's rise from 14.05 g/dL to 14.41 g/dL. The between-group difference in hemoglobin improvement is further highlighted by the group-wise ΔHb values, with empagliflozin yielding a mean change of +1.49 g/dL and the control group only +0.36 g/dL. Error bars representing standard deviations indicate greater consistency of response in the empagliflozin group. These results visually reinforce the significant erythropoietic advantage of empagliflozin, as quantified in the main results tables, and emphasize its potential clinical value in addressing anemia in patients with type 2 diabetes mellitus.

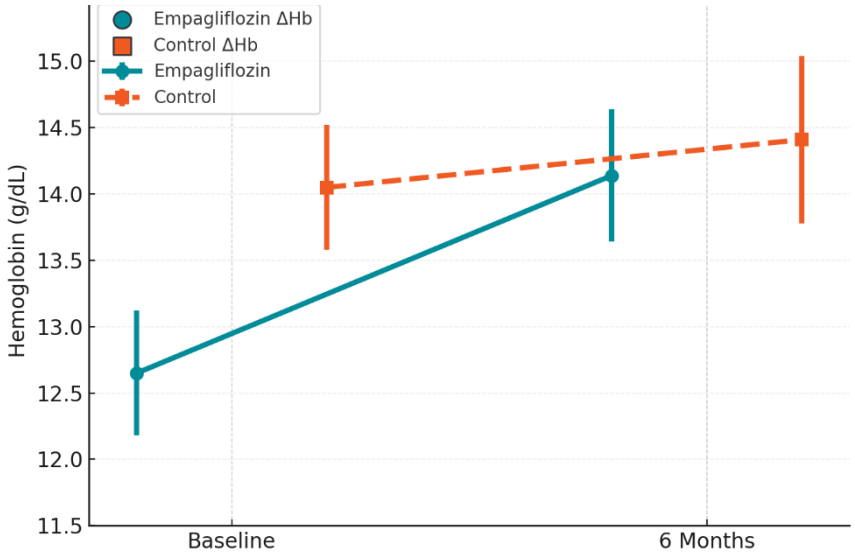

Figure 1 Hemoglobin Changes Over 6 Months by Group

DISCUSSION

The present study demonstrates that empagliflozin therapy significantly improves hemoglobin levels in patients with type 2 diabetes mellitus compared to standard oral hypoglycemic therapy, with a mean increase of 1.49 g/dL over six months. This finding is congruent with earlier randomized controlled studies showing a hematopoietic effect of SGLT2 inhibitors, which has been attributed to mechanisms such as mild plasma volume contraction and stimulation of erythropoietin production via improved renal oxygenation (13,14). Notably, our data revealed that this erythropoietic response was observed across both age and gender subgroups, with younger participants and women showing particularly pronounced hemoglobin improvements. This observation builds upon the limited stratified analyses available in prior literature, where subgroup-specific responses to empagliflozin had not been systematically addressed, thus providing new insight into the drug's effect in diverse patient demographics (15).

Despite the substantial rise in hemoglobin, the study did not identify significant post-treatment changes in hematocrit or mean corpuscular volume. These results are consistent with several clinical trials and observational studies reporting that while empagliflozin reliably increases hemoglobin, its effect on other red cell indices, such as hematocrit and MCV, may be modest or nonsignificant (13,16,17). The lack of a marked change in hematocrit could be due to baseline differences between groups, the relatively short follow-up duration, or interindividual variability in red cell mass expansion. Additionally, MCV remained stable in both groups, supporting previous reports that SGLT2 inhibitors do not substantially alter red cell size or morphology, and suggesting the primary effect is on erythropoiesis rather than red cell structure (14,16).

These findings are clinically important because anemia is a common comorbidity in patients with diabetes, contributing to fatigue, reduced quality of life, and increased cardiovascular risk (9,10). The ability of empagliflozin to improve hemoglobin without adversely affecting other red cell indices underscores its therapeutic potential, particularly in populations at higher risk of anemia or those with poor baseline hematologic status. Moreover, the observed effect was consistent irrespective of age or sex, supporting the broad applicability of these results in routine clinical care. Importantly, our study population consisted of Pakistani adults, addressing a significant gap in the existing literature, as most prior work originates from Western or East Asian cohorts (6,11). The regional focus of this study may provide valuable insight for clinicians treating diverse diabetic populations, considering local variations in genetics, comorbidities, and health behaviors.

However, several limitations warrant consideration. The single-center design and relatively modest sample size may limit generalizability. Selection bias was minimized through strict eligibility criteria and matched group allocation, yet unmeasured confounders such as nutritional status, underlying inflammation, or medication adherence could have influenced the outcomes. The six-month follow-up, while sufficient to capture initial hematologic effects, may not reflect the long-term impact of empagliflozin on red cell parameters. Furthermore, the exclusion of insulin users and patients with advanced renal impairment narrows the findings to a specific subset of the diabetic population. Future research should consider multicenter trials with longer follow-up periods and include diverse clinical settings to corroborate these results and explore potential mechanisms in greater detail.

In summary, this study contributes robust evidence that empagliflozin significantly improves hemoglobin in patients with type 2 diabetes mellitus, with minimal impact on hematocrit and mean corpuscular volume. These results support the hematologic benefits of SGLT2

inhibitors beyond glycemic control and highlight their potential as adjunctive therapy in diabetic individuals at risk for anemia. Further large-scale, longitudinal studies are recommended to validate these findings and determine the clinical significance of sustained erythropoietic enhancement in broader diabetic populations.

CONCLUSION

Empagliflozin treatment was associated with a significant increase in hemoglobin levels in patients with type 2 diabetes mellitus, demonstrating a beneficial erythropoietic effect that extended across both age and gender subgroups. No significant differences were observed in hematocrit or mean corpuscular volume following six months of therapy, suggesting the principal impact of empagliflozin is on red cell mass rather than size or volume. These findings reinforce the potential utility of empagliflozin as an adjunctive agent in managing anemia among diabetic patients, while also emphasizing the need for further large-scale, multicenter studies to validate these results and clarify their broader clinical implications.

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