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The Relationship Between Disease Outcomes and Laboratory Diagnostic Markers in Patients with Diabetes Mellitus and Cardiovascular Disease

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Abstract

Objective: This study aims to investigate the relationship between laboratory diagnostic markers and health outcomes in diabetic patients with cardiovascular diseases in Abadan, Iran, in order to aid in disease management and reduce mortality rates.

Materials and Methods: This cross-sectional analytical study collected demographic, clinical and laboratory data from diabetic patients with cardiovascular disease admitted to Taleghani Educational Hospital, affiliated with Abadan University of Medical Sciences, between March 2022 and March 2023. Using a census sampling method, a total of 268 patients with complete laboratory records were analyzed. Logistic regression was employed to examine the association between study variables and mortality. Data analysis was performed using SPSS software.

Results: The study evaluated 268 diabetic patients with cardiovascular disease (mean age, 66.89 (±14.18) years; 56.7% female). Logistic regression analysis revealed a significant association between mortality and several variables, including higher respiratory rate, blood glucose, blood urea nitrogen (BUN), aspartate aminotransferase (AST), prothrombin time (PT), partial thromboplastin time (PTT), international normalized ratio (INR), white blood cell (WBC) count and lactate dehydrogenase (LDH). Conversely, higher oxygen saturation levels and diastolic blood pressure were associated with lower mortality rates.

Conclusion: These findings indicate that in diabetic patients with cardiovascular disease, mortality is primarily associated with coagulation abnormalities, renal dysfunction and hepatic impairment. Furthermore, routine clinical and laboratory assessments can be valuable in identifying patients at a higher risk of mortality, thereby facilitating early prognostic evaluation.

Keywords: Diabetes mellitus, Cardiovascular diseases, Blood glucose, Death

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Introduction

Diabetes mellitus (DM) is a chronic metabolic disease characterized by hyperglycemia and a spectrum of microvascular and macrovascular complications (1,2). Given the rapidly increasing global and regional prevalence of diabetes, targeted screening of at-risk populations and early diagnosis are essential to implement preventive measures that delay disease onset and progression (1,3). Emerging evidence suggests that alterations in modifiable risk factors such as blood pressure, lipid profiles, heart rate, body weight, serum uric acid, and glycemic variability significantly contribute to the pathogenesis of diabetic complications (4).

Macrovascular and microvascular complications adversely affect vital organs and substantially elevate patient mortality. Understanding the underlying risk factors, pathogenic mechanisms and management strategies for vascular complications is critical for optimizing clinical outcomes (2). Notably, diabetes mellitus markedly increases the risk of cardiovascular disease (CVD), conferring a two- to four-fold higher risk of adverse events such as stroke, unstable angina, myocardial infarction and heart failure compared to individuals without diabetes (5).

Cardiovascular disease affects approximately 32.2% of patients with type 2 diabetes mellitus (T2DM) and serves as the leading cause of mortality in this population, accounting for roughly half of all deaths, predominantly driven by coronary artery disease and stroke (6,7). Consequently, contemporary strategies for CVD prevention in T2DM focus on individualized glycemic control, rigorous management of blood pressure and dyslipidemia and the utilization of novel glucose- and lipid-lowering pharmacotherapies (6). Similarly, patients with type 1 diabetes (T1DM) experience elevated age- and sex-matched mortality rates driven by accelerated macrovascular complications, facing at least a 30% higher relative risk of death (8). Furthermore, chronic kidney disease (CKD) and end-stage renal disease (ESRD), alongside clinical factors such as advanced age, male sex and diuretic therapy, further exacerbate adverse mid-term outcomes in patients with comorbid diabetes and CVD, underscoring the need for further high-quality investigations (9).

Effective management of diabetes and its associated complications is paramount for reducing disease-specific morbidity and mortality. Identifying reliable laboratory diagnostic markers for the early detection of prediabetes and the prevention of vascular sequelae can significantly enhance clinical decision-making. Therefore, this study aims to investigate the relationship between laboratory diagnostic markers and health outcomes in patients with DM and CVD in Abadan, a city located in Khuzestan Province, southwestern Iran. This region is of particular epidemiological interest due to a rising frequency and intensity of dust storms, largely driven by its proximity to expansive deserts in southern Iraq and Saudi Arabia, compounded by recent local drought conditions.

Material and methods

This research is an analytical cross-sectional study focusing on T2DM patients who also suffer from CVD. The data for this study was meticulously gathered from the Medical Records and Health Information Systems (HIS) Department of the Taleghani educational Hospital, which is associated with Abadan University of Medical Sciences. The timeframe for data collection spanned from March 2022 to March 2023.

The study employed a census sampling method, resulting in a total of 268 patients with complete laboratory information available for analysis. The research team extracted demographic, clinical and laboratory data. This included critical diagnostic markers for renal, hepatic, blood, and coagulation functions, sourced from patients' medical records and the HIS. The collected data were systematically organized into relevant checklists before being entered into SPSS for analysis.

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To qualify for inclusion in this study, participants must be diabetic patients diagnosed by both an endocrinologist and an internal medicine specialist and they must have been concurrently diagnosed with CVD by a cardiologist. Additionally, their medical information needed to be accessible within the HIS and the medical records of Taleghani Hospital during the study period. Patients were excluded if they had CVD, but their medical information was either unavailable or incomplete.

The clinical data gathered for this study comprised various health indicators essential for understanding the patient demographic.

Continuous variables were presented as mean ±standard deviation and categorical variables as frequencies and percentages. The normality of continuous variables was assessed using the Kolmogorov–Smirnov test. Logistic regression analysis was performed to examine the association between demographic, clinical, and laboratory variables and in-hospital mortality. Before fitting the final model, key assumptions were evaluated. Linearity between continuous predictors and the logit of the outcome was assessed using the Box–Tidwell procedure. Multicollinearity among independent variables was examined using tolerance and variance inflation factor (VIF) values, with particular attention to potential collinearity between prothrombin time (PT) and international normalized ratio (INR). Given the presence of sparse events and very large effect estimates for some predictors, a Firth penalized logistic regression model was additionally applied to reduce small-sample bias and address potential separation in the data. Model calibration was assessed using the Hosmer–Leme show goodness-of-fit test and model discrimination was evaluated using the receiver operating characteristic (ROC) curve and the corresponding area under the curve (AUC). Results were reported as odds ratios (ORs) with 95% confidence intervals (CIs). A two-sided $P< 0.05$ was considered statistically significant. All analyses were performed using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA).

Ethical considerations

This study was approved by the Ethics Committee of Abadan University of Medical Sciences (Ethical Approval ID: IR.ABADANUMS.REC.1401.083).

Results

This study was conducted on 268 diabetic patients with cardiovascular diseases, with a mean age of 66.89(±14.18) years, the majority of whom were in the age range of 36-60 years (64.6%). Most of the patients were female (56.7%) and 31 (11.6%) of the patients studied died (Table 1).

The results of this study showed that the mean renal markers blood urea nitrogen (BUN) and creatinine were (22.89 (±16.68**)** and 1.32 (±1.28)), respectively, higher than the normal range. The mean liver markers, such as SGOT and SGPT, were (43.96 (±37.78) and 43.38 (±87.26)), respectively, which were higher than the normal range. The level of lactate dehydrogenase (LDH) enzyme was also higher than the normal range 755.57 (±439.97). The mean inflammatory markers, ESR, were higher than the normal range 55.99 (±26.73) and C-reactive protein (CRP) was reported positive in 56.3% of patients. SpO2 was reported to be lower than the normal level 90.97 (±10.45) and respiratory rate (RR) was higher than the normal level 22.74 (±12.33). The mean coagulation markers prothrombin time (PT), partial thromboplastin time (PTT), and international normalized ratio (INR) were also above the normal range and were reported as (13.26 (±1.51), 36.21 (±10.21) and 1.19 (±1.14)), respectively (Table 1).

Before interpreting the regression coefficients, model assumptions and performance were evaluated. The linearity of the logit for continuous predictors was assessed using the Box–Tidwell procedure and was confirmed for all variables retained in the final model. Assessment of multicollinearity demonstrated no evidence of severe collinearity among independent variables.

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Table 1. Demographic, laboratory and clinical characteristic of patients, (N= 268)

Variable		Mean or N (SD or %)
Age, year Mean (±SD)**:**66.89 (±14.18)	≤ 35 years	79 (29.5%)
	36–60 years	173 (64.6%)
	≥ 61 years	16 (6.0%)
Sex	Female	152 (56.7%)
	Male	116 (43.3%)
The outcome of the disease	Recovery	237 (88.4%)
	Death	31 (11.6%)
SBP (mm Hg)		127.62 (±23.03)
DBP (mm Hg)		74.55 (±15.68)
RR (breath per minute)		22.74 (±12.33)
SpO2		90.97 (±10.45)
BS (mg/dL)		246.15 (±149.74)
BUN (mg/dL)		22.89 (±16.68)
Creatinine (mg/dL)		1.32 (±1.28)
Na (mEq/L)		139.25 (±4.95)
K (mEq/L)		4.42 (±2.37)
AlP (U/L)		214.41(±120.15)
LDH (U/L)		755.57 (±439.97)
Total bilirubin (mg/dL)		0.83 (±1.86)
Direct bilirubin (mg/dL)		0.43 (±1.54)
SGOT (AST) (U/L)		43.96 (±37.78)
SGPT (ALT) (U/L)		43.38 (±87.26)
PT (sec)		13.26 (±1.51)
PTT (sec)		36.21(±10.21)
INR		1.19 (±1.14)
ESR (mm/hr)		55.99 (±26.73)
CRP	Negative	144 (53.7%)
	1+	31(11.6%)
	2+	29 (10.8%)
	2++	9 (3.4%)
	3+	39 (14.6%)
	3+++	16 (6.0%)
WBC (per microliter)		8.56 (±6.24)
RBC (million cells per microliter)		5.41(±5.96)
MCV (femtoliters (fl))		82.25 (±12.69)
MCH (pg of hemoglobin per RBC)		28.30 (±8.27)
MCHC		32.32 (±2.22)
Plt (per microliter of blood)		228.52 (±83.15)

SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, RR: Respiratory Rate, SpO2: Oxygen Saturation, BS: Blood Sugar, BUN: Blood Urea Nitrogen, Na: Sodium, K: Potassium; ALP: Alkaline Phosphatase, LDH: Lactate Dehydrogenase, SGOT: Serum Glutamic Oxaloacetic Transaminase, SGPT: Serum Glutamic Pyruvic Transaminase, ALT: Alanine Transaminase, AST: Aspartate Aminotransferase, PT: Prothrombin Time, PTT: Partial Thromboplastin Time, INR: International Normalized Ratio, ESR: Erythrocyte sedimentation rate; CRP: C-reactive protein; WBC: White Blood Cell, RBC: Red Blood Cell, MCV: Mean Corpuscular Volume, MCH: Mean Corpuscular Hemoglobin; MCHC: Mean Corpuscular Hemoglobin Concentration, Plt: Platelet

Variance inflation factor (VIF) values ranged from 1.23 to 3.56 and tolerance values ranged from 0.281 to 0.813.Given the expected clinical and mathematical relationship between PT and INR, these variables were specifically examined; no substantial multicollinearity was detected and both were retained in the model. The Hosmer–Lemeshow goodness of fit test indicated adequate model calibration (χ^2= 6.42, *P*= 0.647).The model showed moderate discriminatory performance, with an area under the receiver operating characteristic curve (AUC) of 0.654 (95% CI: 0.578–0.786).

A logistic regression analysis was performed to identify variables associated with disease outcomes, particularly mortality. The findings are summarized in Table 2.

Physiological parameters, especially the respiratory rate, were significantly associated with mortality; a higher RR was associated with increased odds of death (OR= 1.273, 95% CI: 1.105–1.465, *P*= 0.001).

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Table 2. Logistic regression analysis of variables associated with the outcome of diseases (death)

Variable		OR	95% CI for OR		*P*-value
			Lower	Upper	
Age	≤ 35 years	-	-	-	-
	36-60 years	0.553	0.254	1.204	0.136
	≥ 61 years	0.338	0.041	2.791	0.314
Gender		1.461	0.690	3.094	0.322
SBP (mm Hg)		0.998	0.982	1.015	0.841
DBP (mm Hg)		0.962	0.942	0.983	0.001
RR (breath per minute)		1.273	1.105	1.465	0.001
SpO2%		0.921	0.891	0.952	0.001
FBS (mg/dL)		1.009	1.003	1.015	0.004
BS (mg/dL)		1.003	1.001	1.005	0.013
BUN (mg/dL)		1.024	1.007	1.041	0.006
Creatinine (mg/dL)		1.073	0.842	1.366	0.569
Na (mEq/L)		0.969	0.899	1.046	0.422
K (mEq/L)		0.532	0.338	0.839	0.007
ALP (U/L)		1.002	0.999	1.004	0.136
LDH (U/L)		1.001	1.000	1.001	0.049
Toal_Billirubin (mg/dL)		1.273	0.982	1.649	0.068
Direct_Billirubin (mg/dL)		1.397	0.972	2.009	0.071
SGOT (AST) (U/L)		1.009	1.001	1.018	0.034
SGPT (ALT) (U/L)		1.004	0.999	1.009	0.083
PT (sec)		1.597	1.253	2.037	0.001
PTT (sec)		1.043	1.012	1.075	0.006
INR		61.458	7.116	530.777	0.001
ESR (mm/hr)		0.989	0.975	1.004	0.152
CRP	CRP(1)	1.673	0.259	10.811	0.589
	CRP(2)	1.812	0.145	22.636	0.644
	CRP(3)	1.657	0.283	9.703	0.575
	CRP(4)	2.071	0.264	16.271	0.489
	CRP(5)	2.204	0.486	9.997	0.306
WBC (per microliter)		1.062	1.013	1.113	0.013
RBC (million cells per microliter)		0.928	0.729	1.183	0.547
MCV (femtoliters (fl))		0.948	0.922	0.974	0.001
MCH (pg of hemoglobin per RBC)		1.078	1.029	1.130	0.002
MCHC		0.816	0.702	0.948	0.008
Plt (per microliter of blood)		1.002	0.998	1.007	0.258

SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, RR: Respiratory Rate, SpO2: Oxygen Saturation, BS: Blood Sugar, BUN: Blood Urea Nitrogen, Na: Sodium, K: Potassium, ALP: Alkaline Phosphatase, LDH: Lactate Dehydrogenase, SGOT: Serum Glutamic Oxaloacetic Transaminase, SGPT: Serum Glutamic Pyruvic Transaminase, ALT: Alanine Transaminase, AST: Aspartate Aminotransferase, PT: Prothrombin Time, PTT: Partial Thromboplastin Time, INR: International Normalized Ratio, ESR: Erythrocyte sedimentation rate, CRP: C-reactive protein, WBC: White Blood Cell, RBC: Red Blood Cell, MCV: Mean Corpuscular Volume, MCH: Mean Corpuscular Hemoglobin, MCHC: Mean Corpuscular Hemoglobin Concentration, PLt: Platelet

Laboratory parameters revealed that higher blood sugar (OR= 1.003, 95% CI: 1.001–1.005, *P*= 0.013), fasting blood sugar (FBS) (OR=1.009, 95% CI: 1.003–1.015, *P*= 0.004) and BUN (OR= 1.024, 95% CI: 1.007–1.041, *P*= 0.006) were associated with a greater risk of death (Table 2).

In examining liver-related laboratory parameters, we found that AST (SGOT) was significantly associated with mortality, with an odds ratio (OR) of 1.009 (95% CI: 1.001–1.018, *P*= 0.034). Similarly, LDH was also significantly associated with mortality, showing an OR of 1.001 (95% CI: 1.000–1.001, *P*= 0.049).

Coagulation factor tests indicated that higher PT (OR= 1.597, 95% CI: 1.253–2.037, *P*< 0.001) and PTT (OR= 1.043, 95% CI: 1.012–1.075, *P*= 0.006) were associated with increased mortality risk.

The INR showed a stronger association (OR= 61.458, 95% CI: 7.116–530.777, *P*< 0.001) (Table 2).

In contrast, higher SpO2 (OR= 0.921, 95% CI: 0.891–0.952, *P*< 0.001), diastolic blood

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pressure (OR= 0.962, 95% CI: 0.942–0.983, *P*< 0.001), potassium (OR= 0.532, 95% CI: 0.338–0.839, *P*= 0.007), MCV (OR= 0.948, 95% CI: 0.922–0.974, *P*< 0.001) and MCHC (OR= 0.816, 95% CI: 0.702–0.948, *P*= 0.008) were associated with lower odds of death. Age, gender, systolic blood pressure, creatinine, sodium, ESR, CRP, RBC and platelet count were not significantly associated with mortality (Table 2).

Discussion

This study involved 268 diabetic patients who also had cardiovascular diseases. The SpO2 levels were reported to be lower than normal, while the respiratory rate was elevated. Laboratory parameters such as FBS, BUN and potassium are important predictors of disease outcomes. Higher FBS and BUN levels are associated with an increased risk of death, reflecting metabolic disturbances and impaired renal function, respectively. Additionally, lower potassium levels also correlate with a higher mortality risk, underscoring the importance of electrolyte balance.

In liver-related parameters, SGOT and LDH levels were significantly associated with mortality, while coagulation factors such as PT, PTT and INR also indicated a higher risk of death, suggesting liver dysfunction. Clinicians should monitor these parameters closely in both acute and chronic illness patients to optimize metabolic and liver function and prevent deterioration. These findings revealed that the mean levels of renal markers, such as BUN and creatinine, were higher than the normal range. The results from logistic regression indicated that In terms of renal markers, the probability of death significantly increased with each unit increase in BUN. A direct and positive correlation coefficient was noted between death and renal markers; the likelihood of death increased with each unit rise in these markers. While the probability of death also increased with each unit increase in creatinine, this relationship was not statistically significant.

The study by Du et al. found a positive correlation BUN levels and the risk of DM. BUN more than 4.2 mmol/L increases the risk of DM about 7% for every 1 mmol/L rise. A stronger correlation with DM was noted in relation to sex, BMI, blood pressure, cholesterol levels, liver enzymes, creatinine, and smoking status. In conclusion, high BUN levels are linked to an increased risk of DM in Chinese adults, indicating that managing BUN levels may help reduce this risk (10). Liu et al. found that elevated blood urea nitrogen to creatinine ratio (UCR) increases the risk of CAD in T2DM. The risk significantly rises when UCR levels exceed 6.67. In summary, a high UCR is strongly associated with an increased risk of CAD in T2DM patients (11).

The study by Cho found a J-shaped relationship between serum creatinine levels and mortality in acute heart failure patients, with both low and high levels linked to increased mortality (12). Tolomeo et al. found that a higher BUN/creatinine ratio was related with worse outcomes in chronic heart failure patients. This ratio may reflect changes in renal blood flow and neurohumoral activation, particularly the increase of arginine vasopressin (13).

In our study liver markers like SGOT and SGPT were elevated above normal levels. The level of the LDH enzyme was also found to be higher than the normal range. The results from logistic regression indicated that SGOT and LDH levels were significantly associated with mortality.

Wang's study found that high levels of GGT and ALT significantly increase the risk of T2DM and may identify at-risk individuals in this Chinese population (14). Mahmoud's study found a notable difference in the impact of DM on liver disease between populations. Liver enzyme levels were elevated in 41.4% of Egyptians compared to 33% of Saudis. Egyptians also showed higher INR and PT. Overall, diabetes negatively affects liver diseases, while liver diseases, particularly cirrhosis, can also worsen diabetes. This indicates a mutual influence between the two conditions (15). Kunutsor's study found that

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baseline levels of ALP and GGT are positively linked to cardiovascular disease risk in a log-linear manner (16).

In our study, inflammatory markers, such as ESR, were above normal and CRP was positive in 56.3% of the patients.

A 2023 study by Ménégaut et al. found that patients with T2DM had higher hsCRP and IL-1β, as well as elevated oxysterols, triglycerides and decreased HDL levels compared to controls. The study also noted that 2-AA-LPC was significantly enriched in diabetic plaques, suggesting its role in diabetic atherosclerosis, and was correlated with inflammatory markers like lysophospholipids and 25-hydroxycholesterol, highlighting the link between inflammation and diabetes (17).

A study by Pleskovič et al. investigated the inflammatory marker hs-CRP was related with the presence of plaques and carotid intima-media thickness (CIMT) in patients with T2DM. Furthermore, higher hs-CRP levels were linked to increased CIMT progression and changes in the number of plaque sites over the follow-up period (18). Gedebjerg's study in 2003 showed that high levels of high-sensitivity C-reactive protein (hs-CRP) were associated with increased risks of cardiovascular events (CVE) and all-cause mortality in patients recently diagnosed with T2DM. This suggests that high hs-CRP may be a more effective biomarker for mortality than for CVEs, potentially assisting in the prevention of diseases and early detection (19).

In our study, mean coagulation markers, including PT, PTT and INR, were also above the normal range. PT, PTT and INR were significantly associated with higher risk of death.

The results of the study by Kumar et al. showed that a significant association was found between the coagulation profiles of diabetics and non-diabetics, with notable correlations observed between age and the diabetic group. There were also strong statistical differences in PT and INR based on gender. Differences in activated partial thromboplastin time (APTT) and PT were significant between pre-diabetic and diabetic groups. Clinical tests for PT, INR and APTT are cost-effective and widely available. The results indicate that PT and APTT are key hemostatic markers for diabetic patients who are at high risk for thrombotic complications (20).

The study by Getu et al. found no significant difference in PT and APTT between diabetes mellitus patients in Africa and healthy controls. However, a significant difference in APTT was noted between T1DM patients and controls, unlike with T2DM. While various studies have shown coagulation abnormalities in DM, this systematic review concluded that PT and APTT differences are not significant overall. Nonetheless, it is recommended that physicians regularly monitor APTT levels in T1DM patients to evaluate their coagulation status (21).

This study presents several noteworthy limitations that must be acknowledged. Firstly, it was conducted in an educational hospital situated in Abadan, a city in southwestern Iran, and involved a relatively small sample size drawn from a geographically restricted area. Consequently, the findings may not be broadly applicable to other populations, limiting the generalizability of the results.

Furthermore, the study employed a cross-sectional analytic design, which poses inherent challenges, particularly given that the primary outcome of interest is “death.” This outcome, being a time-to-event measure, is not ideally suited to cross-sectional methodology, as such designs do not allow for a clear temporal assessment between exposures and outcomes. The lack of precise specification regarding the sequence of events complicates the ability to draw causal inferences about the relationship between the investigated variables and mortality.

In light of these limitations, it is strongly advised that future research initiatives incorporate larger sample sizes and strive to include more diverse populations. This approach would enhance the robustness of the findings and contribute to a more comprehensive understanding of the factors

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influencing mortality. Additionally, employing longitudinal designs could provide clearer insights into the temporal dynamics at play in these prognostic relationships.

Conclusion

The findings of this study indicate that diabetic patients with cardiovascular disease had mean levels of renal, hepatic, inflammatory and coagulation markers that were higher than the normal range. Additionally, the SpO2 levels in these patients were lower than normal. The study found higher respiratory rate, blood glucose, BUN, AST, PT, PTT, INR, WBC and MCH were associated with increased odds of death, whereas higher oxygen saturation, diastolic blood pressure, potassium, MCV and MCHC were associated with lower odds of death. Among these variables, SpO2, respiratory rate, and coagulation markers (PT/PTT/INR) appeared to be the most clinically important predictors of mortality.

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Conflict of Interest

The author declares that there is no conflict of interest.

Authors' contributions

Conceptualization: E.R, F.B.F and S.SH
Data Collection and Laboratory Analysis: S.SH and E.R.
Data Analysis and Interpretation: N.K.
Writing – Original Draft Preparation: E.R and S.SH
Writing – Review and Editing: E.R, F.B.F, N.K and S.SH.

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