



Comparative analysis of Hematological changes in Type 2 DM and Hypertensive Patients Post-Covid 19 Vaccination.

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Abstract

Background: The global response to COVID-19 emphasizes vaccination's crucial role, raising concerns about potential hematological changes in individuals with Type 2 diabetes mellitus (DM) and hypertension. Type 2 DM, linked to elevated blood glucose and organ dysfunction, and hypertension, impacting cardiovascular and kidney health, pose challenges. This research aims to analyze post-COVID-19 vaccination hematological changes in these populations, offering insights for tailored vaccination strategies.

Material and Method: The study, involving 100 patients (50 each with Type 2 DM and hypertension), obtained ethical clearance and analyzed hematological parameters using Sysmex XN-330. Inclusion criteria covered clinically diagnosed adults who completed the COVID-19 vaccination series within six months, ensuring accessible medical records and informed consent.

Result: Post-COVID-19 vaccination, T2DM patients demonstrated significantly higher Hemoglobin levels (T2DM: 13.37 ± 2.05 gm/dl; Hypertensive: 11.95 ± 1.87 gm/dl, $P < 0.001$) and elevated Total Red Blood Cell count (T2DM: 4.73 ± 0.57 million/microliter; Hypertensive: 4.2 ± 0.6 million/microliter, $P < 0.001$). Absolute leukocyte counts in T2DM were notably increased for Neutrophils, Lymphocytes, Monocytes, and Eosinophils compared to Hypertensive patients. Haematocrit was higher in T2DM ($41.33 \pm 5.37\%$) than in Hypertensive patients ($37.44 \pm 5.5\%$, $P = 0.00028$). Platelet Count, Total Leukocyte Count, and differential leukocyte counts showed no significant differences.

Conclusion: The study emphasizes the nuanced hematological responses post-COVID-19 vaccination in Type 2 Diabetes Mellitus and Hypertensive patients. Recognizing these variations underscores the significance of considering underlying health conditions when assessing post-vaccination hematological profiles.

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1. Background

The global response to the COVID-19 pandemic has been characterized by an unprecedented reliance on vaccination as a pivotal strategy to mitigate virus spread (R et al., 2022). While vaccination efforts have proven instrumental, concerns have emerged regarding potential hematological changes in individuals with underlying health conditions, notably Type 2 diabetes mellitus (DM) and hypertension (staff, n.d.2023) .

Type 2 diabetes, a metabolic disorder marked by elevated blood glucose levels, poses significant challenges due to its association with enduring impairment and dysfunction of various organs, including the eyes, kidneys, nerves, heart, and blood vessels. (Diabetes Care 2004;27(suppl_1): s5–s10) The continual hyperglycemia linked to diabetes underscores the importance of preventive measures, given its alarming global prevalence and escalating healthcare costs (Faghilimnai et al., 2006; Ezzati et al., 2016; WHO, 2016). Lifestyle factors, such as poor diet, sedentary behaviour, and obesity, contribute to the majority of Type 2 diabetes cases, emphasizing the critical need for interventions promoting healthier lifestyles (Nuha et al., 2023; Rodriguez et al., 2016).

Hypertension, identified by elevated blood pressure (CDC, 2023) , is a chronic medical condition with far-reaching implications for cardiovascular and kidney health. The increased risk of mortality related to cardiovascular diseases highlights the critical role of hypertension in shaping health outcomes (Whelton et al., 2018). In individuals with diabetes, hypertension prevalence is influenced by a range of factors, including diabetes type, duration, age, sex, race, BMI, glycemic control, and the presence of kidney disease (Jia & Sowers, 2021). The confluence of diabetes and hypertension significantly elevates the risk of atherosclerotic cardiovascular disease (ASCVD), heart failure, and microvascular complications, contributing substantially to associated healthcare costs (de Boer et al., 2017) .

Given the interplay between Type 2 DM and hypertension, this paper aims to provide a comprehensive comparative analysis of hematological changes observed post-COVID-19 vaccination in individuals with these prevalent health conditions. By elucidating the intricate relationship between vaccination, hematological alterations, and the unique health challenges posed by diabetes and hypertension, this research contributes valuable insights to guide tailored vaccination strategies and address potential concerns in these vulnerable populations.

2. Objectives of the Study

1. **Investigate Hematological Changes:** Examine and analyze hematological changes observed in Type 2 DM and hypertensive patients post-COVID-19 vaccination.
2. **Compare Hematological Responses:** Assess whether there is a significant difference in hematological changes between Type 2 DM and hypertensive patients.

3. Material and Method

After obtaining the clearance from Ethical Committee of the Institution, Teerthanker Mahaveer University, College of Paramedical Sciences with certificate reference number: PM/ETHICAL/COPS/2023/021. The present study comprised of 100 patients of both groups (Type 2 DM and Hypertension) in both genders.

3.1 Informed constant

Informed consent was taken from both study group (Type 2 diabetes and hypertensive) subjects after explaining the purpose and procedure of the study.

3.2 Collection of Specimen

Collection of venous blood specimen was done in both patient's groups on the day of admission from antecubital vein with all aseptic precautions in EDTA vacutainers. After sample collection, all the specimen were sent for analysis in laboratory for the estimation of HB, RBCs, Platelet, Total Leucocyte, Neutrophils, Lymphocytes, Monocytes, Eosinophils counts, ANC, ALC, AMC, AEC, PCV, MCV, MCH and MCHC. Complete blood count measured by cell counter (Sysmex XN-330) which is based on principle of fluorescent flow cytometry methods (WBC, Differential count WBC), Hydrodynamic focusing DC detection method (PLT-I {Impedance}, RBC, HCT) and Cyanide-free SLS-haemoglobin method (HGB).

3.3 Inclusion and Exclusion Criteria-

3.3.1 Inclusion Criteria:

1. Patients diagnosed clinically by Physician based on Clinical examination and Laboratory findings.
2. COVID-19 Vaccination: Completed vaccination series
3. Post-Vaccination Period: Within 6 months post-final dose
4. Age: Adults (18 years and above)
5. Medical Records: Accessible medical records
6. Who give informed consent form
7. Patients of either sex

3.3.2 Exclusion Criteria:

1. Type 1 diabetes
2. Vaccination Status: Unvaccinated and incomplete vaccination series
3. Recent COVID-19: Within the last 3 months
4. Pregnancy
5. Other Severe Conditions:
 - a. Severe comorbidities
 - b. Chronic kidney disease
 - c. Hematological disorders
6. Immunocompromised
7. Adverse Reactions: History of severe adverse reactions to vaccines
8. Non-Consenting: Unwilling or unable to provide consent
9. Limited Medical Records: Inaccessible medical records
10. Patient not fitting into criteria.

Statistical analysis

The data of 50 T2DM patients and 50 hypertensive patients thus collected were analysed, correlation of HB, RBCs, Platelet, Total Leucocyte, Neutrophils, Lymphocytes, Monocytes, Eosinophils counts, ANC, ALC, AMC, AEC, PCV, MCV, MCH and MCHC parameters expressed as cross-tabulations. Measurement data in the form of cross-tabulations for observed values were found out and the simple 't' test standard error of difference between two proportions used as tests of significance. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

Result

The hematological changes post-COVID-19 vaccination were comprehensively analyzed in Type 2 Diabetes Mellitus (T2DM) and Hypertensive patients, revealing notable differences between the two groups Table 01. T2DM patients exhibited a significantly higher level of Hemoglobin (Hb) at 13.37 ± 2.05 gm/dl compared to Hypertensive patients with 11.95 ± 1.87 gm/dl ($P < 0.001$). Moreover, the Total Red Blood Cell (RBC) count was markedly elevated in T2DM patients (4.73 ± 0.57 million/microliter) compared to Hypertensive patients (4.2 ± 0.6 million/microliter, $P < 0.001$). Conversely, Platelet Count, Total Leukocyte Count (TLC), and differential leukocyte counts showed no significant differences between the groups. However, absolute leukocyte counts revealed significant increases in T2DM patients for Neutrophils, Lymphocytes, Monocytes, and Eosinophils compared to Hypertensive patients. Additionally, T2DM patients displayed a higher Hematocrit ($41.33 \pm 5.37\%$) compared to Hypertensive patients ($37.44 \pm 5.5\%$, $P = 0.00028$).

Parameter	T2DM Patients		Hypertensive Patients
	Mean \pm Std.		P-value
HB gm/dl	13.37 ± 2.05	11.95 ± 1.87	<0.001
Total RBC millions/microliter	4.73 ± 0.57	4.2 ± 0.6	<0.001
Platelet Count k/microliter	222.98 ± 63.08	223.18 ± 73.4	0.49419
TLC k/microliter	7558.18 ± 2265.27	6982 ± 2491.11	0.11459
Neutrophils %	60.08 ± 8.62	60.44 ± 8.97	0.41916
Lymphocytes %	30.38 ± 8.64	30.6 ± 9.2	0.45109
Monocytes %	6.32 ± 1.67	6.72 ± 3.02	0.2071
Eosinophils %	3.2 ± 1.99	2.7 ± 1.79	0.09463

Absolute Neutrophil Count k/microliter	4.64 ± 1.63	4.01 ± 1.33	0.01794
Absolute Lymphocyte Count k/microliter	2.28 ± 0.8	2 ± 0.71	0.03203
Absolute Monocyte Count k/microliter	0.48 ± 0.14	0.41 ± 0.14	0.01115
Absolute Eosinophil Count k/microliter	0.24 ± 0.14	0.18 ± 0.13	0.01675
Hematocrit %	41.33 ± 5.37	37.44 ± 5.5	0.00028
Mean Corpuscular Volume %	87.34 ± 7.22	89.03 ± 5.17	0.09103
Mean Corpuscular Hemoglobin fL	28.06 ± 2.77	28.35 ± 2.07	0.27855
Mean Corpuscular Hemoglobin Concentration g/dl	32.17 ± 1.31	31.72 ± 1.6	0.0647

Table 01 presents a comprehensive overview of hematological parameters in Type 2 Diabetes Mellitus (T2DM) and Hypertensive patients following COVID-19 vaccination. The mean values and standard deviations are provided for each parameter, accompanied by the corresponding p-values to highlight the statistical significance of observed differences. Notably, significant variations were observed in Hemoglobin levels, Total Red Blood Cell counts, Absolute Neutrophil, Lymphocyte, Monocyte, and Eosinophil counts, as well as Hematocrit percentages between T2DM and Hypertensive patients.

Discussion:

The comparative analysis of hematological changes post-COVID-19 vaccination in Type 2 Diabetes Mellitus (T2DM) and Hypertensive patients reveals intriguing insights. Significantly higher Hemoglobin levels in T2DM patients suggest potential diabetes-related influences on erythropoiesis. Elevated Total Red Blood Cell counts in T2DM align with existing literature on diabetes-related alterations in erythrocyte parameters (Barbieri et al., 2015). The higher absolute counts of Neutrophils, Lymphocytes, Monocytes, and Eosinophils in T2DM patients indicate a potentially more robust immune response compared to Hypertensive patients, reflecting diabetes-related immune dysregulation (Se & Ai, 1999). The notably higher Hematocrit in T2DM may be linked to factors such as blood viscosity and dehydration, influenced by chronic hyperglycemia (Corretti et al., 2002). Platelet Count and Mean Corpuscular Volume show no significant differences between groups. Tailoring vaccination strategies based on individual health conditions, as highlighted by these nuanced hematological responses, could enhance immunization effectiveness.

Limitations:

This study has limitations, including a relatively small sample size and potential confounding factors. Long-term follow-up studies and larger cohorts are warranted for a more comprehensive understanding of post-vaccination hematological changes.

Conclusion:

The study highlights the nuanced hematological response to COVID-19 vaccination in Type 2 Diabetes Mellitus and Hypertensive patients. These findings underscore the importance of considering underlying health conditions in the evaluation of post-vaccination hematological profiles.

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Bibliography

1. R, M., C, S., N, D., F, P., L, S., V, M., R, L. G., Ml, B., P, M., C, N., A, C., & G, P. (2022). Glycaemic control is associated with SARS-CoV-2 breakthrough infections in vaccinated patients with type 2 diabetes. *Nature Communications*, 13(1). <https://doi.org/10.1038/s41467-022-30068-2>
2. staff, B. (n.d.). *Transient Spike in Glucose Levels With COVID-19 Vaccines*. Retrieved December 11, 2023, from <https://www.uspharmacist.com/article/transient-spike-in-glucose-levels-with-covid19-vaccines>
3. Faghilimnai S, Hashemipour M, Kelishadi B. The lipid profile of children with type 1 diabetes as compared to the controls. *ARYA. J* 2006; 2(1):36-38.
4. Ezzati M. Worldwide trends in diabetes since 1980: A pooled analysis of 751 population-based studies with 4 million participants. *Lancet* 2016;387(10027):1513-30.

5. WHO (2016). Diabetes in the South-East Asia Region. WHO South-East Asia Journal of Public Health. 5(1): 1-75.
6. Summary of Revisions: Standards of Care in Diabetes—2023—PMC. (n.d.). Retrieved December 11, 2023, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9810459/>
7. Rodriguez-Gutierrez, R. et al. (2016) “Shared decision making in endocrinology: present and future directions,” *The lancet. Diabetes & endocrinology*, 4(8), pp. 706–716. doi: 10.1016/s2213-8587(15)00468-4.
8. CDC. (2023, May 12). Hypertension Prevalence in the U.S. | Million Hearts®. Centers for Disease Control and Prevention. <https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html>
9. Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Dennison Himmelfarb, C., DePalma, S. M., Gidding, S., Jamerson, K. A., Jones, D. W., MacLaughlin, E. J., Muntner, P., Ovbiagele, B., Smith, S. C., Spencer, C. C., Stafford, R. S., Taler, S. J., Thomas, R. J., Williams, K. A., ... Wright, J. T. (2018). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension*, 71(6). <https://doi.org/10.1161/HYP.0000000000000065>
10. Jia, G., & Sowers, J. R. (2021). Hypertension in Diabetes: An Update of Basic Mechanisms and Clinical Disease. *Hypertension* (Dallas, Tex. : 1979), 78(5), 1197–1205. <https://doi.org/10.1161/HYPERTENSIONAHA.121.17981>
11. de Boer, I. H., Bangalore, S., Benetos, A., Davis, A. M., Michos, E. D., Muntner, P., Rossing, P., Zoungas, S., & Bakris, G. (2017). Diabetes and Hypertension: A Position Statement by the American Diabetes Association. *Diabetes Care*, 40(9), 1273–1284. <https://doi.org/10.2337/dci17-0026>
12. Barbieri, J., Fontela, P. C., Winkelmann, E. R., Zimmermann, C. E. P., Sandri, Y. P., Mallet, E. K. V., & Frizzo, M. N. (2015). Anemia in Patients with Type 2 Diabetes Mellitus. *Anemia*, 2015, 354737. <https://doi.org/10.1155/2015/354737>
13. Se, G., & Ai, H. (1999). Immune dysfunction in patients with diabetes mellitus (DM). *FEMS Immunology and Medical Microbiology*, 26(3–4). <https://doi.org/10.1111/j.1574-695X.1999.tb01397.x>
14. Corretti, M. C., Anderson, T. J., Benjamin, E. J., Celermajer, D., Charbonneau, F., Creager, M. A., Deanfield, J., Drexler, H., Gerhard-Herman, M., Herrington, D., Vallance, P., Vita, J., & Vogel, R. (2002). Guidelines for the ultrasound assessment of endothelial-dependent flow-mediated vasodilation of the brachial artery: A report of the International Brachial Artery Reactivity Task Force. *Journal of the American College of Cardiology*, 39(2), 257–265. [https://doi.org/10.1016/S0735-1097\(01\)01746-6](https://doi.org/10.1016/S0735-1097(01)01746-6)