

Glucometer derived glycemic variability as an early spot prognosticator for insulin dependent critically ill patients

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Abstract

Background: Glycemic variability, as mathematically defined by higher fluctuation rate or higher gap between the maximum and minimum values. In critically ill patients, the blood glucose readings are highly susceptible to fluctuation owing to multi-dimensional confounders.

Aim: In this study, we primarily aim to investigate the prognostic utility of the glucometer derived glycemic variability regarding the overall mortality. Also, we aim to explore the optimal operating cutoff point and the binary logistic regression correlation for the glycemic variability versus mortality.

Methods: A retrospective study was conducted for tested critically ill patients who were admitted in the Intensive Care Unit at King Hussein Medical Center between 1 Jan 2018 and 31 Dec 2022. Patients who had primarily missed data >20% was excluded from our study. Firstly, a receiver operating characteristic and sensitivity analysis was conducted to explore the area under curve and sensitivity indices of the tested mortality prognosticator. A binary logistic regression was also used to explore the association of the glycemic variability with the 28-day overall ICU mortality rate. All statistical analysis will be conducted with p-value <0.05 as a level of significance via SPSS version 25.

Results: Actually, 2528 and 3217 cases were processed as positive actual states (Positive OI, Non-Survivors) and as negative actual states (Negative OI, Survivors) respectively. The AUC±SEM (95 C) for the GLK_BG_Var (%) was significantly higher than that of the GLK_BG_Avg 0.829±0.006 (95% CI; 0.817-0.841) versus 0.597±0.008 (95% CI; 0.582-0.612). The probabilities of our investigated admitted ICU patients' mortality were binary logistically correlated to the GLK_BG_Var% and GLK_BG_Avg via the following constructed BLgR models [$e^{-5.152+10.8 \times \text{GLK_BG_}\% \text{Var}} / 1 + e^{-5.152+10.8 \times \text{GLK_BG_}\% \text{Var}}$] and [$e^{-5.416+0.025 \times \text{GLK_BG_Avg}} / 1 + e^{-5.416+0.025 \times \text{GLK_BG_Avg}}$], respectively. Also, the probabilities of the critically ill patients' mortality at the explored 2 tested BG prognosticators; Var% and Avg, were identified at 48.1% and 43.96% at the optimal thresholds of 47% and 206.94 mg/dl, respectively. Indeed, the explained variations in the dependent variable based on the 2 aforementioned adopted independent investigated mortality's predictors ranged significantly from 26.1%-35% and 3.4%-4.6% depending on whether you reference the Cox & Snell R² or Nagelkerke R² methods, respectively, and they correctly classified approximately 80.1% and 48.4% of the cases, $\chi^2(8) = 926.992$ and 1232.19, respectively.

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Conclusion: that the first investigated glucometer-based BG mortality's prognosticator [GLK_BG_Var%] had higher AUROC, predictive utilities than its comparative average related prognosticator. Also, we revealed a strong correlation between the poor critically ill patients' outcomes and the higher variability in BG values, notably when the variation exceeding 47%.

Keywords: Glucometer; Glycemic variability; Insulin dependent; Critically patients; Mortality prognosticating

1. Introduction

Traditionally BG monitoring is mostly done via either laboratory assay on venous collected samples, behind other biochemical tests, or capillary derived reagent strips as part of bedside point of care (POC). As known, laboratory-based blood glucose (BG_Lab) monitoring is a time lagging care and instead, most facilities benefit from the wide-availability and the affordability of glucometers-based BG checking (BG_Glk) in quicker the critically ill patients' glycemic status evaluation. While the hypoglycemia, rather than hyperglycemia, state is correlated to the worsen probable outcomes, a point of caring in frequent bedside BG monitoring, in addition to the standard laboratory measuring, is estimated to be a red-flag applicable way on frequent BG inspection in these unstable critically ill patients, especially in the early urgent or emergent dysglycemia related complications ¹⁻⁶.

In this study, we primarily aim to investigate the prognostic utility of the glucometer derived glycemic variability regarding the overall mortality. Also, we aim to explore the optimal operating cutoff point and the binary logistic regression correlation for the glycemic variability versus mortality.

2. Material and methods

Our study was retrospectively processed on critically ill patients who were admitted over 60 months at the Intensive Care Unit (ICU) at King Hussein Medical Center, Royal Medical Services, Amman, Jordan. Admitted mechanically or non-mechanically ventilated patients between Jan 2018 and Dec 2022, retrievable patients' data $\geq 80\%$, and admission ICU days ≥ 48 hours were defined as an inclusion criterion for this study. The primary studied outcome of interest in this study was the 28-day overall critically ill patients' mortality rate. The admitted ICU patients' mortality statuses were defined in our study as Survivors versus Non-Survivors, Survivors with LOS < 3 weeks versus Survivors with LOS ≥ 3 weeks, and Early Mortality if LOS ≤ 2 weeks versus Late Mortality if LOS > 2 weeks.

Firstly, the tested patients' GLK_BG_Var (%) and its compared GLK_BG_Avg were processed for the Receiver Operating Characteristic (ROC) analysis to determine their corresponding comparative Area under the ROC curves (AUROC), in addition to their correlated standard of errors and the 95% confidence intervals. Once the serial cutoff points were tabulated with both the sensitivity and false positive values, the Sensitivity Analysis was conducted to explore the optimal operating cutoffs of each investigated mortality's prognosticator. Conjunctively with the explored optimal thresholds, other sensitivity indices, of particular the true positive and negative rates (sensitivity and specificity), positive and negative predictive values, and both the youden's' and accuracy indices, were also presented in this study. In this study, 2528 and 3217 cases were processed as positive actual states and as negative actual states, respectively. For our tested prognosticator, the higher values of the both GLK_BG related investigated mortality's prognosticators; the variability (Var%) and the average (Avg), indicate stronger evidences for the Positive State (Higher %Prob of mortality). While in contrarily the lower values indicate stronger evidences for the Negative State (lower %Prob of mortality).

Thirdly, a Binary Logistic Regression (BLgR) analysis was simultaneously conducted to primarily construct the investigated glucometer-based prognosticators related BLgR models. Also, the Binary Logistic Regression Test was conducted to explore the degree of correlations, the quality of the prediction, and how range of the total variations (VR) in the investigated dependent variable (the probability of mortality) and % of cases that can be explained by the 2 tested glucometer related blood glucose values' prognosticators; the variability of glucose values (GLK_BG_Var%) and the average of glucose values (GLK_BG_Avg). Based on the constructed models and the identified serial prognosticators' thresholds, the binary logistic correlations were plotted and illustrated in Figure 2.

According to the explored GLK_BG_Var% optimal points, which was identified at 47%, all the tested eligible patients were grouped to either lower variability ($< 47\%$) or higher variability ($\geq 47\%$). Data results of the comparative variables between the 2 compared groups were statistically analyzed via the Chi-Square Test (at $p\text{-value} < 0.05$) and the results were expressed as Numbers (Percentage) and as odd ratios (OR) for the strength of associations. The Pearson chi-square statistic (χ^2) which involves the squared difference between the observed and the expected frequencies, the

Goodness of Fit (G-Test of independence) which uses the log of the ratio of two likelihoods and tests the goodness of fit of observed frequencies to their expected, and the Mantel-Haenszel (M-H) test for linear association or linear by linear association chi-square which is an ordinal measure of significance, were also used for the comparative patients' results. Additionally, Both the interval by interval (Pearson, r) and the ordinal by ordinal (Spearman, ρ) correlations were expressed as value $\pm$ standard error of value. Statistical analysis was performed using Statistical Package for Social Science (SPSS) software version 23.0. Statistical significance was set at 5%.

3. Results

Actually, 2528 and 3217 cases were processed as positive actual states (Positive OI, Non-Survivors) and as negative actual states (Negative OI, Survivors) respectively. The AUC $\pm$ SEM (95% CI) for the GLK_BG_Var (%) was significantly higher than that of the GLK_BG Avg 0.829 $\pm$ 0.006 (95% CI; 0.817-0.841) versus 0.597 $\pm$ 0.008 (95% CI; 0.582-0.612)

The probabilities of our investigated admitted ICU patients' mortality were binary logistically correlated to the GLK_BG_Var% and GLK_BG_Avg via the following constructed BLGR models [$e^{-5.152+10.8 \times \text{GLK_BG_Var}} / 1 + e^{-5.152+10.8 \times \text{GLK_BG_Var}}$] and [$e^{-5.416+0.025 \times \text{GLK_BG_Avg}} / 1 + e^{-5.416+0.025 \times \text{GLK_BG_Avg}}$], respectively]. Also, the probabilities of the critically ill patients' mortality at the explored 2 tested BG prognosticators; Var% and Avg, were identified at 48.1% and 43.96% at the optimal thresholds of 47% and 206.94 mg/dl, respectively. Indeed, the explained variations in the dependent variable based on the 2 aforementioned adopted independent investigated mortality's predictors ranged significantly from 26.1%-35% and 3.4%-4.6% depending on whether you reference the Cox & Snell R² or Nagelkerke R² methods, respectively, and they correctly classified approximately 80.1% and 48.4% of the cases, $\chi^2(8) = 926.992$ and 1232.19, respectively.

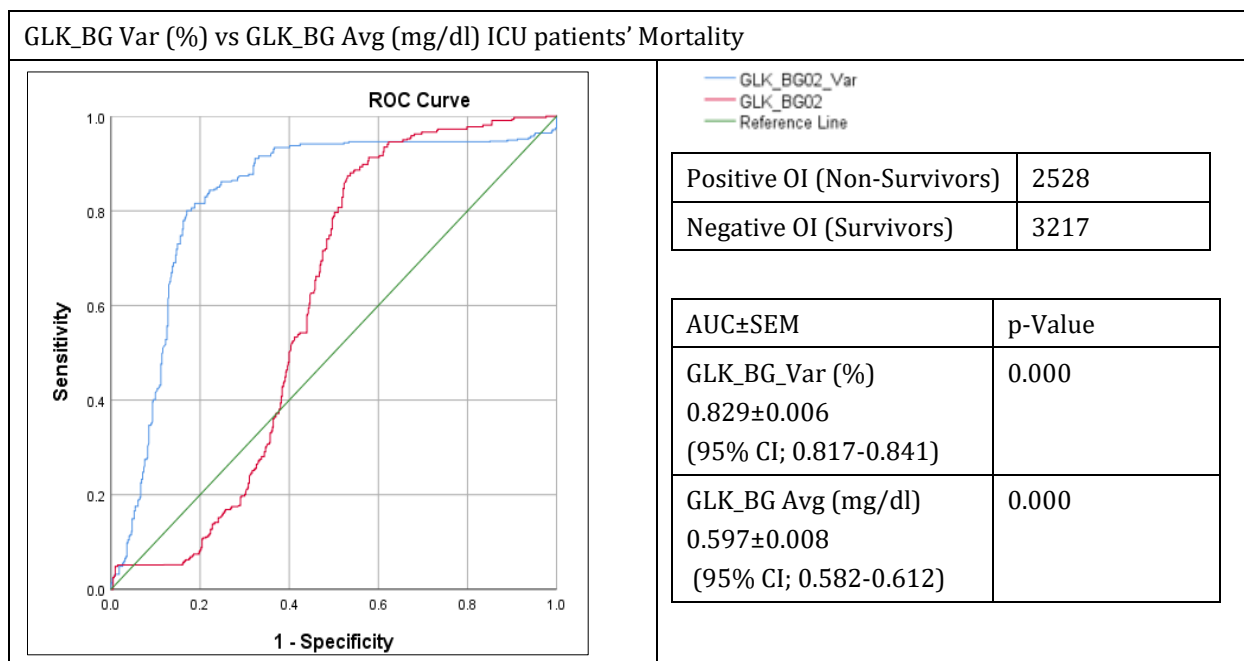


Figure 1 The Receiver Operating Characteristic (ROC) test was conducted to explore the area under the ROC curves (AUROCs) for the both 2 tested glucometer related blood glucose values' prognosticators; the variability of glucose values (GLK_BG_Var%) and the average of glucose values (GLK_BG_Avg), against the probability of mortality, for our admitted critically ill patients in the Intensive Care Unit (ICU) at the King Hussein Medical Center (KHMC) between the Jan 2018 and Dec 2022

The overall tested gender's ratio (Male: Female ratio, M: F) in this study was assigned at 2.262: 1 with significantly distributions across the 2 BG related variability's groups; Group I with lower GLK_BG_Var% or GLK_BG_Var% <447% versus Group II with higher GLK_BG_Var% or GLK_BG_Var% $\geq$ 47%. The M: F ratio in Group I versus Group II was [2.104: 1 (2152 (67.8%): 1023 (32.2%)) vs 2.479: 1 (1832 (71.3%): 738 (28.7%)), respectively], 0.038 $\pm$ 0.013, $\chi^2=8.206$, p-value=0.004. The unadjusted risk estimate for higher variability in glucometer-based BG values was 1.180 (95% CI; 1.054-1.322) for male in relative female.

Prognostically, the overall survival rate was 3217 (56%) compared to the overall mortality rate of 2528 (44.0%). The mortality rate was significantly higher the higher BG variability's group compared to the lower BG variability's group [2023 (78.7%) vs 505 (15.9%), respectively, $\chi^2=2768.683$, $p\text{-value}=0.000$]. All the tested patients' analysis results and illustrations were clearly and fully presented in Table 1-3 and Figure 1-3.

Table 1 The optimal cutoffs thresholds and other sensitivity correlated indices of the both 2 tested glucometer related blood glucose values' prognosticators; the variability of glucose values (GLK_BG_Var%) and the average of glucose values (GLK_BG_Avg), against the probability of mortality, for our admitted critically ill patients in the Intensive Care Unit (ICU) at the King Hussein Medical Center (KHMC) between the Jan 2018 and Dec 2022

Prognostic Indicator	Cutoff	TPR	FPR	YI	TNR	PPV	NPV	NLR	PLR	AI
GLK_BG_Var (%)	47%	80%	17%	63.02%	83.00%	92.23%	62.23%	24.07%	470.63%	80.87%
GLK_BG_Avg (mg/dl)	206.935	87.4%	53.1%	34.36%	46.94%	80.60%	59.68%	26.80%	164.75%	75.92%

The sensitivity analysis was processed on a total of 5745 processed cases for the investigated prognosticator in the Jordanian investigated patients, against the higher probability of 28-day overall mortality (Positive state and assigned as 1) versus the lower probability (Negative state and assigned as 0) to explore the optimal cut-off points, sensitivities (TPRs), specificities (TNRs), positive and negative predictive values (PPVs and NPVs), positive and negative likelihoods ratios (PLRs and NLRs), and the Youden and accuracy indices (YIs and AIs). 2528 and 3217 cases were processed as positive actual states and as negative actual states, respectively. For our tested prognosticator, the higher values of the both GLK_BG related investigated mortality's prognosticators; the variability (Var%) and the average (Avg), indicate stronger evidences for the Positive State (Higher %Prob of mortality). While in contrarily the lower values indicate stronger evidences for the Negative State (lower %Prob of mortality).

Table 2 The Binary Logistic Regression (BLgR) analysis' results for our admitted critically ill patients in the Intensive Care Unit (ICU) at the King Hussein Medical Center (KHMC) between the Jan 2018 and Dec 2022 regarding the tested prognosticator; the both 2 tested glucometer related blood glucose values' prognosticators; the variability of glucose values (GLK_BG_Var%) and the average of glucose values (GLK_BG_Avg), against the probability of mortality

Tested predictors	B±SEM	Wald	Sig.	Exp(B)	95% C.I.for EXP(B)		χ2(df)	VR	%Cases
					Lower	Upper			
Mortality rate	= e ^(-5.152+10.8×GLK_BG_%Var) / 1+ e ^(-5.152+10.8×GLK_BG_%Var)								
GLK_BG_Var (%)	10.8±0.3	1163.342	0.000	1.114	1.107	1.121	(8) 926.992	26.1%-35%	80.1%
Constant	- 5.152±0.148	1210.961	0.000	0.006					
Mortality rate	= e ^(-5.416+0.025×GLK_BG_Avg) / 1+ e ^(-5.416+0.025×GLK_BG_Avg)								
GLK_BG_Avg (mg/dl)	0.025±0.002	170.286	0.000	1.025	1.021	1.029	(8) 1232.19	3.4%-4.6%	48.4%
Constant	- 5.416±0.397	185.760	0.000	0.004					

The Binary Logistic Regression Test was conducted to explore the degree of correlations, the quality of the prediction, and how range of the total variations (VR) in the investigated dependent variable (the probability of mortality) and % of cases that can be explained by the 2 tested glucometer related blood glucose values' prognosticators; the variability of glucose values (GLK_BG_Var%) and the average of glucose values (GLK_BG_Avg).

Also, this test was conducted to abstract the necessary coefficients to present the corresponding explored Binary Logistic Regression models.

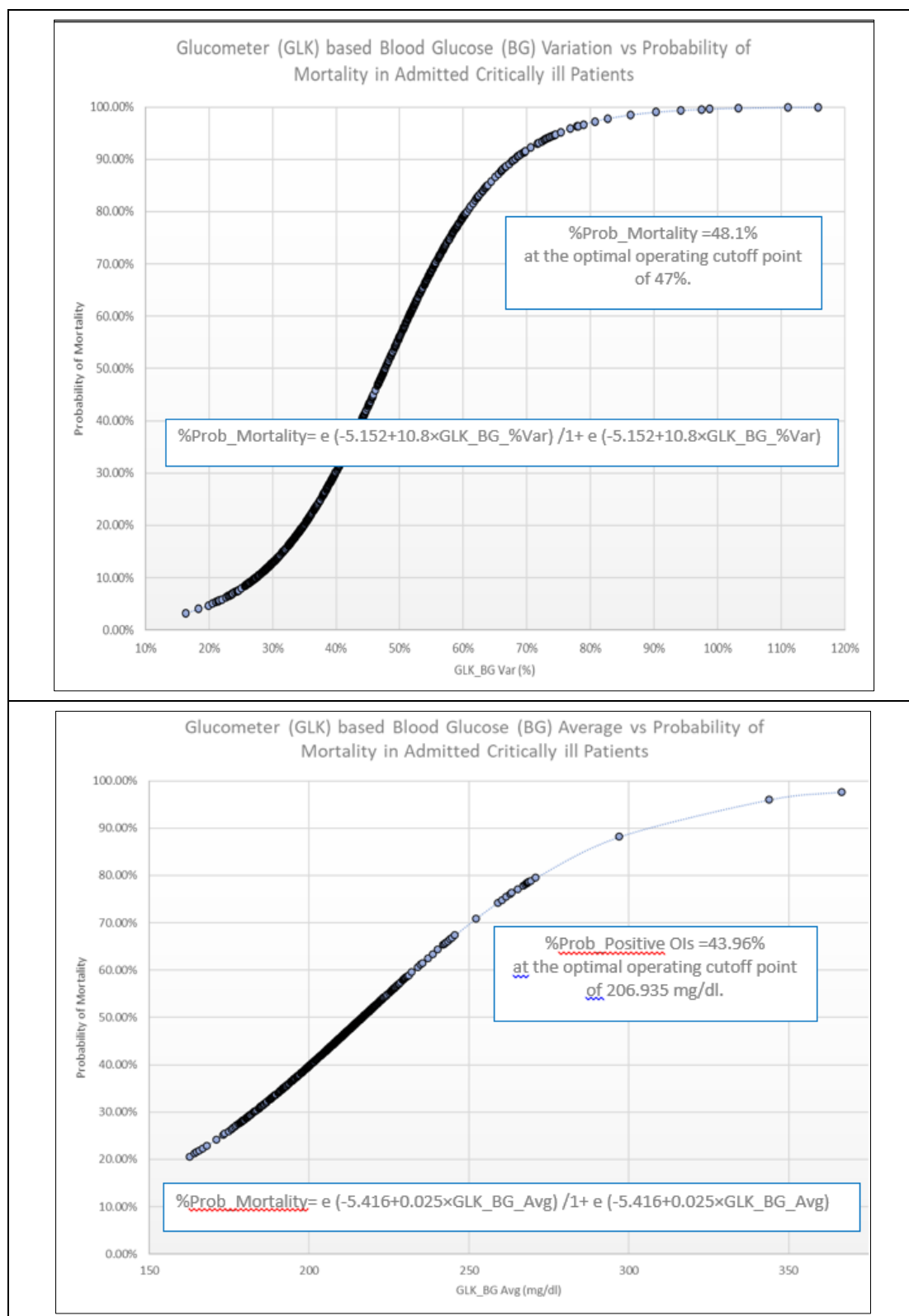


Figure 2 The Binary Logistic Regression (BLgR) analyses' illustration for the both 2 tested glucometer related blood glucose values' prognosticators; the variability of glucose values (GLK_BG_Var%) and the average of glucose values (GLK_BG_Avg), against the probability of mortality, for our admitted critically ill patients in the Intensive Care Unit (ICU) at the King Hussein Medical Center (KHMC) between the Jan 2018 and Dec 2022

Table 3 Comparatively studied variables across Group I-II; the lower GLK_BG_Var% variability (<47%) [Group I] versus the GLK_BG_Var% variability (≥47%) [Group II] for the tested Jordanian critically ill patients who were admitted at King Hussein Medical Center between Jan 2018 and Dec 2022

	Lower (<47%) GLK_BG Variability (3175, 55.26%)	Higher (≥47%) GLK_BG Variability (2570, 44.74%)	Total (5745, 100%)	OR	R ρ	χ 2 G-Test M-H	p- Value
Gender							
Female	1023 (32.2%)	738 (28.7%)	1761 (30.7%)	1.180 (95% CI; 1.054-1.322)	0.038±0.013* 0.038±0.013*	8.206	0.004
Male	2152 (67.8%)	1832 (71.3%)	3984 (69.3%)			8.228	0.004
Female: Male	2.104: 1	2.479: 1	2.262: 1			8.205	0.004
MORT							
Survivors	2670 (84.1%)	547 (21.3%)	3217 (56.0%)	19.554 (95% CI; 17.10-22.36)	0.629±0.010* 0.629±0.010*	2274.1	0.000
Non-Survivors	505 (15.9%)	2023 (78.7%)	2528 (44.0%)			2438.5	0.000
						2273.7	0.000
MORT.DIS							
Survivors (<3wks LOS)	2022 (63.7%)	50 (1.9%)	2072 (36.1%)	NA	0.680±0.007* 0.689±0.007*	2768.683	0.000
Survivors (≥3wks LOS)	751 (23.7%)	789 (30.7%)	1540 (26.8%)			3433.902	0.000
Late MORT (≥2wks LOS)	385 (12.1%)	1108 (43.1%)	1493 (26.0%)			2652.862	0.000
Early MORT (<2wks LOS)	17 (0.5%)	623 (24.2%)	640 (11.1%)				
GLK_BG (mg/dl)							
150-199	989 (31.1%)	189 (7.4%)	1178 (20.5%)	NA	0.217±0.012* 0.232±0.012*	637.053	0.000
200-249	2041 (64.3%)	2374 (92.4%)	4415 (76.8%)			710.732	0.000
≥250	145 (4.6%)	7 (0.3%)	152 (2.6%)			270.544	0.000
Lab_BG (mg/dl)							
100-149	22 (0.7%)	46 (1.8%)	68 (1.2%)	NA	0.340±0.013* 0.391±0.011*	1704.642	0.000
150-199	1412 (44.5%)	12 (0.5%)	1424 (24.8%)			2166.283	0.000
200-249	1535 (48.3%)	2486 (96.7%)	4021 (70.0%)			664.452	0.000

≥250	206 (6.5%)	26 (1.0%)	232 (4.0%)				
BG_Gap (mg/dl)							
-200 to -50	137 (4.3%)	0 (0.0%)	137 (2.4%)	NA	- 0.457±0.015*	3041.918	0.000
-50 to -25	22 (0.7%)	186 (7.3%)	208 (3.6%)		- 0.598±0.010*	3916.675	0.000
-25 to 0	888 (28.0%)	2329 (90.9%)	3217 (56.1%)		1196.788	0.000	
0 to 25	2120 (66.9%)	2 (0.1%)	2122 (37.0%)				
25 to 50	0 (0.0%)	46 (1.8%)	46 (0.8%)				
Data results of the comparative variables between the 2 tested cohorts were statistically analyzed by Chi-Square Test (at p-value< 0.05) and expressed as Numbers (Percentage). The strength of associations was also described as odd ratios (OR). The Pearson chi-square statistic (χ^2) involves the squared difference between the observed and the expected frequencies. The Goodness of Fit (G-Test of independence) uses the log of the ratio of two likelihoods and tests the goodness of fit of observed frequencies to their expected. The Mantel-Haenszel (M-H) test for linear association or linear by linear association chi-square, unlike ordinary and likelihood ratio chi-square, is an ordinal measure of significance. Both the interval by interval (Pearson, r) and the ordinal by ordinal (Spearman, ρ) correlations were expressed as value± standard error of value. The studied patients were dichotomously categorized into the 2 comparatives' glucometer-based blood values related variabilities; lower variability (Group I) versus higher variability (Group II). The study's explored optimal GLK_BG_Var% threshold of 47% was adopted to discriminate the tested patients' GLK_BG_Var% into either Group I or Group II.							
MORT: Overall mortality. MORT.DIST: Mortality distributions. LOS: Length of stay			Lab_BG: The laboratory blood glucose levels. GLK_BG: The glucometer-based blood glucose values. BG_Gap: The blood glucose values differences between glucometer readings and laboratory results.				

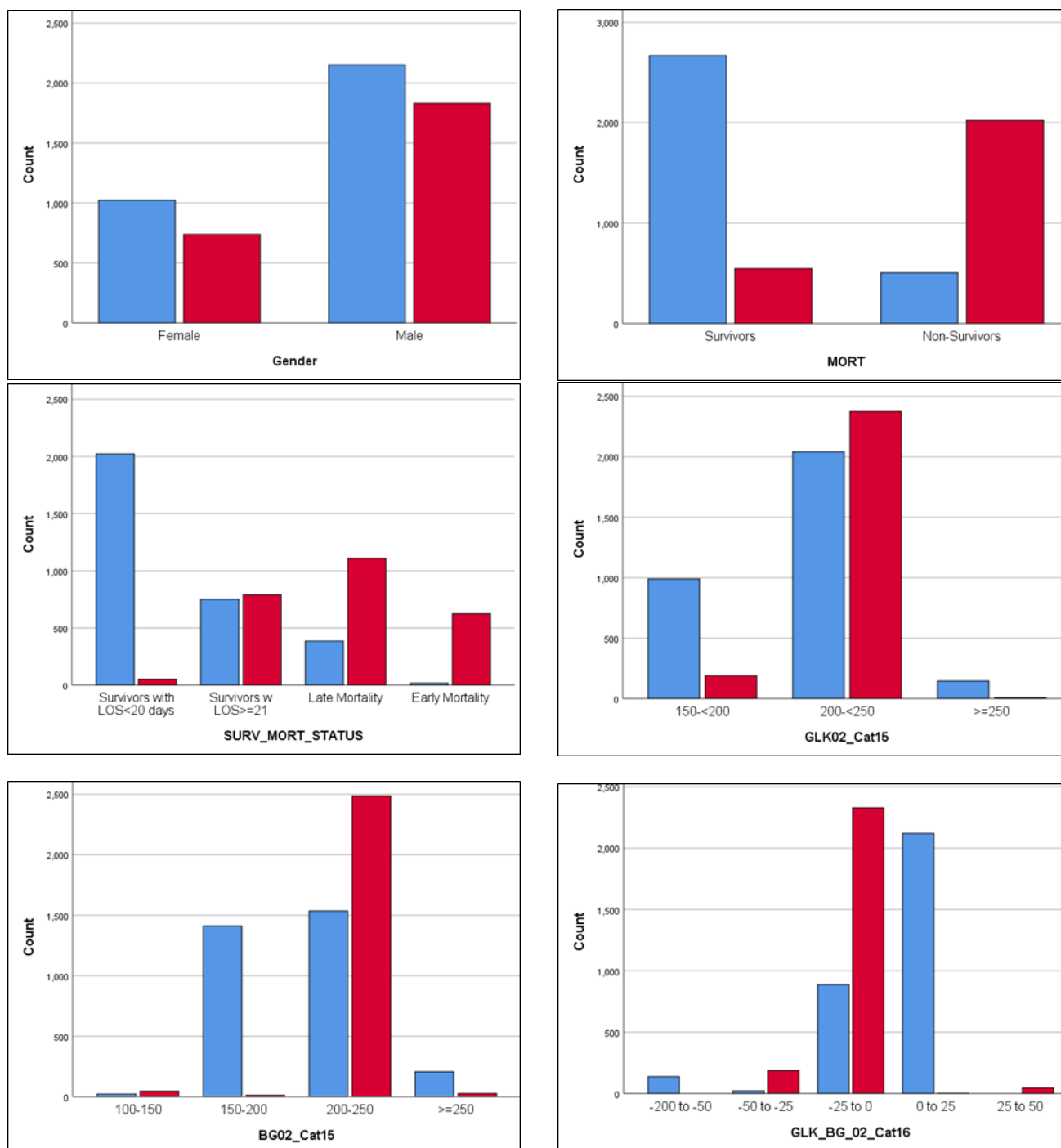


Figure 3. Bar charts' visualizations for the comparatively studied variables across Group I-II; the lower GLK_BG_Var% variability (<47%) [Group I] versus the GLK_BG_Var% variability (≥47%) [Group II] for the tested Jordanian critically ill patients who were admitted at King Hussein Medical Center between Jan 2018 and Dec 2022

4. Discussion

This study reveals a non-sponsored, observational retrospective study which was conducted over 60 months in a multi-specialties ICU at the largest tertiary medical center in our country of Jordan. The primary uniqueness of our study is emphasized on the broad range of eligible criteria for the tested critically ill patients which preferentially improve this study external validity. Also, this study was conducted on both surgical and medical ICU patients, mechanically ventilated and non-mechanically ventilated patients. Additionally, in this study we explored the prognostic utilities of the 2 interrelated BG calculated parameters; the GLK_BG_Var% versus the GLK_BG_Avg, and investigated their AUROCs,

optimal thresholds and their correlated sensitivity indices, and constructed their corresponding BLgR models against the overall mortality rate.

In this study, we found a strong correlation between the higher variability in GLK_BG values and the overall mortality in admitted critically ill patients, approximately a pearson correlation of 0.629 ± 0.010 we identified in this study. An overall unadjusted risk estimate for mortality liability in admitted ICU patients was picked at 19.554 (95% CI; 17.10-22.36) in the higher GLK_BG_Var% group (Group II) compared to the lower GLK_BG_Var% group (Group I). According to tested patients' length of stay (LOS), the Survivors cohort was subdivided to survivors discharged before 3 weeks of ICU LOS and survivors' cohort who were discharged beyond the 3 weeks. Also, the Non-Survivors' cohort was subdivided to either early Mortality's cohort (LOS <2 weeks) or late Mortality's cohort (LOS $\geq$ 2 weeks). In this study we revealed that the early discharged survivors' cohort had significantly higher distribution rates in the lower GLK_BG_Var% versus the higher GLK_BG_Var% [2022 (63.7%) vs 50 (1.9%), respectively]. While the late discharged survivors' cohort had significantly higher distribution rates in the higher variability's group compared to the lower variability's group [789 (30.7%) vs 751 (23.7%), respectively]. Both the late and early mortality's cohorts had significantly higher distribution rates in the higher BG related variability's group than in the lower BG related variability's group [1108 (43.1%) and 623 (24.2%) vs 385 (12.1%) and 17 (0.5%), respectively].

A two correlated GLK_BG mortality's prognosticators were in this study to explore their sensitivity utilities in predicting the probability of being on the Non-Survivors' Cohort rather than being on the Survivors' Cohort. At the optimal thresholds of each tested aforementioned predictors; 48.1% and 206.94 mg/dl respectively, we expressed that the sensitivity, septicity, and the positive/negative predictive values were 80%, 83.00%, 92.23%, and 62.23% vs 87.4%, 46.94%, 80.60%, and 59.68%. So, we concluded in this study that the GLK_BG_Var% had higher specificity and positive/negative predictive values than its compared GLK_BG prognosticators. Contrarily, the GLK_BG_Avg had higher sensitivity than the GLK_BG_Var%.

5. Conclusion

Our results revealed that the first investigated glucometer-based BG mortality's prognosticator [GLK_BG_Var%] had higher AUROC, predictive utilities than its comparative average related prognosticator. Also, we revealed a strong correlation between the poor critically ill patients' outcomes and the higher variability in BG values, notably when the variation exceeding 47%. This study is limited by its retrospective design, single-center, and relatively small sample size.

Compliance with ethical standards

Acknowledgement

Our appreciation goes to staff of the department of King Hussein Medical Center for their enormous assistance and advice.

Disclosure of conflict of interest

There is no conflict of interest in this manuscript.

Statement of ethical approval

There is no animal/human subject involvement in this manuscript.

Statement of informed consent

Owing to the retrospective design of this study, the informed consent form was waived.

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