RESEARCH PAPER

Clinical Outcomes and Metabolic Safety of Two Intravenous Insulin Infusion Protocols in Diabetic Critically Ill Patients: A Comparative Study

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ABSTRACT

Background: Hyperglycemia is common among critically ill patients with diabetes and requires effective intravenous insulin therapy while minimizing hypoglycemia and metabolic complications.

Aim: This study aimed to compare the clinical outcomes and metabolic safety of the Suez Canal University (SCU) and National Health Service (NHS) intravenous insulin infusion protocols.

Methods: This randomized controlled study included 100 adult diabetic critically ill patients admitted to the ICU of Suez Canal University Hospital, Egypt, from November 2024 to April 2025. Patients were randomly allocated to the SCU protocol group (n=50) or NHS protocol group (n=50). Both protocols used continuous intravenous regular insulin with point-of-care glucose monitoring every 2 hours.

Results: Baseline demographic characteristics were comparable between groups. ICU stay (8.9±6.8 vs. 9.28±7.43 days, p=0.790), hospital stay (12.16±7.27 vs. 13.02±7.57 days, p=0.564), need for mechanical ventilation (28% vs. 22%, p=0.488), and duration of ventilation (6.07±1.69 vs. 6.82±1.78 days, p=0.294) showed no significant differences between SCU and NHS groups, respectively. Mortality was also comparable (24% vs. 18%, p=0.461). Hypoglycemia occurred in 24% and 22% (p=0.812), while hypokalemia occurred in 4% and 2% (p=1.000). No diabetic ketoacidosis occurred in either group. Laboratory and electrolyte parameters were comparable throughout follow-up.

Conclusion: The SCU and NHS intravenous insulin protocols demonstrated comparable clinical outcomes and metabolic safety in critically ill diabetic patients. Both protocols appear effective and safe when accompanied by close glucose, electrolyte, renal, and nutritional monitoring.

Keywords: Intravenous insulin; Critical illness; Diabetes mellitus; Glycemic control.

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INTRODUCTION

Hyperglycemia is a common issue in critically ill patients and is associated with increased morbidity and mortality (1).

Although control of hyperglycemia reduces infection rates, a net benefit was tempered by higher rates of hypoglycemia and mortality. Despite these differences, most of the studies agreed that hypoglycemia is associated with worse outcomes. The danger of both hyperglycemia and hypoglycemia is related to the level and duration of the glucose abnormality (2).

Most of the studies investigating the optimal blood glucose targets for patients treated with intravenous insulin infusions have been in the critical care setting. conventional insulin treatment usually aiming for 110-180 mg/dl, and it was associated with a reduction in ICU mortality from 8% to 4.6% and in-hospital mortality from 10.9% to 7.2% (3).

NHS protocol in UK is intended to achieve a good glycemic control (110-180 mg/dl). It aims to be a practical guide for when and how to use an intravenous insulin infusion and how to transition patients to other glucose lowering medication after stabilization. The safe and effective use of variable rate intravenous insulin infusion will depend on close monitoring and decision making by health care professionals. It shows less morbidity and mortality rate among critically ill patients in ICU. It also lowers the incidence of hypoglycemia along with medical errors among patients (4). The SCU Protocol for Intravenous Insulin infusion for diabetic critically ill patients has been implemented for more than ten years by one of the supervisors Prof. Mohamed Emad Abdel-Ghaffar and has shown effective results for good glycemic control.

This study aimed to compare the clinical outcomes and metabolic safety of the Suez Canal University (SCU) and National Health Service (NHS) intravenous insulin infusion protocols.

PATIENTS AND METHODS

This randomized controlled study included 100 adult diabetic critically ill patients admitted to the Intensive Care Unit (ICU) of Suez Canal University Hospital, Egypt, from November 2024 to April 2025.

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Ethical consideration

The study was approved by the Ethics Committee of the Faculty of Medicine, Suez Canal University, and registered at ClinicalTrials.gov (NCT06810596). Written informed consent was obtained from patients or their legally authorized representatives.

Inclusion criteria: adults >18 years of either sex with diabetes mellitus, critical illness requiring ICU admission, and HbA1c >6.0%.

Exclusion criteria: Patients with diabetic ketoacidosis, hyperosmolar non-ketotic coma, pregnancy, or breastfeeding.

Randomization

A total of 100 patients were randomly allocated in a 1:1 ratio using an online randomization program to either the Suez Canal University (SCU) protocol group (n=50) or the UK National Health Service (NHS) protocol group (n=50). Allocation codes were concealed in opaque sealed envelopes.

METHODS

All patients were subjected to the following:

Insulin Protocols and Monitoring

In both groups, glycemic control was achieved using continuous intravenous regular insulin diluted in 0.9% sodium chloride at a concentration of 1 unit/mL. Infusion rates were adjusted according to the assigned protocol. Two nurses prepared and independently checked the insulin infusion and each subsequent rate adjustment.

In the SCU group, insulin infusion was adjusted according to random blood glucose (RBS) and adjusted body weight. Patients initially received the standard regimen and were reassessed after 24 hours. Patients meeting predefined criteria for insulin sensitivity or resistance were subsequently shifted to the corresponding regimen.

In the NHS group, insulin infusion rates were adjusted according to predefined RBS ranges using standard, insulin-sensitive, or insulin-resistant regimens. VRIII was discontinued when RBS fell below 80 mg/dL, with repeat glucose measurement after one hour.

RBS was monitored using a point-of-care glucometer every 2 hours. Serum electrolytes, complete blood count, and arterial blood gases were assessed daily, while coagulation profile, liver function, and kidney function tests were performed every 3 days. Potassium was monitored more frequently in patients with abnormalities and replaced according to serum potassium levels and clinical requirements.

Clinical and Laboratory Assessment

Baseline assessment included demographic characteristics, body weight, height, BMI, comorbidities, HbA1c, Glasgow Coma Scale (GCS), and Acute Physiology and Chronic Health Evaluation II (APACHE II) score. During ICU admission, patients were followed for glycemic control, nutritional support, mechanical ventilation, electrolyte disturbances, hypoglycemia, hyperglycemia, diabetic ketoacidosis, ICU and hospital length of stay, and clinical outcome (discharge or death).

Outcomes

The primary outcome was the proportion of patients achieving time in range (TIR) of 80–180 mg/dL for >70% of the ICU stay.

Secondary outcomes included the incidence of hypoglycemia, the effect of demographic and clinical factors on glycemic control, ventilator-free days, ICU and hospital length of stay, nutritional support, metabolic complications, and mortality.

Statistical Analysis

Data were analyzed using SPSS version 26 (IBM Corp., Chicago, IL, USA). Normality was assessed using the Shapiro–Wilk test and histograms. Quantitative variables were expressed as mean ± standard deviation and compared using the unpaired Student's t-test. Categorical variables were presented as frequencies and percentages and compared using the chi-square test or Fisher's exact test, as appropriate. A p value <0.05 was considered statistically significant.

RESULTS

The Patients' characteristics were insignificantly different between the two groups p>0.05. (Table 1)

Table (1): Patient characteristics of the studied groups

		SCU group (n=50)	NHS group (n=50)	P value
Age (years)	**Mean ± SD**	57.22 ± 10.55	55.64 ± 10.62	0.109
	Range	32 - 71	27 - 83	
Gender	**Male**	22 (44%)	23 (46%)	0.841
	Female	28 (56%)	27 (54%)	
Weight (kg)	**Mean ± SD**	81.96 ± 10.67	79.8 ± 11.02	0.322
	Range	65 - 99	62 - 101	
Height (m)	**Mean ± SD**	169.4 ± 6.65	168.44 ± 5.7	0.440
	Range	150 - 188	153 - 181	
BMI (kg/m^2)	**Mean ± SD**	28.66 ± 4.15	27.25 ± 4.58	0.635
	Range	21.7 - 37.3	21 - 39.7	

BMI: Body mass index. SD: standard deviation. SCU: Suez Canal University; NHS: National Health System. P: p value for comparing between the two studied groups.

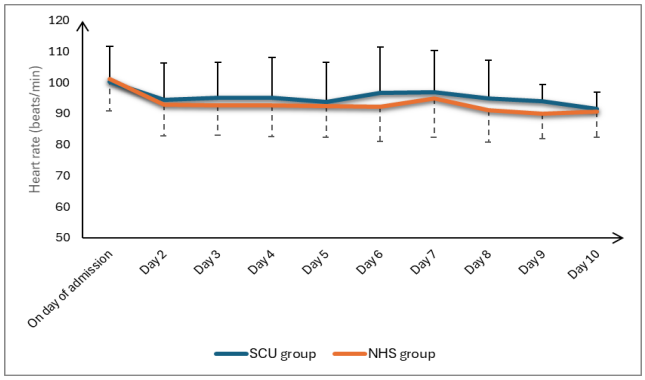


Figure (1): Heart rate of the studied groups

Heart rate was insignificantly different between SCU group and NHS group on day of admission (100.18±11.42 and 101.06±10.16), after 2 days (94.5±11.85 and 92.78±9.9), after 3 days (95.09±11.43 and 92.74±9.71), after 4 days (95.06±12.95 and 92.67±10.11), after 5 days (93.85±12.69 and 92.52±10.12), after 6 days (96.77±14.64 and 92.18±11.06), after 7 days (96.84±13.45 and 94.89±12.62), after 8 days (94.82±12.37 and 91.11±10.27), after 9 days (94.1±5.22 and 89.9±8.06) and after 10 days (91.6±5.21 and 90.56±8.28). (Table1)

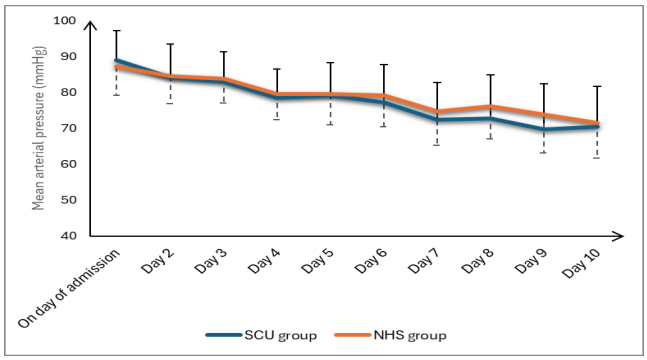


Figure (2): Mean arterial pressure of the studied groups

Mean arterial pressure was insignificantly different between SCU group and NHS group on day of admission (88.98±8.11 and 87.18±8), after 2 days (84.2±9.23 and 84.58±7.76), after 3 days (82.96±8.34 and 83.8±6.86), after 4 days (78.38±8.04 and 79.54±7.09), after 5 days (79.15±9.15 and 79.52±8.5), after 6 days (77.23±10.52 and 79.18±8.72), after 7 days (72.32±10.46 and 74.63±9.43), after 8 days (72.76±12.08 and 76.16±9.07), after 9 days (69.8±12.48 and 73.8±10.66) and after 10 days (70.5±11.17 and 71.56±9.86). (Figure 2)

Table (2): ICU and hospital stay, clinical condition, need for mechanical ventilation, mechanical ventilation and outcome of the studied groups

		SCU group (n=50)	NHS group (n=50)	P value
ICU stay (days)		8.9 ± 6.8	9.28 ± 7.43	0.790
Hospital stay (days)		12.16 ± 7.27	13.02 ± 7.57	0.564
Clinical condition	**Medical**	27 (54%)	30 (60%)	0.545
	Surgical	23 (46%)	20 (40%)	
Need for mechanical ventilation		14 (28%)	11 (22%)	0.488
Mechanical ventilation (days)	**Mean ± SD**	6.07 ± 1.69	6.82 ± 1.78	0.294
	Range	4 - 10	5 - 10	
Outcome	**Discharge**	38 (76%)	41 (82%)	0.461
	Death	12 (24%)	9 (18%)	

ICU: Intensive care unit. SCU: Suez Canal University; NHS: National Health System. p: p value for comparing between the two studied groups. MG/DL: milligram per deciliter.

ICU stay, hospital stay, clinical condition, need for mechanical ventilation, mechanical ventilation and outcome were insignificantly different between the two groups p>0.05. (Table 2)

The type of nutrition was insignificantly different between the two groups p>0.05. (Table 3)

Sodium and potassium were insignificantly different on day of admission and the rest of the days between both groups p>0.05. (Table 4)

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Table (3): Type of nutrition of the studied groups in the first 48 hours

		SCU group (n=50)	NHS group (n=50)	P value
Type of nutrition	**Parenteral nutrition**	13 (26%)	11 (22%)	0.639
	Enteral nutrition	37 (74%)	39 (78%)	

SCU: Suez Canal University NHS: National health system p: p value for comparing between the two studied groups MG/DL: milligram per deciliter

Table (4): Electrolytes of the studied groups

		SCU group	NHS group	P value
Sodium (mEq/L)	**On day of admission**	140.34±6.52	141.58±4.15	0.259
	Day 2	137.12±1.89	136.54±2.93	0.242
	Day 3	137.02±1.64	136.42±2.34	0.148
	Day 4	136.74±2.85	136.52±2.41	0.680
	Day 5	137.06±3.45	136.79±4.14	0.729
	Day 6	136.3±4.54	136.45±3.35	0.878
	Day 7	134.84±4.76	134.37±5.4	0.776
	Day 8	135.18±3.52	135.42±6.27	0.888
	Day 9	135.2±3.97	135.1±2.85	0.949
	Day 10	136.3±2.75	135.44±2.74	0.507
Potassium (mEq/L)	**On day of admission**	3.6±0.76	3.57±0.78	0.872
	Day 2	4.19±0.51	4.07±0.46	0.222
	Day 3	4.04±0.56	4.02±0.51	0.822
	Day 4	4.01±0.46	4.06±0.44	0.577
	Day 5	4.06±0.54	4.16±0.52	0.347
	Day 6	4.12±0.57	4.07±0.48	0.686
	Day 7	4.24±0.58	4.01±0.57	0.210
	Day 8	4.03±0.46	4.18±0.44	0.309
	Day 9	4.22±0.47	4.2±0.56	0.932
	Day 10	4.23±0.52	4.11±0.63	0.657

Data presented as mean ± SD. SCU: Suez Canal University. NHS: National health system. p: p value for comparing between the two studied groups MEQ/L: Milliequivalent per liter.

Table (5): Laboratory tests of the studied groups

		SCU group	NHS group	P value
Creatinine (mg/dL)	**On day of admission**	1.33±0.56	1.35±0.63	0.880
	Day 3	1.25±0.57	1.28±0.66	0.863
	Day 6	1.09±0.54	1.12±0.51	0.854
Albumin (g/dl)	**On day of admission**	3.32±0.46	3.39±0.48	0.469
	Day 3	3.28±0.41	3.34±0.44	0.533
	Day 6	3.12±0.38	3.17±0.4	0.708
Total bilirubin (mg/dl)	**On day of admission**	1.06±0.58	0.95±0.59	0.361
	Day 3	0.96±0.43	0.82±0.42	0.120
	Day 6	0.94±0.38	0.79±0.43	0.273
Ca (mg/dL)	**On day of admission**	7.74±0.65	7.8±0.8	0.671
	Day 3	7.9±0.81	7.95±0.86	0.790
	Day 6	7.95±0.89	7.92±0.99	0.916
Mg (mg/dL)	**On day of admission**	1.9±0.2	1.84±0.15	0.069
	Day 3	1.84±0.24	1.78±0.22	0.158
	Day 6	1.76±0.31	1.67±0.23	0.346
Prothrombin time (Sec)	**On day of admission**	13.94±2.1	13.41±2.01	0.199
	Day 3	13.59±2.26	13.46±2.11	0.778
	Day 6	14.17±2.16	13.31±2.79	0.297
Partial thromboplastin time (Sec)	**On day of admission**	32.81±6.44	31.47±4.62	0.234
	Day 3	32.23±5.79	31.95±4.59	0.792
	Day 6	31.82±8.65	30.87±5.18	0.685
INR	**On day of admission**	1.05±0.38	1.04±0.38	0.833
	Day 3	1.01±0.4	0.99±0.43	0.767
	Day 6	1.14±0.41	1.11±0.49	0.858
ALT (U/L)	**On day of admission**	34.86±11.72	33.74±7.17	0.566
	Day 3	37.98±11.5	35.92±5.49	0.266
	Day 6	33.53±11.47	32.84±8.02	0.832
AST (U/L)	**On day of admission**	32.68±14.22	30.9±13.84	0.527
	Day 3	34.09±14.36	31.85±13.85	0.443
	Day 6	38.84±17.03	37.89±16.04	0.861

Data presented as mean ± SD..CA:total serum calcium..MG:serum magnesium..INR:international ratio. ALT: Alanine Aminotransferase. AST: Aspartate Aminotransferase. SCU:suez canal university. NHS:national health system. p: p value for comparing between the two studied groups MG/DL:milligram per deciliter. U/L: Units per Liter.

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Creatinine, albumin, total bilirubin, Ca, Mg, prothrombin time, partial thromboplastin time, INR, ALT and AST were insignificantly different between SCU group and NHS group on day of admission, after 3 days and after 6 days. (Table 5)

Hypoglycemia and hypokalemia were insignificantly different between the two groups. DKA did not occur in any patients in both groups p>0.05. (Table 6)

Table (6): Adverse events of the studied groups

	SCU group	NHS group	P value
Hypoglycemia	12 (24%)	11 (22%)	0.812
Hypokalemia	2 (4%)	1 (2%)	1
DKA	0 (0%)	0 (0%)	---

DKA: Diabetic ketoacidosis. SCU: Suez Canal University; NHS: National Health System. p: p value for comparing between the two studied groups.

DISCUSSION

These findings are further validated by analyses of insulin sensitivity variability, which confirm that a marked increase in stability typically occurs between day 1 and day 2 of ICU admission (5). Our results therefore corroborate the notion that rapid glycemic control is both achievable and a fundamental marker of effective protocol execution.

The need for mechanical ventilation was comparable and similar between the two groups in our study results: 28% (SCU) versus 22% (NHS), p=0.488. Among ventilated patients, duration was 6.07±1.69 versus 6.82±1.78 days, p=0.294.

Mechanical ventilation requirements reflect respiratory function and overall clinical severity. Similar rates suggest neither protocol offers advantage in preventing respiratory complications. For diabetic patients, mechanical ventilation carries additional risks including ventilator-associated pneumonia (6), making the equivalent outcomes clinically reassuring.

Likewise, a study by Bhatti et al., (7) assessed glycemic control in 1,200+ ICU diabetic patients and found lower mechanical ventilation needs in those with reasonable control (HbA1c <7%), with durations around 6-7 days. This aligns with our non-significant differences in ventilation needs (22-28%) and durations, suggesting that effective protocols like ours maintain similar respiratory support requirements.

Overall, our study strongly confirms that both protocols offer balanced clinical performance in terms of length of stay, ventilation needs, mortality, and glycemic safety, fitting well within the benchmarks and recommendations set by recent expert consensus and comparative clinical studies.

In our study, hypokalemia occurred in 4% (SCU) versus 2% (NHS), p=1.000; and no diabetic ketoacidosis episodes occurred in either group.

The low rates of electrolyte disturbances indicate both protocols maintain appropriate metabolic balance. The absence of DKA episodes demonstrates effective prevention of severe metabolic decompensation, which is crucial given DKA's high mortality risk in critically ill patients, a finding consistent with current recommendations for metabolic management in critically ill diabetic patients.

In terms of Laboratory Parameters, hemoglobin levels in our study improved in both groups from admission (9.66±1.58 vs 9.19±1.58 mg/dL) to Day 10 (10.84±1 vs 10.68±1.48 mg/dL). White blood cell counts normalized from elevated admission values (12.69±3.08 vs 12.21±2.4 ×10⁹/L) to normal ranges by Day 10 (10.61±1.43 vs 10.82±0.84 ×10⁹/L).

The gradual hemoglobin improvement and WBC normalization reflect successful management of critical illness in both groups. The initial anemia (Hb ~9 g/dL) and leukocytosis (WBC ~12×10⁹/L) are typical of critically ill patients, with improvement indicating clinical recovery regardless of insulin protocol used.

Our study's laboratory trajectory closely aligns with published ICU research emphasizing the importance of serial monitoring of parameters such as hemoglobin, WBC, creatinine, and albumin for prognostic assessment during glycemic management. These markers not only reflect acute physiologic recovery but also guide safe insulin therapy, with comparable improvements between protocols reaffirming their equivalence (8).

Furthermore, the relationship between anemia and diabetes is well-established, as low hemoglobin levels are a frequent complication, particularly in patients with nephropathy and those at risk for microvascular complications. Our observations align with research showing that improved hemoglobin values correspond to better renal outcomes and reduced risk of complications (9, 10).

Moreover, creatinine levels improved from admission (1.33±0.56 vs 1.35±0.63 mg/dL) to Day 6 (1.09±0.54 vs 1.12±0.51 mg/dL); whereas albumin levels decreased slightly from admission (3.32±0.46 vs 3.39±0.48 g/dL) to Day 6 (3.12±0.38 vs 3.17±0.4 g/dL).

The downward trend in creatinine levels reinforces preserved or improving renal function, essential given the high prevalence of acute kidney injury among critically ill patients. This improvement is corroborated by studies demonstrating a direct link between baseline and subsequent changes in creatinine with hypoglycemia risk, underscoring the clinical importance of renal function as part of glycemic safety mechanisms (11,12) .

Furthermore, admission serum albumin levels and their changes during hospitalization are significantly associated with hypoglycemia occurrence. Khanimov et al., (13) has reported that low or declining albumin may reflect poor nutritional status or systemic illness severity, both of which can exacerbate glycemic instability and increase hypoglycemia susceptibility. Clinically, albumin serves as an important marker for identifying patients at higher risk for hypoglycemic episodes.

The similar distribution of nutritional support types (parenteral 26% vs 22%, enteral 74% vs 78%, p=0.639) in

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our study demonstrates that both protocols integrate effectively with different nutritional approaches.

Moreover, balanced nutrition is recognized as a critical factor in minimizing hypoglycemic risk during intensive insulin therapy. Large retrospective studies have demonstrated that patients receiving comprehensive nutritional support have a significantly lower likelihood of hypoglycemic events, underscoring the protective effect of adequate macronutrient provision (14). Our findings further support this by showing both protocols maintain safe glycemic control across nutrition types.

CONCLUSION

Both the SCU and NHS insulin protocols provided comparable and effective glycemic control in critically ill diabetic patients, with similar clinical outcomes, including length of ICU stay, mechanical ventilation requirements and duration, mortality, and metabolic safety. Both protocols were associated with low rates of hypokalemia and no episodes of diabetic ketoacidosis. Improvements in hemoglobin, WBC count, and creatinine, together with comparable nutritional support, further indicate similar overall clinical recovery. These findings suggest that both protocols are safe and effective options for glycemic management in the ICU, with appropriate monitoring of glucose, electrolytes, renal function, and nutritional status essential to minimize hypoglycemia and other metabolic complications.

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