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Original article

Comparing Fair Control of Hyperglycaemia Contrary to Intensive Control in Patients after Coronary Artery Bypass Grafting Procedure

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Abstract

Background: Postoperative glycaemic control is a critical concern in patients undergoing coronary artery bypass grafting (CABG) surgery. Variations in glycaemic management strategies have been studied, with conflicting evidence regarding the optimal glycaemic target. This study aimed to compare the effect of tight glycaemic control versus fair glycaemic control for post cardiac surgery patients. **Methods:** This prospective randomized controlled clinical trial included 50 adult CABG patients. The study assessed postoperative outcomes, including ICU stay duration, ventilation time, inotropes/vasopressors use, hypoglycaemic episodes, wound infections, and arrhythmias. Patients were randomly allocated into two groups: Group I; received insulin infusion to maintain blood sugar between 80-110 mg/dL, while Group II; aimed for 140-180 mg/dL. **Results:** Both groups have similar mean ages (Group A: 59.2 ± 5.57 years, Group B: 56.24 ± 9.66 years) and gender distribution (Group A: 24.0% females, Group B: 32.0% females). Group B had a longer ICU stay (mean: 56.6 ± 10.51 hours) compared to Group A (mean: 49.24 ± 11.91 hours, p=0.025), and Group B also required more support time (median: 35 hours, IQR: 17-42 hours) compared to Group A (median: 22 hours, IQR: 18-29 hours, p=0.041). **Conclusion:** This study demonstrates that fair glycaemic control in post cardiac surgery patients after CABG procedure resulted in a significant longer ICU stay and required a longer duration of support compared to tight glycaemic control. Despite similar complication rates between the two groups.

Keywords: Coronary Artery Bypass Grafting; Glycaemic Control; Intensive Care Unit; Hypoglycaemia.

Introduction

Diabetes is a chronic disease resulting from insufficient insulin production by the pancreas or ineffective insulin utilization by the body, leading to elevated blood glucose levels. Prolonged uncontrolled diabetes can cause severe damage to the heart, blood vessels, eyes, kidneys, and nerves- contributing significantly to premature mortality and disability. There are two main types of diabetes: Type 1; characterized by inadequate insulin production, necessitating daily insulin administration, with symptoms including excessive urination, thirst, hunger, weight loss, vision changes, and fatigue [1]; Type 2; stemming from ineffective insulin utilization, with symptoms often less pronounced than Type 1 [2]. Impaired glucose tolerance (IGT) and impaired fasting glycemia (IFG) represent intermediary conditions between normal blood glucose levels and diabetes, notably Type 2, carrying increased risks of heart attacks and strokes [3].

In cardiac surgery, hyperglycaemia frequently occurs in patients, irrespective of their diabetic status, as stress-induced diabetes can be triggered by the physiological stress and catabolic state induced by the surgery. Diabetes is a complex metabolic disorder characterized by hyperglycaemia, hyperinsulinemia, insulin resistance, and increased glucose production mechanisms, including; glycogenolysis and gluconeogenesis. Studies in cardiac surgery patients have linked hyperglycaemia to higher rates of sepsis, mediastinitis, prolonged mechanical ventilation, cardiac arrhythmias, and extended stays in the intensive care unit and hospital. The management of glycaemic levels and the threshold for initiating therapy remain subjects of significant debate in this context. [4]

Under normal conditions, insulin helps inhibit platelet aggregation and thrombosis by suppressing tissue factor and plasminogen activator inhibitor-1 (PAI-1) while promoting tissue plasminogen activator production. Conversely, insulin resistance promotes increased PAI-1 and fibrinogen synthesis, coupled with reduced tissue plasminogen activator production, collectively fostering atherothrombosis. [5] This heightened oxidative vascular stress leads to thrombosis, impaired platelet function, plaque rupture, and reduced graft patency, increased ischemic events, and a greater likelihood of repeat revascularization in coronary artery disease and diabetes. Hyperglycaemia is associated with worse outcomes following acute coronary syndrome, acute myocardial infarction, or coronary artery surgery. [6]

Previously published evidence suggested that “tight” glycaemic control (defined as blood glucose maintained at 70-110 mg/dL) in critically ill, surgical and non-surgical patients, improves morbidity and mortality. However, the results of another large randomized controlled trial (NICE-SUGAR (Normoglycemia in Intensive Care Evaluation)) indicated that glycaemic control below 108 mg/dL may actually increase the rate of all-cause mortality in ICU patients, both surgical and nonsurgical. [7, 8]

Glycaemic control in post-operative cardiac surgery patients could lead to decreased early mortality, incidence atrial fibrillation (AF), length of ICU stays, time on mechanical ventilation. But such control remains an open question. [9]

Therefore, the purpose of this study is to compare the effect of tight glycaemic control versus fair glycaemic control for post cardiac surgery patients.

Patients and Methods

Patients:

This randomized controlled clinical trial was carried out on 50 patients who were admitted to ICU after CABG. They were selected from Intensive Care Department and Cardiothoracic Surgery Department, Benha University, during the period from December 2022 to December 2023.

The study was done after being approved by the Institutional Review Board Code No: MS.14.4.2024 and informed written consent was obtained from all the participants included. The study was conducted in compliance with the principles of the Declaration of Helsinki and all applicable laws and regulations governing human research subjects.

Inclusion criteria were adult patients aged 18 years and older of diverse racial backgrounds and both sexes who were admitted to the ICU following CABG surgery. Exclusion criteria were individuals under 18 years of age, those undergoing non-cardiac surgical procedures, patients with a primary diagnosis indicative of preoperative infectious diseases, individuals with burn injuries or recipients of organ transplants, as well as patients requiring dialysis or those with compromised immune systems.

Patients:

Patients were divided into two groups:

Group I: included 25 patients; they were treated post operatively using insulin infusion (50 ml Normal saline 0.9% + 50 international unit of regular insulin) by rate following a protocol to target blood sugar range (80-110 mg/dL). **Group II:** included 25 patients; they were treated post operatively using insulin infusion (50 ml Normal saline 0.9% + 50 international unit of regular insulin) by rate following a protocol to target blood sugar range (140-180 mg/dL). Blood glucose levels were measured hourly and every 30 min if hypoglycaemia occurred.

Methods:

A- **Preoperative assessment:**

Methodology for preoperative assessment included fasting patients for 8 hours for solid food and 2 hours for clear fluids, monitoring weight changes to calculate body mass index and anticoagulation dosage. Medical history assessments involved collecting detailed information on patients' past medical conditions, allergies, and family history of cardiovascular diseases. A comprehensive clinical examination evaluated cardiovascular and respiratory health, while vital signs were continuously monitored. Laboratory tests encompassed complete blood count, electrolyte levels, coagulation profiles, renal function tests, and blood glucose measurements. Radiological and imaging studies included chest X-rays, ECGs, and echocardiography to assess lung, cardiac, and electrical activity, as well as cardiac chamber dimensions and valvular function.

B- **On Admission Assessment:**

Upon admission, the assessment protocol included the prompt collection of basal arterial blood gases to gauge acid-base balance, oxygenation, and respiratory function. Each patient underwent a chest X-ray to assess lung health, congestion, infection, and heart positioning within the chest cavity, informing respiratory and cardiac status. An electrocardiogram (ECG) recorded cardiac electrical activity, identified arrhythmias, and highlighted conduction abnormalities.

Cardiac enzymes like troponin, creatine kinase (CK), and CK-MB were measured to diagnose cardiac muscle damage or stress, aiding in cardiac risk assessment. Comprehensive laboratory testing covered a range of parameters, including complete blood count, electrolyte levels, kidney and liver function tests, coagulation profiles, lipid profiles, and other relevant markers, offering insights into overall health, underlying conditions, and treatment planning.

C- **Postoperative assessment:**

In the postoperative assessment within the ICU, continuous monitoring and measurements included the real-time tracking of vital signs such as heart rate, arterial blood pressure, and haemoglobin oxygen saturation to assess cardiovascular status.

Hourly temperature measurements were diligently recorded to identify trends in body temperature, aiding in the detection of fever or hypothermia with clinical significance. The hourly assessment of urine output was crucial for evaluating renal function, fluid balance, and perfusion status, with prompt responses to deviations from expected output levels. Additionally, hourly blood glucose monitoring was rigorously carried out to maintain optimal glycemic control and prevent fluctuations in blood sugar levels, facilitating prompt adjustments in insulin therapy and other interventions as needed.

D- **Outcome measures:**

Length of stay in the ICU is defined as time from ICU arrival to transfer to the floor or step-down unit. Before transfer, patients will be extubated with stable vital signs and without any inotropic support. Criteria for discharge included well perfused air warm peripheries and maintained urine output, a stable cardiac rhythm, free lung bases, temperature 37.2, a well-healed incision, and oxygen saturations > 92% on room. [10]

The time that was spent on the ventilator was recorded in hours from the time of admission to the ICU admission to the time of extubation. Need of inotropes / vasopressors were measured by hours of their use during the ICU Stay. The number of Hypoglycaemic episodes was recorded for each patient, defining Hypoglycaemia as blood glucose level below 45 mg/dL. Mediastinitis, wound infection and blood stream infection- were monitored by daily wound examination, total leucocytic Count, fever >38.3 and Punctures. Incidence of Arrhythmia or need of pacing were recorded and documented by Electrocardiogram.

Statistical analysis:

Data management and statistical analysis were done using SPSS Version 25.0. (Armonk, NY: IBM Corp.). Quantitative data were assessed for normality using the Shapiro-Wilk test and direct data visualization methods. According to normality, quantitative data were summarized as means and standard deviations or medians and ranges. Categorical data were summarized as numbers and percentages. Quantitative data were compared between the studied groups using the independent t-test or Mann-Whitney U test for normally and non-normally distributed quantitative variables, respectively. Categorical data were compared using the Chi-square or Fisher's exact test. All statistical tests were two-sided. P values less than 0.05 were considered significant.

Results

In this study, we initially enrolled 75 patients. However, during the screening process, 25 patients were excluded, with 18 not meeting our inclusion criteria and 7 declining to participate. As a result, we proceeded with a total of 50 eligible patients, who were then randomized into two equal groups for further analysis **(Figure 1)**.

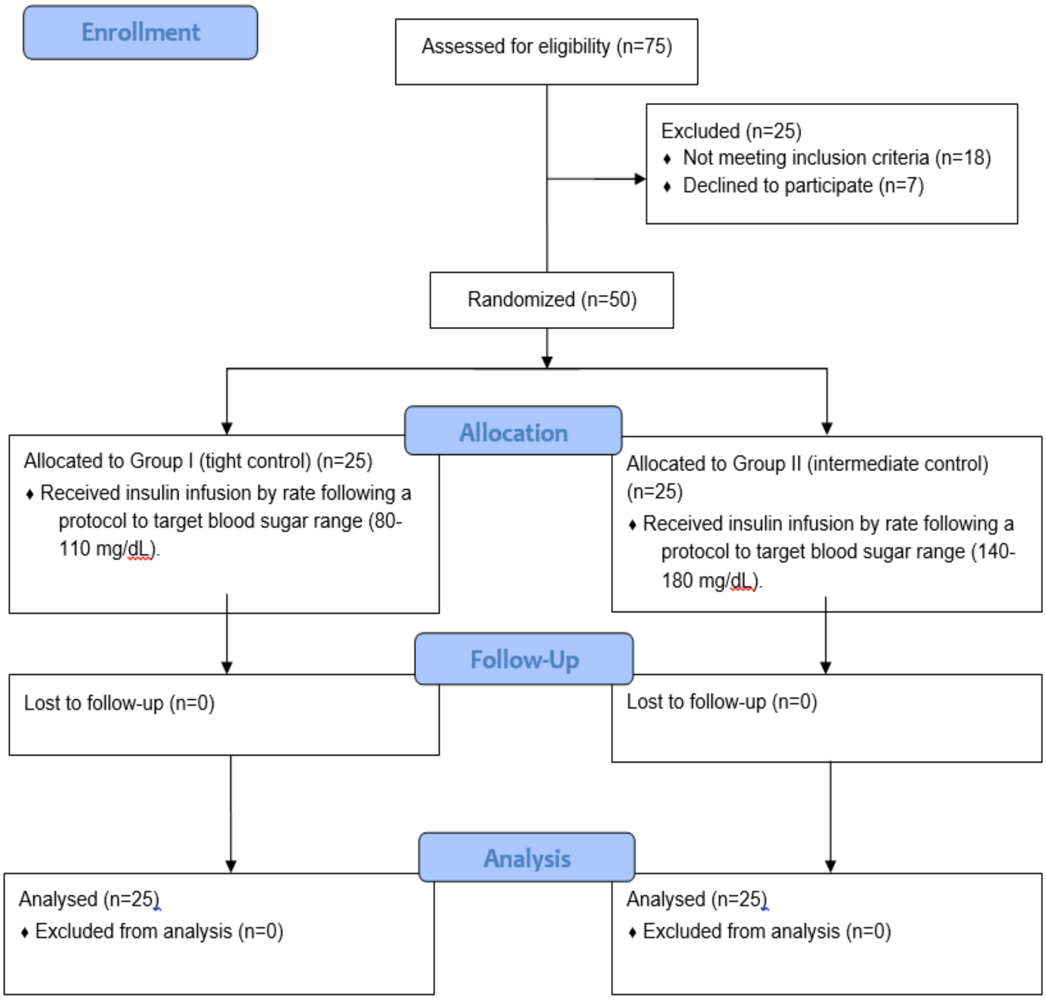

Figure 1: CONSORT flowchart of the studied participants

There was no statistically significant difference between the two studied groups regarding demographic characteristics, weight, BMI and comorbidities including (diabetes, diabetes treatment, diabetes duration or hypertension) **(Table 1)**.

APACHE score, ASA classification and surgery type were insignificantly different between both studied groups **(Table 2)**.

There was no statistically significant difference between the two studied groups regarding time of ventilation (P-value = 0.528). For Group A, the time of support needed ranges from 4 to 41 hours, with a median of 22 hours and an interquartile range (IQR) of 18 to 29 hours. For Group B, the time of support needed ranges from 7 to 54 hours, with a median of 35 hours and an IQR of 17 to 42 hours. There was a significant difference in the time of support needed between Group A and Group B. Group B required a longer duration of support compared to Group A (P-value = 0.041). There was no statistically significant difference between the two studied groups regarding need of blood transfusions **(Table 3)**.

There were no statistically significant differences in the incidence of these complications between the two groups. Both groups demonstrated comparable rates of complications including (Hypoglycaemic episodes, infection, atrial fibrillation, ICU mortality and need of renal replacement) **(Figure 2)**.

Table 1: Comparison between studied cases according to demographic data

	Group A (n=25)		Group B (n=25)		Test of sig.	p
Age						
Range.	49 – 70		39 – 76		t=	0.191
Mean ± SD.	59.2 ± 5.57		56.24 ± 9.66		1.328	
Gender	No.	%	No.	%		
Female	6	24.0	8	32.0	χ^2=	0.529
Male	19	76.0	17	68.0	0.397	
Weight						
Range.	85 – 130		76 – 128.5		t=	0.438
Mean ± SD.	107.5 ± 12.76		104.42 ± 15.02		0.781	
BMI						
Range.	29.4 – 41.5		28.2 – 39.6		t=	0.540
Mean ± SD.	35.78 ± 3.84		35.14 ± 3.38		0.618	
Diabetes	No.	%	No.	%		
No	6	24.0	7	28.0	χ^2=	0.747
Yes	19	76.0	18	72.0	0.104	
Diabetes treatment						
Insulin	8	32.0	13	52.0	χ^2=	0.065
OHG	11	44.0	5	20.0	3.416	
Duration of diabetes						
Range.	5 – 21		4 – 23		U=	0.869
Median (IQR)	14 (8 – 16)		12.5 (8.3 – 16.5)		165.5	
Hypertension						
No	11	44.0	10	40.0	χ^2=	0.774
Yes	14	56.0	15	60.0	0.082	

Data are presented as frequency (%) unless otherwise mentioned, SD: Standard deviation, IQR: Interquartile range.

Table 2: Comparison between studied cases according to history data and surgery data

	Group A (n=25)		Group B (n=25)		Test of sig.	p
APACHE score						
Range.	16 – 27		17 – 27		t=	0.550
Mean ± SD.	21.52 ± 3.44		22.08 ± 3.12		0.603	
ASA classification	No.	%	No.	%		
Grade 3	2	8.0	3	12.0	χ^2=	0.637
Grade 4	23	92.0	22	88.0	0.222	
Surgery	No.	%	No.	%		
Elective	3	12.0	4	16.0	χ^2=	0.684
Urgent	22	88.0	21	84.0	0.166	
Type of surgery						
Primary isolated CABG	4	16.0	3	12.0	χ^2=	0.338
CABG + valve repair	21	84.0	20	80.0	2.167	
Redo CABG	0	0.0	2	8.0		

Data are presented as frequency (%), SD: Standard deviation.

Table 3: Comparison between studied cases according to ICU stay, time of ventilation, time of Support Need and need of blood transfusions

	Group A (n=25)	Group B (n=25)	Test of sig.	p
ICU Stay (Hrs.)				
Range.	32 – 67	42 – 76	t=	**0.025***
Mean ± SD.	49.24 ± 11.91	56.6 ± 10.51	2.317	
Time Of Ventilation (Hrs.)				
Range.	8 – 37	9 – 39	U=	0.528
Median (IQR)	24 (14 – 29)	22 (19 – 33)	280.0	
Time of support need (Hours)				
Range.	4 – 41	7 – 54	U=	**0.041***
Median (IQR)	22 (18 – 29)	35 (17 – 42)	207.5	
Range.	1 – 6	1 – 6	U=	0.747
Median (IQR)	4 (3 – 5)	3 (2 – 5)	285.0	

Data are presented as Mean ± SD, SD: Standard deviation, IQR: Interquartile range.

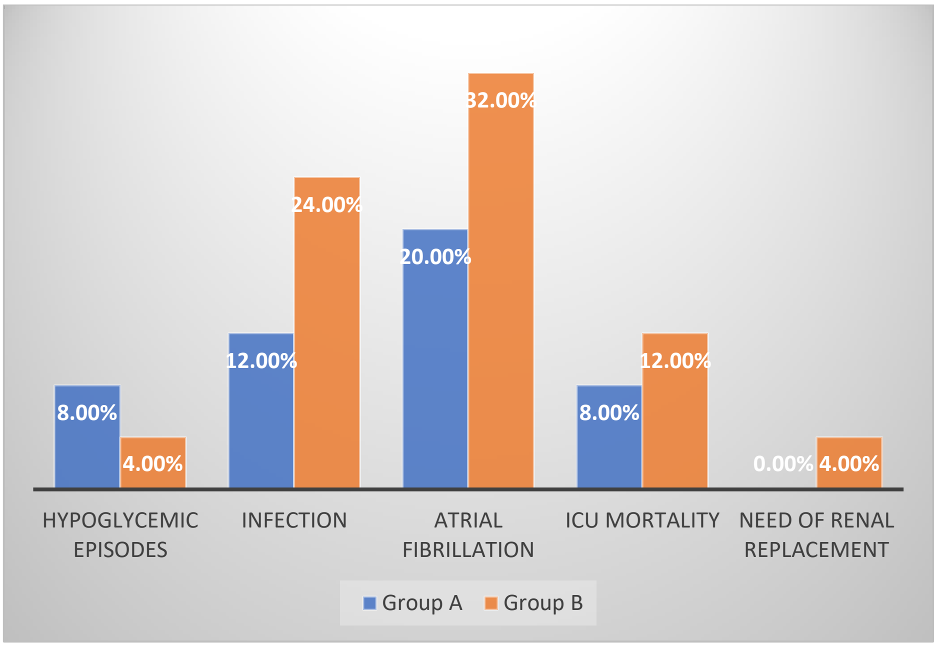

Figure 2: Comparison between studied cases according to complications

Discussion

Hyperglycaemia in the immediate postoperative period has been linked to various adverse outcomes among CABG patients, such as increased risks of wound infections, prolonged hospital stays, and higher mortality rates. However, overly aggressive glucose-lowering strategies can lead to higher rates of hypoglycaemia, which can also negatively impact patient outcomes. As a result, finding the right balance between tight glycaemic control and fair glycaemic control remains a subject of ongoing investigation in critical care. In recent years, there has been a shift in the approach to glucose management, moving away from rigid protocols toward individualized glycaemic targets, reflecting the recognition that strict glucose control may not universally benefit all patient populations. Therefore, understanding the impact of varying glycaemic control strategies on post-CABG patients is crucial for optimizing clinical outcomes and resource utilization. [11] Given the inconclusive and sometimes contradictory evidence in this area, this study aims to compare the effects of tight glycaemic control versus fair glycaemic control for post-cardiac surgery patients. [12, 13]

This study is to compare the effect of tight glycaemic control versus fair glycaemic control for post cardiac surgery patients.

In the current study, both groups have similar mean ages (Group A: 59.2 ± 5.57 years, Group B: 56.24 ± 9.66 years) and gender distribution (Group A: 24.0% females, Group B: 32.0% females). There are no significant differences in comorbidities (diabetes, diabetes treatment, diabetes duration, or hypertension) or surgical parameters (elective/urgent surgery, primary isolated CABG or CABG combined with valve repair) between the two groups (p=0.684 and 0.338, respectively). However, Group

B had a longer ICU stay (mean: 56.6 ± 10.51 hours) compared to Group A (mean: 49.24 ± 11.91 hours, p=0.025), and Group B also required more support time (median: 35 hours, IQR: 17-42 hours) compared to Group A (median: 22 hours, IQR: 18-29 hours, p=0.041).

In harmony with our findings, **Jin et al.** [13] conducted a systematic review and meta-analysis examining perioperative glycaemic control strategies in diabetic cardiac surgery patients. They discovered that strict glycaemic control (target blood sugar <140 mg/dL or 7.8 mmol/L) was linked to reduced atrial fibrillation risk and a significant decrease in sternal wound infections compared to other approaches. Additionally, they noted a significant disparity in postoperative mortality between moderate glycaemic control (target blood sugar 140-180 mg/dL or 7.8-10.0 mmol/L) and liberal glycaemic control (target blood sugar >180 mg/dL or 10.0 mmol/L). However, no significant differences were found in stroke and hypoglycaemic episodes between strict and moderate glycaemic control strategies. Furthermore, they concurred that moderate glycaemic control was advantageous in reducing atrial fibrillation compared to liberal glycaemic control.

The study by **Lazar et al.** [14] corroborates our findings, as it compared strict and moderate glycaemic control in CABG surgery patients, administering continuous insulin infusion with varying glycaemic targets. The strict glycaemic control group, aiming for blood sugar levels between 90-120 mg/dl, exhibited a lower postoperative mean PG level (103 mg/dl) compared to the moderate glycaemic control group, with a target range of 120-180 mg/dl, which had a higher postoperative mean PG level (135 mg/dl). This mirrors our results showing that strict glycaemic control led to lower postoperative mean PG levels compared to moderate glycaemic control.

Similarly, **Estrada et al.** [15] agree with our findings in terms of morbidity and mortality among diabetic and non-diabetic patients undergoing cardiac surgery. They measured the association between perioperative hyperglycaemia and outcomes among patients undergoing CABG. They found no difference between diabetic and non-diabetic patients regarding morbidity and mortality. However, they did find that diabetic patients had a longer stay in the ICU if their blood glucose levels were not controlled. This supports our result that strict glycaemic control was associated with a shorter ICU stay in Group A compared to Group B.

In accordance with our study, **Haga et al.** [16] conducted a systematic review that examined the effects of tight versus normal glycaemic control during and after cardiac surgery. They identified several advantages associated with tight glycaemic control, including a reduced incidence of early mortality in the ICU, decreased post-surgical atrial fibrillation, reduced use of epicardial pacing, shortened duration of mechanical ventilation, and a decreased length of stay in the ICU. However, they noted heterogeneity in the data for measures of time spent on mechanical ventilation and time spent in the ICU, indicating varying effects of tight glycaemic control on these outcomes across studies. Parallel to our results, **Van den Berghe et al.** [17] conducted a large prospective trial on intensive insulin therapy in surgical ICU patients, predominantly from cardiovascular surgeries (62% of patients). They reported shorter ICU stays for patients staying over 5 days, reduced transfusion requirements per patient, a significant decrease in Blood Stream Infections, and lower ICU mortality in the tight glycaemic control group.

In disagreement with our study, **Hoedemaekers et al.**[18] conducted a study on only 10 patients who were mainly non-diabetic patients. Critically ill patients were excluded from the study. They reported no statistically significant difference between intensive and conventional control regarding the length of ICU stay. Also, they found no significant statistical difference between both groups regarding the time of mechanical ventilation.

In contrast, **Preiser et al.** [19] showed no statistically significant difference between both groups regarding the length of ICU stay. Also, they revealed no significant statistical difference between the studied groups regarding the time of mechanical ventilation.

Finally, this study had some limitations, as it was a single-centre study with a relatively small sample size which may limit the generalizability of the findings to a larger population. The study's relatively short follow-up period of 9 months may not capture long-term effects of glycaemic control on patient outcomes. The study did not account for individual variations in insulin sensitivity, which could influence glycaemic control outcomes.

Conclusions

In conclusion, this study demonstrates that fair glycemic control in post cardiac surgery patients after CABG procedure resulted in a significantly longer ICU stay and required a longer duration of support compared to tight glycemic control. Despite similar complication rates between the two groups, this reveals that achieving tighter glycemic control may have potential benefits in terms of reducing ICU stay and support duration for these patients.

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