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Association between preoperative level of hemoglobin A1c and the incidence of acute kindey injury after coronary artery bypass grafting surgery: a cohort study



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Abstract

Background: The development of acute kidney injury (AKI) is an important indicator of clinical outcomes after cardiac surgery. Elevated preoperative hemoglobin A1c level may be associated with acute kidney injury in patients undergoing coronary artery bypass grafting. This study will investigate the association of preoperative HbA1c levels with AKI after isolated coronary artery bypass grafting (CABG).

Results: Forty patients undergoing elective CABG were enrolled in this cohort study. Patients are divided into 2 equal groups who underwent isolated coronary artery bypass grafting (CABG): patients with preoperative HbA1c 5.7–6.4% (group A) (prediabetics) and patients with preoperative HbA1c > or = 6.5% (group B) (diabetics). Acute kidney injury according to the Kidney Disease: Improving Global Outcomes criteria developed in 11 patients (27.5%). There was a significant difference between the two groups as regards postoperative urinary NGAL, creatinine level on the 1st day, creatinine level on the 2nd day, urine output on the 1st day, and urine output on the 2nd day (p value was 0.001, 0.002, 0.006, 0.0002, and 0.012 respectively). Postoperative ICU stay duration was statistically significant in the diabetic group (P value 0.009). The need for renal replacement therapy was higher in the diabetic group, but it was not statistically significant between the two groups. Roc analysis shows AUC 0.922 with a significant p value (< 0.0001) and cut of value (≥ 7) with sensitivity 81.82 and specificity 93.10.

Conclusion: This study revealed that elevated preoperative HbA1c level above 7% showed an increase in incidence of post CABG acute kidney injury along with increase length of postoperative ICU stay.

Keywords: Acute renal injury, Hemoglobin A1c, Neutrophil gelatinase-associated lipocalin, Serum creatinine, Coronary artery bypass grafting surgery

Background

Acute kidney injury is a major complication related to cardiac surgery. According to the literature using different definitions of acute kidney injury, cardiac surgery-associated kidney injury concerns about 30% of the patients. Mortality usually raises from 1% up to 50% for

patients who undergo renal replacement therapy following cardiac surgery (Thiele et al., 2015).

Early identification of renal dysfunction is crucial and considered as a "holy grail" because it could allow early interventions (both diagnostic and therapeutic) to hinder the evolution to renal failure (Bataille et al., 2017).

Multiple hazardous factors were reported to upstroke the incidence of AKI following cardiac surgery. Age, hypertension, diabetes, and peripheral vascular disease

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usually considered to be prevalent unmodifiable risk factors (Lopez-Delgado et al., 2013).

Others, such as the usage of cardiopulmonary bypass (CPB), transfusion of blood product, and preoperative and intraoperative medications, may also elevate the risk of postoperative AKI. In spite of the multifactorial etiology of AKI, numerous pathophysiological processes could have important impacts on the development of postoperative AKI. These comprise microcirculatory dysfunction, endothelial dysfunction, renal tubules injury and renal inflammation, and microvascular thrombus formation, altering renal perfusion and thus resulting in evolution of AKI (Ostermann & Liu, 2017).

Currently, the early spotting of AKI by clinical and laboratory tools remains difficult. In clinical practice, creatinine level and urine output are the most frequently used indicators of renal dysfunction despite their limited sensitivity and specificity (Arun et al., 2015).

Over the last five decades, serum creatinine has been accustomed to detect changes in kidney function. The half-life of serum creatinine in healthy adult male is about 4 h. At a point of 50% decrease in creatinine clearance, the half-life of serum creatinine is found to be 8 h, and it takes another 3 to 5 half-lives before hitting its peak or reaching a steady state (it takes 24 to 40 h). That limitation causes serum creatinine to be a delayed marker of AKI even after decline of glomerular filtration rate (GFR) to nearly half (Srisawat & Kellum, 2020).

Many urinary proteins such as neutrophil gelatinase-associated lipocalin (NGAL), kidney injury molecule-1 (KIM-1), cystatin C, and interleukin-18 (IL-18) were studied to reveal their role as early biomarkers of AKI in patients undergoing cardiac surgery (Arun et al., 2015).

Hemoglobin A1c (HbA1c) is widely measured and used as a marker of average blood glucose concentrations over the preceding 2 to 3 months, and it has advantages over the other glucose tests. Some proved evidence indicates that the high HbA1c levels prior to surgery were strongly associated with the severity of adverse events after CABG (Faritous et al., 2014).

Methods

After obtaining the approval of our institute hospitals' ethical committee (FMASU MD 368/2018), informed consent was taken from 40 patients of ASA physical status II–III, aged 45–70 years, scheduled to undergo isolated coronary artery bypass grafting (CABG) in this prospective cohort study at our institute hospitals, from June 2019 until July 2020.

Preoperative evaluation included a detailed history, physical examination along with cardiological assessment, and investigations, which included the following: complete blood count, the coagulation profile, liver function tests, kidney function tests [serum creatinine; s.Cr)],

fasting blood glucose (FBG), glycosylated hemoglobin (HbA1c), electrocardiography (ECG), echocardiography, and diagnostic coronary catheterization. All preoperative cardiac medications were continued until the morning of surgery, except the drugs with renal effects like angiotensin converting enzyme (ACE) inhibitors.

Exclusion criteria

Patients with history of renal, hepatic failure or heart failure, previous cardiac surgery, cerebrovascular event in the last 30 days, percutaneous coronary intervention in the last 30 days prior to operation, peripheral arterial disease, malignancy, infectious diseases, patients who required surgical revision, patients who required postoperative intra-aortic balloon pump, and patients with CBP time > 120 min or aortic cross clamp time > 90 min were excluded from the study.

Study interventions

Upon arriving to the operating theater, patients had a 16 G intravenous cannula inserted in the right upper limb side under local anesthesia of 1 ml lidocaine hydrochloride 2% (Sigma Tec Industries Co packed by Al-Debeiky pharmaceutical Industries, A.R.E., Obour City Ind. Zone). As preoperative sedation, all patients received the following: 0.05 mg/kg IV midazolam hydrochloride (dormicum, 5 mg/ml; Roche, Basel, Switzerland) and 0.5-1 μg/kg fentanyl (Sunny Pharmaceutical, Industrial Zone, Badr City, Egypt under license of Hamelin Pharmaceuticals, Germany) as well as intravenous infusion of 0.5-1 μg/kg nitroglycerine (Nitronal, glyceryl trinitrate, 1 mg/ ml, Sunny Pharmaceutical, Industrial Zone, Badr City, Egypt under license of Hamelin Pharmaceuticals, Germany). Left radial artery cannulation was then done by Vygon arterial leadercath under xylocaine local anesthesia.

Intraoperative basic monitors were applied using 5-lead ECG, pulse oximetry, and capnography. The monitor used was Dash 5000; General Electric, Medical Systems Information Technologies, Inc. Tower Ave., Milwaukee, WI, USA, and the anesthetic machine used was Datex-Ohmeda, Inc. 3030 Ohmeda Drive, Madison, WI 53707-7550, USA.

Anesthesia was induced with intravenous $3 \mu g/kg$ fentanyl, 1 mg/kg propofol (Propofol 1%; Fresenius Kabi Deutschland GmbH Grazia), and 0.15 mg/kg cisatracurium besylate [Nimbex, 10 mg cisatracurium (bis-cation) in 5 ml. GlaxoSmithKline manufacturing S.p.A, Parma, Italy]. After 3 min of controlled mechanical ventilation using oxygen (81 of 100% O_2) and 1.2% isoflurane (forane, isoflurane, USP, liquid for inhalation, 250 ml; Baxter Healthcare Corporation, Deerfield, Illinois, USA), the patients were intubated using a Macintosh laryngoscope

blade, and a cuffed 7.5–8 mm I.D. endotracheal tube was inserted orally and fixed on the left side of the mouth.

Right internal jugular vein cannulation by (Braun, Certofix trio, 7F) was then done under ultrasound guidance; the ultrasound (M-Turbo; SonoSite, Washington, DC, USA) with a high frequency linear transducer (frequency 10–15 MHz) was used.

Maintenance of anesthesia was done with oxygen (31 of 60% O₂) and 1.2% isoflurane; furthermore, neuromuscular blockade was maintained with intermittent boluses of 0.03 mg/kg cisatracurium besylate intravenously as needed. Maintenance dose of Ringer lactate solution was infused. Patients were mechanically ventilated using a Datex-Ohmeda Inc. (3030 Ohmeda Drive Madison WI 53707-7550 USA.) anesthesia machine attached to a closed circuit system fitted with a circle absorber. Intermittent positive pressure ventilation was adjusted to maintain an end-tidal carbon dioxide (EtCO₂) value within normal limits such that the airway pressures were kept to a minimum with tidal volume at 6 ml/kg and a respiratory rate of 12 breaths/min. Insulin infusion [Actrapid 100 IU/ml, Insulin human (rDNA)] was started and calculated as intraoperative blood glucose divided by 100, to keep blood glucose level < 180 mg/dl; 4 mg/kg of heparin (heparin sodium 5000 IU/1 ml ampoule, Misr Co., For pharmaceuticals, Alexandria, Egypt) was given after left internal mammary artery harvesting.

Cardio pulmonary bypass (CPB) was managed to maintain mean arterial pressure (MAP) 40-60 mmHg, with tepid hypothermia (32–34 °C) and keeping hematocrit at 30% with the addition of fresh packed red blood cells (RBCs) as needed. Weaning from CPB and reperfusion of the heart was performed according to the patient's hemodynamics and cross-clamp time by pharmaceutical or mechanical support. Patients were followed in the intensive care unit (ICU) in the postoperative period; electrocardiography, systemic mean arterial pressure, central venous pressure, arterial blood gasses, chest tube drainage, and urine output were monitored. Weaning from mechanical ventilation and extubation was done after hemodynamic stability (MAP of 60-90 mmHg, heart rate (HR) between 60 and 90 bpm, a central venous pressure (CVP) between 10 and 15 mmHg) and ventilatory stability (spontaneous tidal volume $^{>}$ 4 ml/kg, negative inspiratory force ≥ -30 cmH₂o, FIO_2 $^{\circ}$ 0.5, PEEP $^{\circ}$ 8 cm H_2 o).

Sample size

Using STATA program, setting alpha error at 5% and power at 80% results from the previous study (Arun et al., 2015), showed that among diabetic patients, 80% of cases developed AKI compared to 26.6% of non-diabetic. Based on this, the needed sample is 20 diabetics (elevated HbA1c) and 20 with non-elevated HbA1c,

taking in consideration a 20% drop out rate with a calculated effect size of 0.35.

This study was done as a prospective cohort study, in which 40 patients were divided into 2 equal groups who underwent isolated coronary artery bypass grafting (CABG).

- Patients with preoperative HbA1c 5.7–6.4% (group A) (prediabetics)
- Patients with preoperative HbA1c > or = 6.5% till 7% or > 7% in case of emergency surgery or rapidly progressive cases with no time for long-term glycemic control (group B) (diabetics)

Primary outcome

The primary outcome is acute kidney injury (AKI). Diagnosis of postoperative AKI was made in accordance with the International Kidney Disease: Improving Global Outcomes (KDIGO) definition of AKI KDIGO Classification (Khwaja, 2012). AKI is defined as any of the following: increase in serum creatinine by ≥ 0.3 mg/dl within 48 h of surgery or increase in serum creatinine to ≥ 1.5 times baseline within 3 days of cardiac surgery

Secondary outcomes

Patients in need of RRT Length of ICU stay

Collected data

Preoperative hemoglobin level Left ventricle ejection fraction

Preoperative s.Cr

Preoperative fasting blood sugar

Preoperative HgbA1C

Aortic cross-clamp time

Duration of CPB

Incidence of AKI

Postoperative urinary neutrophil gelatinase-associated lipocalin (NGAL) was measured after 12 h.

Postoperative s. Cr was measured after $12\,h$, $24\,h$, and $48\,h$.

Urine output (UOP) after 24 h and 48 h was measured, and any decrease under 0.5 ml/kg/h for 6 consecutive hours was recorded

Statistical analysis

The collected data was revised, coded, and introduced to a PC using statistical package for social science (SPSS 15.0.1. for Windows; SPSS Inc., Chicago, IL, 2001). Quantitative data were expressed as mean \pm standard deviation (SD). Qualitative data were expressed as frequency and percentage. Independent samples t-test of significance was used when comparing between two means. Chi-square (χ^2) test of significance was used in order to compare proportions between two qualitative

Table 1 Comparison between the two studied groups according to demographic data

	Pre diabetic group $(N = 20)$	Diabetic group $(N = 20)$	T	P value
Age (years)	57.85 ± 5.43	59.05 ± 5.35	0.7	0.49
BMI	25.7 ± 2.23	25.25 ± 1.97	0.68	0.503
Sex (M/F)	14/6	12/8	$\chi^2 = 0.11$	0.74

Data expressed as mean ± SD

T = student t test

 χ^2 = Chi square test

parameters. Mann-Whitney U test was used for two-group comparisons in non-parametric data. The confidence interval was set to 95%, and the margin of error accepted was set to 5%. P value < 0.05 was considered significant, and P value < 0.01 was considered highly significant.

Results

Forty patients were enrolled in the study, 20 patients in each group. Groups were comparable in demographic data (in terms of age, sex, and BMI), and there were no statistically significant differences between groups (p value > 0.05 NS) (Table 1).

Preoperative investigations were compared between the two groups as regards preoperative hemoglobin level, left ventricle ejection fraction creatinine level, and fasting blood sugar, and it was not significant (Table 2).

Intraoperative events were compared between two groups as regards aortic cross clamp and bypass time, and it was not significant (Table 3).

Postoperative acute kidney injury was compared between two groups as regards incidence of AKI, and it was significant between the two groups as there is only two patients in prediabetics and nine patients in diabetic patients (*p* value is 0.034) (Table 4).

And as regards AKI markers, it was significant between two groups as regards postoperative urinary NGAL, creatinine level on the 1st day, creatinine level on the 2nd day, urine output on the 1st day, and urine output on the 2nd day (p value was 0.001, 0.002, 0.006, 0.0002, and 0.012 respectively), except creatinine level after 12 h; it was not significant between the two groups (*P* value is 0.072).

Also, the need for renal replacement therapy was higher in the diabetic group, but it was not statistically significant between the two groups as only one patient needed RRT in the prediabetic group and four patients in the diabetic patients (*P* value 0.339).

Postoperative ICU stay was compared between the two groups, and it was significant (P value = 0.009) (Table 5).

There is a significant relation between AKI and preoperative Hgb A1C as the study showed 11 patients had AKI (27.5%) with elevated Hgb A1c, and Roc analysis shows AUC 0.922 (95% confidence interval 0.792 to 0.983) with significant p value (< 0.0001) and cut of value (≥ 7) with sensitivity 81.82 and specificity 93.10 (Fig. 1).

Logistic regression for AKI and preoperative Hgb A1C showed odds ratios (26.0979) with 95% confidence intervals (2.9604 to 230.0675) (Table 6).

There is a strong positive correlation between preoperative HbA1c and postoperative urinary NGAL, creatinine in day 1 and moderate positive correlation to creatinine in day 2 (r = 0.715, 0.726, and 0.694 respectively), and moderate negative correlation to UOP in day 1 and day 2 (r = -0.696, -0.623 respectively) (Table 7).

Discussion

This study compared the AKI incidence between patients with prediabetic level of HbA1c (5.7-6.4) and patients with elevated levels of HbA1c (> or = 6.5). Forty patients who underwent elective CABG were enrolled in this cohort study.

Patients were divided into 2 groups according to their HbA1c level: patients with preoperative HbA1c 5.7–6.4%

Table 2 Comparison between the two studied groups according to preoperative investigations

	Pre diabetic group ($N = 20$)	Diabetic group ($N = 20$)	T	P value
Preoperative hemoglobin level	13.02 ± 1.47	12.94 ± 1.09	0.18	0.86
Left ventricle ejection fraction	56.2 ± 4.47	55.05 ± 4.29	0.83	0.41
preoperative creatinine level	0.89 ± 0.12	0.94 ± 0.12	1.24	0.22
preoperative fasting blood sugar	96.6 ± 12.96	101.45 ± 20.53	0.89	0.38

Table 3 Comparison between the two studied groups according to intraoperative events

	Pre diabetic group ($N = 20$)	Diabetic group ($N = 20$)	T	P value
Aortic cross clamp (min)	72.35 ± 16.01	66.55 ± 12.75	1.27	0.213
Bypass time (min)	93.25 ± 15.43	88.65 ± 13.24	1.01	0.318

Data expressed as mean ± SD

T = student t test

(group A) (prediabetics) and patients with preoperative HbA1c > or = 6.5% (group B) (diabetics).

Postoperative AKI during the 2-day follow-up period was determined according to the Kidney Disease: Improving Global Outcomes (KDIGO) criteria.

UOP is measured, and any decrease under 0.5 ml/h for 6 consecutive hours is recorded. Urinary neutrophil gelatinase associated-lipocalin (NGAL) is measured after 12 h with a cutoff value of 65 ng/mL for diagnosis of AKI.

According to our demographic data analysis (in terms of age, sex, and BMI), there were no statistically significant differences between the groups (p value > 0.05 NS).

Preoperative investigations were compared between the two groups as regards preoperative hemoglobin level, left ventricle ejection fraction creatinine level, and fasting blood sugar, and it was not significant.

This result in keeping with the Kocogullari et al. study that is discussed later to predict acute kidney injury after coronary artery bypass surgery in non-diabetic patients where demographic data and preoperative investigations were insignificant (Kocogulları et al., 2017).

According to the KDIGO criteria11, the patient developed AKI with a significantly higher incidence in the diabetic group (p value = 0.035) and 5 patients developed the need for RRT with no significant incidence between the two groups.

Our study clearly indicate that elevated preoperative HbA_{1c} level is associated with postoperative AKI and prolonged ICU stay in patients undergoing CABG.

Kocogullari et al.'s study on 315 patients with AKI diagnosis was made by comparing the baseline and

postoperative serum creatinine to determine the presence of predefined significant change based on the Kidney Disease Improving Global Outcomes which found that elevated preoperative HbA1c level is associated with increased incidence of postoperative AKI and increase in the duration of the ICU stay in nondiabetic patients undergoing CABG. The cutoff value of HbA1c was determined as 5.75% with test sensitivity and test specificity calculated to be 73.7% and 65% respectively. The AUC were calculated as 0.76 (Kocogulları et al., 2017).

In keeping with this study, Gumus and his colleagues revealed the association between elevated HbA1c level and increased renal complications. The incidence of AKI was greatly elevated in patients with high HbA1c (11.9% vs. 1.8%, p value = 0.0001) and high incidence of renal morbidity (odds ratio = 4.608) and that every 1% increase in the HbA1c above 5.9% increased the risk of renal complications by 23.6% (Gumus et al., 2013).

The ROC analysis of the study revealed that the cutoff values for HbA1c level measured preoperatively was determined as 7%, with sensitivity (81.82%) and specificity (93.10%), and AUC was calculated as 0.922.

Halkos et al. hypothesized that there is a strong association between elevated HbA1c above 7% and AKI after CABG. There is a statistically significant difference in renal failure incidence between diabetic and nondiabetic patient (4.9% vs. 1.8%), p value (< 0.01) (Halkos et al., 2008).

Oezkur et al. found that HbA1c > 6% is considered to be a strong determinant of postoperative AKI in their cohort study done to determine risk of chronic

Table 4 Comparison between the two studied groups regarding the incidence and determinants of AKI

	Pre-diabetic group (N = 20)	Diabetic group (N = 20)	T or χ ²	P value
Incidence of AKI	2 (10%)	9 (45%)	4.5 [¶]	0.034
Postoperative urinary NGAL (ng/ml)	56.95 ± 11.75	72.25 ± 15.88	3.46*	0.001
Creatinine level 12 h postoperative (mg/dl)	1.025 ± 0.192	1.14 ± 0.2	1.85*	0.072
Creatinine level 1st day (mg/dl)	1.07 ± 0.29	1.44 ± 0.43	3.25*	0.002
Creatinine level 2nd day (mg/dl)	1.05 ± 0.42	1.66 ± 0.85	2.89*	0.006
Urinary output 1st day (ml/kg/h)	0.97 ± 0.22	0.67 ± 0.23	4.135*	0.0002
Urinary output 2nd day (ml/kg/h)	1.04 ± 0.28	0.77 ± 0.36	2.63*	0.012
Need for RRT	1 (5%)	4 (20%)	0.914 [¶]	0.339

Data expressed as mean \pm SD or percentage

T = student t test*

 $[\]chi^2$ = Chi square test[¶]

p is significant when $p \le 0.05$

Table 5 Comparison between the two studied groups regarding ICU stay

	Pre diabetic group ($N = 20$)	Diabetic group ($N = 20$)	Z	P value*
ICU stay (days)	2 (2-3)	3 (2-5)	2.63	0.009

Data expressed as median (IQR) *Mann-Whitney U test

hyperglycemia (CHG) with HbA1c as an indicator affects postoperative mortality and morbidity after coronary artery bypass grafting surgery (p value = 0.008) (Oezkur et al., 2015).

Kim et al. found that increased HbA1c level above 7% was associated with increased incidence of AKI of diabetic patients going off-pump CABG and that was consistent with our ROC analysis for preoperative HbA1c level (Kim et al., 2020).

In addition, there was significant increase in the ICU stay duration and increased need for RRT with no significant difference between the two groups.

Contrarily, Finger et al. found no correlation between increased HbA1c > 7% and development of AKI. Incidence of AKI was 14.14% in the patient group with HbA1c < or = 7% vs. 8.77% in the group with patients with HbA1c > 7% (p value = 0.264). In this study, AKI was defined as elevation in serum creatinine level 150%

from the baseline value but found an association between length of hospital stay (p value 0.009) and elevated levels of HbA1c with no significance in the duration of ICU stay (p value 0.382). This can be contributed to the usage of only serum creatinine level to detect postoperative AKI which can show a slow rise and inaccuracy except lately where we used urinary NGAL and UOP together with serum creatinine (Finger et al., 2017).

Intraoperative events were compared between the two groups as regards aortic cross clamp and bypass time, and it was not significant.

Aortic cross clamping time also is associated with postoperative AKI, as observed by Karim et al. who found that the incidence of AKI increased along with the increase in the CPB and cross clamp time significantly. The CPB time > 120 min increased the AKI risk by an odds ratio (OR) 4.76 as compared to 71-140 min and by an OR 6.30 for > 140 min (P < 0.01), while for the

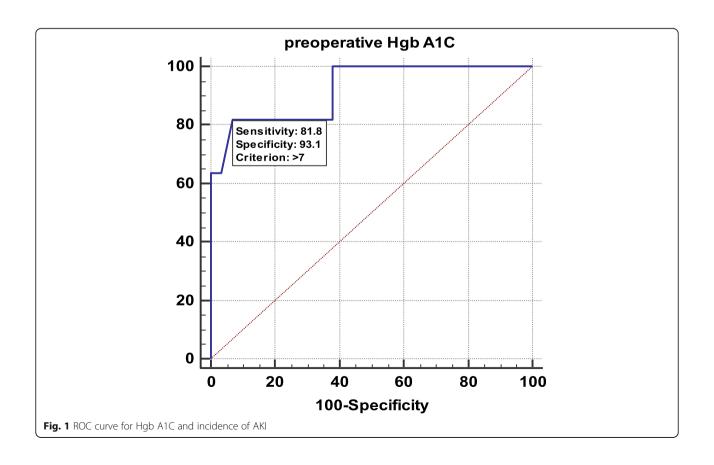


Table 6 Logistic regression for AKI and preoperative Hgb A1C AKI in relation to Hgb A1c

	Odds ratio	95% CI
Preoperative HgbA1C	26.0979	2.9604 to 230.0675

aortic cross clamp time > 90 min increased the AKI risk by an OR of 2.84 as compared to 61-120 min and by an OR 3.64 for > 120 min (P=0.01). In this study, the insignificance is explained by the exclusion of patients with long CBP time or prolonged aortic cross clamp time (Karim et al., 2017).

Conclusion

This study revealed that elevated preoperative HbA1c level above 7% showed an increase in incidence of post CABG acute kidney injury along with increase length of postoperative ICU stay. AKI following cardiac surgery causes multiple postoperative complications and leads to prolonged hospitalization, increased costs, and eventually increased mortality rates.

Limitations

The study was carried out in one center.

GFR was not used in the diagnosis of AKI.

NGAL urine level was measured once postoperatively, and no preoperative level was done.

Conflict of interest

There was no conflict of interest throughout the study.

Recommendations

We recommend using a larger sample size, assess patients with GFR, creatinine clearance, and measuring serial preoperative and postoperative NGAL level for better detection of AKI.

Table 7 Correlation table between preoperative Hgb A1c and AKI investigations

		Postop urine NGAL	Creat D1	Creat D2	UOP 1	UOP 2
Preoperative Hgb A1C	Correlation coefficient r	0.715	0.726	0.694	- 0.696	- 0.623
	P value	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001

R = Pearson correlation coefficient

Creat D1 (creatinine day 1), Creat D2 (creatinine day 2), UOP 1(urine output day 1), UOP 2 (urine output day 2

Abbreviations

HbA1c: Glycosylated hemoglobin; NGAL: Neutrophil gelatinase-associated lipocalin; ASA: American Society of Anesthesiologist; CPB: Cardiopulmonary bypass; RRT: Renal replacement therapy; CABG: Coronary artery bypass grafting; AKI: Acute kidney injury; KDIGO: Kidney Disease: Improving Global Outcomes; GFR: Glomerular filtration rate; MAP: Mean arterial pressure; HR: Heart rate; CVP: Central venous pressure; CAD: Coronary artery disease; LVEF: Left ventricular ejection fraction; SCr: Serum creatinine; ROC: Receiver operating characteristic

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Authors' contributions

OA designed the study, revised literature and followed the patients, HF analyzed the data and critically reviewed the manuscript and revised the statistical analysis, GS and MZ designed the study, analyzed the data, wrote and critically revised the manuscript, ME revised literature, followed the patients, collected the data, performed the analysis and wrote the manuscript. All authors approved the final version of the manuscript

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None.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Approval of Research Ethical Committee of Faculty of Medicine, Ain Shams University, was obtained (Code number: FMASU MD 368/2018), and informed written consent was obtained from the patients.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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