The Association of Perioperative Glycemic control with Post-operative wound Infection after Coronary Artery Bypass Grafting in Veterans with Diabetes Mellitus

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Research Article

Keywords:

Posted Date: December 29th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-1190125/v1>

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Abstract

Introduction: After coronary artery bypass (CABG), diabetes mellitus is associated with increased risk of infection. We model the inter-relationship of pre- and post-operative glycemic control and their composite influence on post-operative wound infection.

Methods: 2,899 Veterans that underwent isolated CABG were stratified (Group I: < 8%, Group II: 8 - 10%, Group III: > 10%) according to preoperative HbA1c levels. We obtained the median blood sugar level (BSL) on post-operative days 0 - 4 (POD) and compared trends in BSL readings according to HbA1c groups. We fit a multi-variable random effects mixed model to understand the odds (OR) of developing postoperative mediastinitis. A two-stage joint model was fit to evaluate the adjusted hazard (HR) of pre-operative HbA1c, post-operative BSL and clinical factors on 90-day readmission for infection.

Results: In groups I, II, and III had 66%, 25% and 9% patients respectively. In 148,810 post-operative BSL readings, median BSL values peaked at POD 2 (145 mg/dl). In group III, 29% BSL reading was above the recommended limit (< 180 mg/dl). Group III (OR 3.5; $p < 0.01$) and COPD (OR 2.51; $p < 0.01$) were associated with higher rates of mediastinitis. Groups II (HR 1.4; $p = 0.01$) and III (HR 1.5; $p = 0.04$) were associated with increased risk for 90-day readmission for infection. Post-operative blood sugar levels ($p = 0.5$) were not associated with increased risk for wound infection at 90 days.

Conclusion: Among Veterans undergoing coronary artery bypass, a large proportion had HbA1c levels > 8%. In the post-operative period, 22% of the blood sugar readings are higher than 180 mg/dl. Preoperative HbA1c (rather than postoperative glycemic control) is associated with higher rates of deep sternal wound infection.

Introduction

Coronary artery bypass grafting (CABG), rather than percutaneous intervention, is the procedure of choice among diabetic patients with multi-vessel disease [1]. Mediastinitis and post-operative wound infection remains a concern among diabetes mellitus (DM) patients after cardiac surgery [2]. The Society of Thoracic Surgeons guidelines recommend that postoperative blood sugar should be maintained < 180 mg% for 72 hours [3].

In 2009, the Joint Commission introduced the Surgical Care Improvement Project to promote uniform evidence-based patient care. An important metric was to ensure a target blood sugar value < 200 mg% on the first postoperative day at 6 AM [4]. While many researchers have evaluated the independent association of either preoperative or postoperative glycemic control and wound infection, evidence investigating the composite association of pre-and postoperative glycemic control is limited. Thus, we analyzed the Veterans Affairs Database motivated by the following questions (1) What proportion of diabetic patients achieve the target of < 180 mg% after surgery? How does the preoperative glycated hemoglobin (HbA1C) levels, a marker of glycemic control over a period of 90 days, influence our ability to achieve optimal postoperative glycemic control (defined as average blood sugar < 180 mg/dl after

surgery)? (2) What is the composite impact of preoperative HbA1c and post-operative blood sugar control (defined as BSL < 180 mg/dl) on infection during the early post-operative period?

Methods

This is an observational cohort study based on the Veterans Affairs National database. The study was approved by the Institutional Review Board, North-East Ohio VA Medical Center, IRB # 16004-H03. The review committee waived the need for individual patient consent.

Data source

The Veteran Health Affairs Department is the largest integrated health care system in the United States, providing care at 170 hospitals and 1025 out-patient facilities [5]. The VA Informatics and Computing Infrastructure (VINCI) contains treatment information regarding Veterans receiving care at their centers [6].

Study cohort

From the VASQIP database, we initially identified Veterans who underwent isolated CABG at 41 different VA medical centers nationwide (January 2007 – December 2014). Included Veterans underwent CABG with or without cardiopulmonary bypass. We further limited our study to only include patients (1) with a diagnosis of diabetes mellitus at admission and (2) where data regarding perioperative glycemic control was documented. A flowchart of patient selection is provided in the supplement (S-Figure 1).

Categorization of CABG patients into groups stratified by preoperative HbA1C levels

HbA1C within 90 days prior to surgery was used as a measure of preoperative glycemic control. When multiple laboratory values were available, we selected the most recent value prior to surgical date. The American Diabetes Association recommends a more liberal HbA1c target < 8% among elderly or those with complex atherosclerotic disease [7]. Thus, study Veterans were categorized into three groups: group I - $\leq 8\%$, group II - $8 - 10\%$, and group III - $> 10\%$.

Postoperative protocol used for blood sugar control:

The VA Modified Portland Insulin Protocol was used for managing postoperative blood sugar level (BSL) after cardiac surgery (Supplement)[8]. Briefly, patients are initiated on intravenous insulin therapy when BSL values > 175 mg%. Initiation of intravenous Insulin can occur in the intraoperative period. In the intensive care unit, BSL measurements are done hourly while on intravenous infusion and intravenous Insulin dose is titrated to maintain BSL values $125 - 175$ mg%. After adequate oral intake is established, intermittent injectable Insulin is administered according to a sliding scale and BSL measurements are done before every meal and with the morning lab tests. We collected BSL measurements for 5 postoperative days for all patients (postoperative day 0 – day 4). To account for temporal fluctuation of

readings during a 24-hour period and variation in sample collection timing, we included the daily median BSL value for each patient in our statistical models.

Clinical data:

Demographic information (age, sex, race), clinical comorbidities (hypertension, dyslipidemia, CKD) and past medical history (prior myocardial infarction, prior percutaneous intervention, prior heart surgery) were obtained from VINCI. The International Classification of Diseases 9th or 10th version or the Common Procedures Terminology codes were used to define clinical conditions and procedures. Operative details like number of grafts performed and use of arterial conduit was also available. Left ventricular dysfunction was defined as a left ventricular systolic function < 40% on preoperative echocardiography. We calculated the estimated glomerular filtration rate (eGFR) and defined chronic kidney disease (CKD) as eGFR < 60. Patients with a body mass index > 30 kg/m² were defined as obese.

Definition of Endpoints

We evaluated patients for two end-points: (1) Mediastinitis / deep sternal wound infection in the post-operative period (2) Readmission within 90 days due to deep sternal wound infection, harvest site infection or sepsis. Patients that died within 90 days of the index procedure were excluded in the analysis of this end-point. Hence, we were certain that all included patients were at risk for occurrence of event.

Statistical Methods

Continuous data was reported as median (interquartile range) while categorical information was presented as counts (percentages). To compare categorical variables between groups I, II and III, the chi² test was used. Continuous data was compared using the Kruskal-Wallis test. We used the Nelson-Aalen estimator to obtain non-parametric 90-day estimates for readmission in groups I, II and III; these were compared with the log-rank test. We also estimated and compared 90-day readmission rates according to adequacy of postoperative glycemic control. We fit statistical models to present adjusted results for both our study aims (1) To evaluate the association of preoperative glycemic control on DSWI, we chose to fit a hierarchical generalized logistic model. As patients were operated at 41 different institutions, an anonymous center code was included as a random effect, while patient-level clinical covariates were fitted as fixed effects. (2) To understand the independent association of pre- and post-operative glycemic control with 90-day infection rates, we fit a two-stage joint model. The joint model framework consists of two components: a longitudinal component fitted with a linear mixed model and a time-to-event component which is fit using standard survival methods. Our linear mixed model allows us to report the association between pre-operative HbA1c values and postoperative glycemic control adjusted for demographic, clinical and operative covariates. The time-to-event component provides a measure of association between pre- and post-operative BSL values and probability of 90-day readmission. This time-to-event analysis was fit as a Cox proportional hazards model. Along with our primary co-variate (HbA1c group), the other variables included in our model were (1) Patient demographics: age, sex, obesity, insulin treated DM, COPD, PAD, prior myocardial infarction, prior percutaneous intervention, chronic kidney

disease and (2) Operative details: cardiopulmonary bypass time. Missing values were observed in the following variables: serum creatinine (2.7%) and cardiopulmonary bypass time (0.03%). All categorical variables included in the models were complete. Given the small proportion of missing data, missing fields were imputed with the variable mean prior to fitting models. Statistical analysis was performed in R 3.5.3 (The R Foundation for Statistical Computing, Austria). The supplement contains further details regarding the statistical methods used in the study.

Results

Cohort characteristics stratified by preoperative HbA1c levels (Table 1):

There were 1,915 (66%), 733 (25%) and 251 (9%) patients in groups I (HbA1c < 8%), II (HbA1c 8 – 10%) and III (HbA1c > 10%) respectively (Table 1). The median HbA1c values in groups I, II and III were 6.8 %, 8.7 % and 10.9 % respectively. Compared to group III, Veterans in group I were older (median age 65 vs 61 years). We observed a higher proportion of Blacks in Group III vs Group I (11.6% vs 8.9%; binomial test for proportions p-value = 0.04). In group III, a very high percentage of patients (78.5% vs 43.3% in Group I) were treated with Insulin prior to CABG. Group II patients had a higher rate of left ventricular systolic dysfunction (19% vs 13% in Group I) prior to surgery. Prior myocardial infarction rates were also higher in patients in Group III vs Group I (52% vs 41%). We did not observe any patient receiving bilateral internal thoracic artery grafts. The majority of patients underwent elective surgery.

	Group I HbA1c < 8 % (N = 1915)	Group II HbA1c 8 - 10% (N = 733)	Group III HbA1c > 10% (N = 215)	p-value
Age (years)*	65 [61, 71]	63 [59, 67]	61 [57.5, 65]	<0.001
Obesity	767 (40.1)	318 (43.4)	98 (39.0)	0.248
Race				0.545
• Black	171 (8.9)	76 (10.4)	29 (11.6)	
• Others	385 (20.1)	137 (18.7)	50 (19.9)	
• White	1359 (71.0)	520 (70.9)	172 (68.5)	
COPD	502 (26.2)	176 (24.0)	68 (27.1)	0.447
Insulin Treated Diabetes mellitus	830 (43.3)	511 (69.7)	197 (78.5)	<0.001
Dialysis dependence	77 (4)	34 (4.6)	9 (3.6)	0.597
Baseline Serum Creatinine*	1.1 [0.9, 1.4]	1.1 [0.9, 1.4]	1.1 [0.9, 1.5]	0.401
Prior heart surgery	25 (1.3)	10 (1.4)	3 (1.2)	0.979
Priority of surgery	1618 (84.5)	616 (84)	206 (82.1)	0.192
Significant weight-loss	44 (2.3)	18 (2.5)	6 (2.4)	0.966
Radial A used as conduit	35 (1.8)	10 (1.4)	9 (3.6)	0.079
Distal anastomoses performed				0.178
• 1	100 (5.2)	29 (4.0)	13 (5.2)	
• 2	445 (23.2)	191 (26.1)	48 (19.1)	
• 3	923 (48.2)	356 (48.6)	121 (48.2)	
• more than 3	447 (23.3)	157 (21.4)	69 (27.5)	
LV Systolic dysfunction	251 (13.1)	104 (14.2)	49 (19.5)	0.05
Prior stroke	31 (1.6)	15 (2.0)	9 (3.6)	0.094
Prior MI	908 (47.4)	392 (53.5)	132 (52.6)	0.012
Prior PCI	79 (4.1)	23 (3.1)	11 (4.4)	0.46
Baseline HbA1c value*	6.8 [6.3, 7.3]	8.7 [8.2, 9.1]	10.9 [10.4, 11.9]	<0.001

Table 1. This table outlines differences in demographics stratified by their preoperative HbA1c levels. Veterans in our study were divided into group I (HbA1c < 8%), group II (HbA1c 8 – 10%) and group III (HbA1c > 10%). Categorical variables and continuous variables between groups were compared with the chi square or Kruskal-Wallis test respectively.

Relationship between HbA1c groups and post-operative BSL (Figures 1 & 2):

We collected 148,810 BSL readings in the post-operative period (mean readings per patient = 51.3). In the whole group, we observed median BSL values of 137, 137, 145, 145 and 142 mg/dl in postoperative days 0 - 4 respectively. Thus, values appear to gradually increase till postoperative day 2 and then decline. For the whole cohort, 32,738/148,810 (22%) BSL readings were greater than 180 mg/dl. The proportion of BSL readings > 180 mg/dl incrementally increased in Groups I (19%), II (27%) and III (29%).

Factors associated with postoperative Mediastinitis (Table 2):

Post-operative mediastinitis was observed in 55/2,899 (1.8%) patients during the index postoperative period. In groups I, II and III, mediastinitis developed in 1.3%, 2.3% and 4.7% patients respectively. Preoperative HbA1c > 10% [OR 3.53(1.72 - 7.24); p < 0.01], COPD [OR 2.51(1.43 - 4.4); p < 0.01] and body mass index [OR 1.98(1.14 - 3.43) per unit increase; p = 0.01] were associated with higher odds of mediastinitis. Veteran age at surgery, re-do surgery and ITDM were other covariates considered and excluded from the final model.

Co-variate	OR	95% LCI	95% UCI	P-value
Pre-operative HbA1C Ref: Group I				
Group II	1.76	0.94	3.30	0.07
Group III	3.53	1.72	7.24	< 0.01
Body mass index (kg/m ²)	1.98	1.14	3.43	0.01
Current smoker	1.64	0.93	2.91	0.09
COPD	2.51	1.43	4.40	< 0.01

Table 2. We fit a generalized linear mixed model to evaluate the association of pre-operative clinical co-variates with post-operative mediastinitis observed in the same admission. Given

that patients were operated at 40 different Veteran Affairs medical centers, we included the hospital code as the level 1 random effect modifier, while clinical co-variables were fit as fixed effects. We observed that patients with preoperative HbA1c levels > 10% and those with COPD had higher odds of developing post-operative mediastinitis.

Abbreviations: OR – Odds ratio, LCI – lower confidence interval, UCI - upper confidence interval

Association of perioperative glycemic control with 90-day Readmission (Table 3):

The 90-day readmission rate was 8.7 (7.6 – 9.7) % in the whole group. Readmission rates increased as HbA1c levels increased. We observed readmission rates of 7.5%, 10.7% and 11.7% in Group I, II and III respectively (log-rank test p-value = 0.006) (Figure 3A). Readmission rates were comparable in patients with BSL values < 180 mg/dl and > 180 mg/dl (log rank test p-value = 0.38) (Figure 3B). Our joint model demonstrates that, compared to group I, groups II [HR 1.42(1.07 - 1.89); p = 0.01] and III [HR 1.54 (1.01 - 2.35); p = 0.04] were associated with increased risk of 90-day readmission. Post-operative BSL [HR 1(0.99 - 1.01); p = 0.5] did not influence readmission rates.

Co-variate	HR	95% LCI	95% UCI	P-value
Pre-operative HbA1C Ref: Group I (HbA1c < 8%)				
Group II (8 - 10%)	1.42	1.07	1.89	0.01
Group III (> 10 %)	1.54	1.01	2.35	0.04
Age at surgery (years)	1.00	0.98	1.01	0.64
Race (Index - Black)				
Others	1.11	0.68	1.81	0.67
White	0.92	0.59	1.41	0.68
Body Mass Index (kg/m ²)	1.32	1.02	1.71	0.03
Current smoker	1.16	0.87	1.55	0.31
Female	2.10	0.93	4.72	0.07
Post-operative BSL value (mg/dl)	1.00	0.99	1.01	0.50

Table 3. This table presents the results of the multi-variable joint model. The joint model developed was a two-stage model where (a) stage 1 - This is a linear mixed effects model to

evaluate the association of clinical co-variables with the median BSL obtained from each patients on postoperative days 0 - 4. (b) stage II - The results of the stage I model are included in a multi-variable Cox proportional hazards model fit to evaluate the association of clinical co-variables and measured post-operative BSL readings with 30-day readmission for infections after isolated coronary artery bypass grafting among Veterans.

Abbreviations: HR – Odds ratio, LCI – lower confidence interval, UCI - upper confidence interval

Discussion

Synopsis of results:

We performed an observational study to understand trends in post-operative blood sugar levels among Veterans with diabetes mellitus undergoing CABG. Using a joint modelling approach, we analyzed the adjusted effects of preoperative HbA1c levels and postoperative BSL readings on mediastinitis and early infection after CABG.

We observed that: (1) A substantial number of patients undergoing CABG at VA medical centers have elevated (8 - 10%) and uncontrolled (> 10 %) HbA1c prior to surgery. (2) Ideal blood sugar control (BSL < 180 mg/dl) is difficult among patients that have poor glycemic control prior to surgery (3) The risk of infection after surgery is increased in patients with elevated HbA1c values. However, adjusting for this fact, high postoperative BSL does not increase this risk. Our graphical abstract provides an overview of our study (Figure 4).

Our results in perspective of the current Guidelines:

Initial studies report higher risk of adverse events among patients with postoperative blood sugar > 200 mg/dl. Over time, research has demonstrated that 180 mg/dl may be the optimal BSL cut-off value after cardiac surgery. The recent NICE-SUGAR trial has outlined the detrimental effect of very restrictive BSL targets < 110 mg/dl in critically ill patients [9]. Consensus statements from the American Diabetes Association and American Academy of Clinical Endocrinologists both recommend a BSL target range of 140 - 180 mg/dl in critically ill patients [3]. The Society of Thoracic Surgeons also recommend target BSL < 180 mg/dl after cardiac surgery, with tighter control (< 150 mg/dl) in sicker patients [10]. However, we demonstrate that maintaining target BSL levels is very difficult in patients with uncontrolled HbA1c levels before surgery; 1/3rd of all readings in patients with HbA1c > 10% were above the ideal range. Subramaniam et al [11] report increased glucose level variability among patients with elevated HbA1c (> 6.5 %) in the 24-hour postoperative window. They report 10% readings of BSL > 200 mg/dl with HbA1c > 6.5 %. Lehwaldt et al [12] audited 150 patients with diabetes mellitus undergoing cardiac surgery in a single center in UK. They report that at least 32%, 24% and 34% readings were above 180 mg/dl (> 10 mmol/lit). Halkos et al [13] prospectively evaluated glycemic control (determined as time period when

BSL was below 180 mg/dl) in 337 patients after cardiac surgery. They report poor glycemic control in patients with high HbA1c levels; both factors were associated with increased wound infection. Our results support and expand on earlier evidence. We demonstrate that ideal glycemic control is very difficult to attain in patients with elevated HbA1c. As reported by Lehwaldt et al [12], BSL values appear to peak on the second postoperative day; however, we add to current literature by also demonstrating that the decline after the peak depends upon preoperative HbA1c. We have demonstrated that in patients with HbA1c > 10%, postoperative BSL levels actually peak on the 3rd postoperative day after which it declines. Ample literature already reports the strong association between preoperative HbA1c levels and adverse postoperative outcome. We focus our attention on infectious complications, and demonstrate that both mediastinitis and 90 readmission rates (for infections) are higher in diabetic patients with HbA1c > 8%.

Clinical Implications of our study

We believe that our study is among the few that attempt to evaluate the composite effect of both pre and postoperative control of diabetes mellitus on wound infection after CABG. Our main message in this analysis is to demonstrate the importance of preoperative rather than postoperative blood sugar control in patients with postoperative wound infection.

Strengths & Limitations:

We present specific strengths and limitations related to our study. We have performed a retrospective analysis; hence, any inferences are association rather than causation. We attempt to adjust for many clinical covariates that were available in our national database. However, our database does not contain information like details regarding inotropic use or duration of Insulin infusion therapy. These and other unmeasured factors do influence postoperative blood sugar levels. Patients in our study were operated over a 10-year period at 40 different VA Medical centers; hence, we agree that practice variation is an important factor. We hence adopted a mixed methods approach to obtain results averaged over institutions. We believe that our study is among the first (and possibly largest) that investigates the composite influence of pre and postoperative blood glucose control on infection after CABG.

Conclusion

Among Veterans undergoing coronary artery bypass, a large proportion had HbA1c levels > 8%.

In the postoperative period, 22% of the blood sugar readings are higher than 180 mg/dl.

Preoperative HbA1c (rather than postoperative glycemic control) is associated with higher rates of deep sternal wound infection.

Abbreviations

BSL - Blood sugar level

CABG - Coronary artery bypass grafting

DM - Diabetes mellitus

DSWI - Deep Sternal wound infection

HbA1c - Glycated Hemoglobin level

ITA - Internal thoracic artery

POD - Postoperative day

ITDM - Insulin treated diabetes mellitus

VINCI - VA Informatics and Computing Infrastructure

VASQIP - VA Surgical Quality Initiative Project

Declarations

Ethics approval and consent to participate: IRB approval date and #: Louis Stokes Cleveland VAMC approval date: 1/20/2016 IRB # 16004-H03. Individual patient consent waived.

Consent for publication: Not applicable

Availability of data and materials: Datasets generated and analyzed during the current study are not publicly available as they are the property of the US Veteran Health Administration. Scripts used for statistical analyses are available for download from the corresponding authors github repository – <https://github.com/svd09>

Competing interests: None

Funding: None

Author's contributions: SD – design, statistical analysis, data collection, writing manuscript

YE – concept and study design, critical review of manuscript

JR – critical review of manuscript

BC – critical review of manuscript, study design

Acknowledgements: We appreciate the help of Brigid Wilson PhD, Research Services, Louis Stokes Cleveland VA Medical Center, who provided programming help and support navigating the VINCI environment during data collection. This material is the result of work supported with services and facilities made available at the Louis Stokes Cleveland VA Medical Center. The views expressed in this

article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

Authors's information: Not applicable

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Figures

Figure 1

We recorded 148,810 BSL readings from 2899 Veterans with diabetes mellitus that underwent coronary artery bypass grafting between 2007 – 2014. We observed that the median value for BSL gradually increased to peak at post-operative day 2 and then declined. However, 22% readings were above the acceptable limit of 180 mg/dl. The dotted line corresponds to 180 mg/dl.

Abbreviations: BSL – blood sugar level

Figure 2

We recorded 148,810 BSL readings from 2899 Veterans with diabetes mellitus that underwent coronary artery bypass grafting between 2007 – 2014. We divided these patients according to their pre-operative HbA1c into Group I (HbA1c < 8%), Group II (HbA1c 8 – 10 %) and Group III (HbA1c > 10%). We observed that the median BSL readings gradually increased to peak at post-operative day 2 and then declined. However, while 19% in group I had readings above the acceptable limit (180 mg/dl), this rate was much higher in groups II (27%) and III (29%).

Abbreviations: BSL – blood sugar level, HbA1C - glycated Hemoglobin level,

Figure 3

We calculated the cumulative hazard for 90-day readmission with the primary diagnosis of mediastinitis/wound infection or sepsis. We observed that 8.7 % patients were readmitted for infection within the study period. (A) Cumulative readmission rates were 7.5 %, 10.7 %, and 11.7 % in patients with baseline HbA1c values > 10% (Group III), 8 – 10% (Group II) and < 8% (Group I) respectively. On adjusted analysis, compared to Group I, patients in Group II (HR) and Group III (HR) were more likely to be readmitted. (B) We also identified those patients that reported at least one reading of post-operative BSL > 180 mg/dl during the postoperative period. We observed that the cumulative readmission rate was similar between patients that did (BSL < 180 mg/dl) and did not (BSL > 180 mg/dl) have acceptable blood sugar control in the postoperative period.

Supplementary Files

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- [supplement.docx](#)