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Use of a Glucose Management Service Improves Glycemic Control Following Vascular Surgery: An Interrupted Time-Series Study

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Article-at-a-Glance

Background—The optimal method for obtaining good blood glucose control in noncritically ill patients undergoing peripheral vascular surgery remains a topic of debate for surgeons, endocrinologists, and others involved in the care of patients with peripheral arterial disease and diabetes. A prospective trial was performed to evaluate the impact of routine use of a glucose

management service (GMS) on glycemic control within 24 hours of lower-extremity revascularization (LER).

Methods—In an interrupted time-series design (May 1, 2011–April 30, 2012), surgeon-directed diabetic care (Baseline phase) to routine GMS involvement (Intervention phase) was compared following LER. GMS assumed responsibility for glucose management through discharge. The main outcome measure was glycemic control, assessed by (1) mean hospitalization glucose and (2) the percentage of recorded glucose values within target range. Statistical process control charts were used to assess the impact of the intervention.

Results—Clinically important differences in patient demographics were noted between groups; the 19 patients in the Intervention arm had worse peripheral vascular disease than the 19 patients in the Baseline arm (74% critical limb ischemia versus 58%; $p = .63$). Routine use of GMS significantly reduced mean hospitalization glucose (191 mg/dL Baseline versus 150 mg/dL Intervention, $p < .001$). Further, the proportion of glucose values in target range increased (48% Baseline versus 78% Intervention, $p = .05$). Following removal of GMS involvement, measures of glycemic control did not significantly decrease for the 19 postintervention patients.

Conclusions—Routine involvement of GMS improved glycemic control in patients undergoing LER. Future work is needed to examine the impact of improved glycemic control on clinical outcomes following LER.

Peripheral arterial disease (PAD) affects more than 20% of the elderly population in the United States.¹ This condition alters patients' ability to ambulate and heal wounds, often resulting in amputation and compromised quality of life. Several risk factors for the development of PAD have been established, including diabetes mellitus, a disease associated with accelerated atherogenesis.² In fact, nearly half of patients undergoing procedural interventions for the treatment of PAD, such as percutaneous revascularization or bypass surgery, are diabetic. Unfortunately for these patients, their diabetes not only predisposes them to PAD but also places them at increased risk of postoperative complications such as myocardial infarction (MI), renal insufficiency, and amputation following intervention for PAD.³

Despite this knowledge, the optimal method for obtaining good blood glucose control in noncritically ill patients undergoing vascular surgery remains a topic of debate for surgeons, endocrinologists, and others involved in the care of patients with PAD and diabetes. Although some investigators offer data to support close glucose control via the use of insulin infusion in vascular surgery patients,^{4,5} other investigators suggest that overly aggressive control may be harmful,⁶ leading to higher rates of hypoglycemia and postoperative complications. This controversy has resulted in significant variation in strategies for managing perioperative glucose among diabetic patients undergoing vascular surgery.

We hypothesized that a uniform, standardized approach to managing all diabetic patients undergoing lower-extremity revascularization (LER) could result in improved glycemic control. Therefore, we conducted a study to test the impact of routine involvement of a glucose management service (GMS)—a dedicated team of specialists trained in managing diabetes—on glycemic control among diabetic patients undergoing LER.

Methods

This study was approved by The Dartmouth College Committee for the Protection of Human Subjects. Because the study was designed as a quality improvement initiative, individual patient consent was waived.

Establishing the Baseline, Intervention, and Postintervention Cohorts

All diabetic patients undergoing LER procedures at a single academic institution from May 1, 2011, through April 30, 2012, were considered for inclusion in this study. LER procedures were defined as any lower-extremity peripheral vascular intervention (PVI), infrainguinal bypass, femoral-femoral artery bypass, or combined procedure requiring at least 24 hours of postintervention admission to the hospital. Any patient admitted for > 24 hours before surgery was excluded from the study for two reasons—such patients (1) may have received aggressive treatments for hyperglycemia during this preoperative admission period that could have affected the results, and (2) were often admitted to nonsurgical providers, and the specific purpose of the study was to compare glycemic control among those cared for by vascular surgeons to that of those cared for by the GMS. For subjects staying longer than 10 days following their procedure, only the first 10 days of data were included in the analysis.

The study enrolled all eligible patients consecutively throughout the study period without a gap between study phases. Nineteen patients undergoing procedures between May 1, 2011, and September 30, 2011, were considered the Baseline Cohort and served as the study control group. These subjects were managed with “standard care” for their diabetes, which included combinations of the following: sliding scale, basal-bolus, or continuous drip insulin managed by the vascular surgery service; oral medications managed by the vascular surgery service; or in some instances, GMS consults.

The next 19 consecutive patients enrolled between October 1, 2011, and January 19, 2012, were considered the Intervention Cohort. These patients each received the intervention of involvement of a GMS (as described below). Finally, 16 patients enrolled between January 20, 2012 and April 30, 2012, were considered the Postintervention Cohort. These patients did not receive mandated GMS consults but were managed by whatever means felt most appropriate by the surgical service.

Study Intervention

The study intervention was routine involvement of a GMS within 24 hours following surgery. The GMS consisted of two physicians, board-certified and fellowship-trained in diabetes [S.S.C., R.C.], two dedicated advanced practice nurses [D.B., K.K.], and two research-study physicians [J.B.W., P.P.G.].

After a request was placed for consultation and assistance in glucose management, the GMS team assumed responsibility for the patient’s diabetic care while he or she was in the hospital following LER. The team’s specific responsibilities were as follows:

1. Evaluate diabetic patients undergoing LER in the immediate postoperative period, and daily thereafter until discharge.

2. Assume responsibility for managing all medications pertaining to glucose control.
3. Communicate with community providers on discharge to ensure a seamless transition of care to the outpatient setting.

Outcome Measures

Our main outcome measure was glycemic control. Because there is uncertainty regarding the optimal strategy for assessing glycemic control,^{7–11} we examined this outcome in two specific ways. First, for mean hospitalization glucose, a single value was calculated using four standardized daily glucose measurements from each day of admission. Our second measure of glycemic control was the percentage of recorded glucose values within the hospital's target range of 70–180 mg/dL. This range was chosen because, at our institution, we aim for glucose range 110–180 mg/dL for ICU patients and 100–140 mg/dL for non-ICU per American Diabetes Association and European Association for the Study of Diabetes guidelines. For the purposes of this study, we did not differentiate between ICU/floor patients and thus, to be all inclusive, chose the higher value (180mg/dL) for the maximum. Also per institutional guidelines, a patient is treated for hypoglycemia if he or she has a glucose of < 70 mg/dL (or < 100 mg/dL with symptoms of hypoglycemia). Therefore, for our analysis the acceptable range for blood glucose control without hypoglycemia or significant hyperglycemia was defined as 70–180 mg/dL range. Standardized glucose measurements were based on time of day. For those patients with more than four daily glucose values recorded in the medical record, only the four values corresponding to the predetermined measurement times (before morning, noon, and evening meals, and before bed) were used in the calculations.

In terms of secondary outcome measures, we also measured the incidence of death; hypoglycemia; and a composite clinical outcome consisting of wound infection (defined as any wound requiring antibiotics or debridement), MI (defined as elevated troponins with or without EKG changes), graft failure, major amputation, and acute renal failure within 30 days of surgery. Hypoglycemia was defined as blood glucose < 70 mg/dL or < 100 mg/dL with symptoms such as confusion, diaphoresis, and shakiness. All data were collected in a prospective fashion by blinded research personnel using electronic chart review.

Statistical Analysis

Our two main outcome measures—mean hospitalization glucose and percentage of glucose values within target range—were each examined in two ways. First, statistical process control (SPC) charts—individuals (i) and proportions (p) charts—were used. SPC charts enable one to test the statistical stability of a process over time (and thus predict future results) and to visualize the data in real time—and typically require a smaller sample size to detect significant change.¹² We assessed mean hospitalization glucose, a continuous variable, using SPC i-charts. Each patient's mean hospitalization glucose was plotted in sequential order throughout the study period. Control limits were fixed for each study period to accurately compare changes in time between the baseline versus intervention versus postintervention periods. The chart was then evaluated for previously defined special-cause signals to identify statistically significant variations in the data.¹² Second, we averaged

individual mean hospitalization glucose values for each study period (baseline, intervention, and postintervention) and compared them by using Student's *t*-test (for comparisons of 2 means) or analysis of Variance (for comparisons of > 2 means). Similarly, we calculated percentage of glucose values within target range for each enrolled individual and plotted on SPC p-charts in sequential order to assess for special-cause signals. Then, for each study period, we compared the total proportion of glucose values in range using the chi-square test. Comparisons with *p* value of .05 or less were considered significant. We assessed the clinical outcomes by using the chi-square test with Fisher's exact correction to compare the incidence of each outcome across the three study periods.

Results

Patient Characteristics

A total of 54 patients were enrolled in the study—19 in the Baseline arm, 19 in the Intervention arm, and 16 in the Postintervention arm. The mean age was similar between groups (66 years versus 70 versus 65, not significant). Home diabetes management regimen (47% insulin-requiring versus 53% versus 50%, not significant) and the incidence of comorbidities varied little, as well (Table 1, page 224). However, there were significantly more woman in the Intervention phase of the study (58% versus 21% in the Baseline period and 25% in the Postintervention period, *p* = .035). Further, 74% of patients in the Intervention arm of the study underwent intervention because of critical limb ischemia (compared to 58% and 50% of patients in the Baseline and Postintervention groups, respectively), although these differences were not statistically significant.

Mean Hospitalization Glucose

During the course of the study, individuals' mean hospitalization glucose ranged between 105mg/dL and 277mg/dL (127–277mg/dL in the baseline cohort, 106–191mg/dL among intervention cohort, and 118–215mg/dL in the postintervention cohort). SPC i-charts demonstrate a special-cause signal beginning with the 20th patient enrolled in the study where there is a shift in the data, defined by > 8 consecutive measurements below the median measurement (Figure 1, page 225). This indicates a significant improvement in mean hospitalization glucose following the intervention. Overall, patients enrolled in the Baseline arm had an average hospitalization glucose of 191 mg/dL, and those enrolled during the Intervention phase had an average hospitalization glucose of 150 mg/dL. In addition to the special-cause signal noted using our SPC i-charts, this decrease is also statistically significant on the basis of traditional Student's *t*-test statistics (*p* < .001).

In the Postintervention phase, SPC charts demonstrated that several patients had an increase in mean hospitalization glucose levels compared to patients in the Intervention phase of this study. However, this increase did not become statistically significant immediately. The overall change in mean hospitalization glucose following removal of mandated GMS consults was an increase from 150 mg/dL to 162 mg/dL (*p* > .2).

Percentage of Glucose Values in Target Range

SPC p-charts demonstrate a significant improvement in the proportion of glucose values within target range among individuals following in the intervention (Figure 2, page 226). On average, the proportion of glucose values in target range during the Baseline period of the study was only 48%—which increased to an average of 78% during the Intervention phase, with many individuals achieving 100% of their values within the target range. This increase is significant ($p = .05$) on the basis of both SPC methods and using a traditional chi-square test.

The proportion of measured glucose values measured at 70–180 mg/dL did not change significantly for most individuals enrolled in the Postintervention phase of the study, with an average of 74% of these individuals' readings landing in this range (Figure 2). However, three individuals in this phase did fall below the lower control limit, with proportion of target readings among these individuals ranging from 11% to 42%.

Differences Between Usual Care and Glucose Management Service Care

Overall, significantly more patients enrolled in the Intervention arm received GMS consult than those enrolled in either the Baseline or Postintervention phase of the study (11% Baseline versus 95% Intervention versus 30% Postintervention, $p < .001$). Further, the glucose management strategies received by these patients differed from the “usual care” received by patients in the Baseline arm who were not treated by the GMS. Specifically, more patients in the Intervention phase of the study received physiologic insulin therapy (long-acting and/or meal-associated insulin) compared to those enrolled in the Baseline phase of the study, who were more likely to be managed with sliding scale insulin alone or no insulin therapy (42% of Baseline patients received long-acting or meal-associated insulin versus 63% of Intervention patients, nonsignificant [Appendix 1, available in online article]). However, this difference was not statistically significant using traditional chi-square tests.

Impact of Improved Glucose Control on Secondary Outcomes

Overall, 17 (31%) of patients experienced at least one of the following postoperative complications: MI, wound infection, major amputation, graft occlusion, acute renal failure. Complications were evenly distributed across Baseline, Intervention, and Postintervention phases of the study. However, there was a trend toward increased complication rates in the Intervention arm (16% versus 47% versus 31%, nonsignificant). There were two deaths during the study (mortality, 4%)—one in the Baseline phase and the other in the Intervention phase. One patient in the Baseline phase of the study and four each in the Intervention and Postintervention phases experienced hypoglycemia (5% versus 21% versus 21%, nonsignificant).

Discussion

The current study demonstrates that in our academic medical center, routine involvement of a GMS among consecutively enrolled diabetic patients undergoing LER procedures significantly improved glycemic control. However, because of the small sample size, the

impact of this intervention on clinical outcomes such as wound infection rates and MI remains unknown.

Impact of Glucose Management Service on Glycemic Control

A few studies^{13,14} have examined the impact of GMSs in the care of diabetic patients. Comi et al. reported standard deviations (SDs) in glucose readings—a measure of variability or glycemic excursions—among medical patients managed by a GMS compared to those receiving standard in-hospital care delivered by hospitalists. This study found, as did ours, that patients managed by a GMS had improved glycemic control (SD among GMS patients 60.0 versus SD among those receiving standard care 70.4).¹⁴ While the study by Comi et al. was performed in medical patients, DeSantis et al. studied the impact of a GMS on surgical patients and also demonstrated that the use of a GMS resulted in substantial improvements in glycemic control, with reduced frequency of hypoglycemia, in patients undergoing a wide variety of surgical procedures.¹³ Our study had similar findings, with a significant reduction in mean hospitalization glucose and a significant increase in the percentage of glucose values within target range for patients whose diabetes was managed by the GMS postoperatively. However, unlike DeSantis et al., we did see a trend toward more episodes of hypoglycemia among patients managed by the GMS. Newton and Young have demonstrated a considerable cost savings from the use of an inpatient diabetes management team.¹⁵ Although the current study does not address the potential cost savings in using a GMS, we intend to do this in the future.

The current study was designed to test the impact of an intervention and then to examine for trends back toward baseline following removal of the intervention. However, when we removed mandated GMS consult, we did not see a dramatic increase in mean hospitalization glucose, nor did the percentage of glucose values within target range decrease significantly. Several potential explanations for the lack of a return to “baseline” exist. First, and perhaps most importantly, we did not allow for a “washout period.” As stated, the study enrolled all eligible patients consecutively throughout the study period without a gap between study phases. Therefore, even though GMS consult was no longer mandated, many of the surgical staff simply continued to request GMS consultation. In fact, at Baseline, only 11% of patients had a GMS consult, while in the Postintervention arm, 30% received GMS assistance. This is a well-described phenomenon in time-series designed studies, in which the effects of the intervention itself persist into the Postintervention phase of the study,¹² and this appears to be reflected in the trends shown in Figure 2. The second reason we suspect that glycemic control remained improved during the Postintervention phase of the study is that the surgical team was more likely to prescribe physiologic insulin (meal-associated and/or long-acting insulin) following the intervention than they were during the Baseline phase of the study (50% versus 42%).

Impact of Improved Glycemic Control on Postoperative Complications

Many studies have demonstrated increased rates of postoperative complications, such as mortality and surgical site infection, in diabetic patients undergoing a wide range of surgical interventions.^{16–18} However, although data surrounding the issues of glucose regulation in diabetic patients are robust among certain populations, they are relatively sparse among

vascular patients. We recently found that insulin-requiring patients with diabetes undergoing lower-extremity bypass surgery were 1.6 times more likely to experience major adverse events following surgery than their non-diabetic counterparts.³ Several other studies have also shown associations between poor glucose control and increased complications, such as cardiovascular events,^{19,20} surgical site infection,^{21–23} graft failure,²¹ and mortality^{20,21} following vascular surgery. For example, in one study, Malmstedt et al. examined the relationship between hyperglycemia (defined as glucose ≥ 110 mg/dL) in the first two days following LER and outcomes among diabetics. This study demonstrated that, in multivariable analyses, higher postoperative blood glucose was associated with a significantly higher risk of wound complications (odds ratio for 4th versus 1st quartile of glucose measure, 14.5, $p = .001$).²¹

Our study did not reveal a clear association between improved glycemic control and better clinical outcomes. Given the pilot nature of our intervention, the individual event rates were low and the study was not powered to detect a difference in our secondary outcomes. However, in view of our success in demonstrating an effect on our primary outcome (glycemic control), future efforts will be powered to study associations between glycemic control and outcomes.

Study Limitations

The current study has several limitations. First, because the study was designed to examine longitudinal changes in glycemic control across consecutive patients, the patients enrolled were not randomized to receive the intervention, and therefore differences in baseline demographics may exist. However, this study design was most practical, given the pilot nature of our intervention and allowed us to examine the impact of our quality improvement intervention in real-world clinical practice. A second limitation pertains to methods for measuring glucose values. Ideally, measurement of glucose values would be continuous or on a very frequent basis (for example, hourly), but cost limitations precluded this type of measurement. However, we did ensure that all glucose values used for purposes of calculating glycemic control outcomes were taken in a standardized fashion at predetermined times of day and extracted from the electronic medical record in a blinded fashion. We recognize one weakness to this approach is that all non-standardized measures taken are excluded (for example, if patients had more than four daily measurements recorded) and thus there is potential to miss an important measure of hyper or hypoglycemia. Future efforts will employ continuous glucose monitoring devices for extremely accurate measures. Third, the mean hospitalization glucose results are not corrected for patient length of stay (LOS). However, there was no significant difference in hospital LOS, as shown in Table 1. Further, while we are unable to graphically incorporate, or control for LOS, when reporting the mean hospitalization glucose, the SPC p- charts (demonstrating the proportions of values within target range) give an excellent representation of the number of values that contributed to the calculations reported. The control limits on the SPC p-charts are affected by the number of values contributing to each point on the chart (that is, the denominator). Those patients with more glucose values (higher denominators) have narrower control limits, and those with fewer contributing values have wider control limits. For those wishing to visually appreciate the number of values that

went into each calculation (determined by LOS) a side-by-side comparison of the SPC i-and p-charts is useful. Fourth, the number of enrollees for each study before initiation of the study and defined study phases were based on time (that is, allocated a number of months to each study phase) rather than numbers of subjects enrolled. Finally, specific data pertaining to the severity of secondary complications, such as hypoglycemia, were not formally collected as part of this study, and therefore we cannot comment on the severity of these events.

Summary

This study demonstrates that routine use of a GMS significantly improves postoperative glycemic control among diabetic patients undergoing LER. This effect was associated with processes of care implemented by our GMS team, such as the use of physiologic insulin (long-acting and meal-associated), rather than simple sliding scale coverage. Our future studies will be powered to assess the impact of improved glycemic control on postoperative outcomes in vascular surgery patients.

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Appendix 1. Percentage of Patients Managed with Sliding Scale vs. Long-Acting and/or Meal-Associated Insulin for the Baseline, Intervention, and Postintervention Phases of the Study

Mean Hospitalization Glucose (mg/dL) for Consecutive Individuals Following Lower-Extremity Revascularization

Figure 1.

Statistical process control i-charts demonstrate a special-cause signal beginning with the 20th patient enrolled in the study, where there is a shift in the data, defined by > 8 consecutive measurements below the median measurement. This indicates a significant improvement in mean hospitalization glucose following the intervention. UCL, upper control limit; CEN, center (mean); LCL, lower control limit.

Percentage of Glucose Readings Within Hospital Target Range (70–180 mg/dL) Before, During, and After the Study Intervention

Figure 2.

Statistical process control p-charts demonstrate a significant improvement in the proportion of glucose values within target range among individuals following in the intervention period. On average, the proportion of glucose values in target range during the Baseline period of the study was only 48%—which increased to an average of 78% during the Intervention phase, with many individuals achieving 100% of their values within the target range. UCL, upper control limit; CEN, center (mean); UCL, lower control limit.

Table 1

Patient and Operative Characteristics for Diabetic Patients Undergoing Lower-Extremity Revascularization Procedures Before Implementation of Mandated Use of a Glucose Management Service (Baseline), During the Intervention Phase (Intervention), and Following Removal of Mandated Use of Glucose Management Service (Postintervention)

	Baseline (N = 19)	Intervention (N = 19)	Postintervention (N = 16)	P Value (vs. Intervention)
Age mean (SD)	66 (9)	70 (8)	65 (12)	.93
Male (%)	79	42	75	.02
Diabetes control (%)				
Diet only	5	5	6	.95
Oral medications	48	42	44	—
Insulin +/- oral medications	47	53	50	—
Preoperative hemoglobin A1C mean (SD)	8.1 (1.8)	7.3 (1.5)	7.3 (0.8)	.07
Renal insufficiency (%)	26	11	6	.41 *
Congestive heart failure (%)	21	32	0	.71 *
Coronary artery disease (%)	53	58	56	.74
Hypertension (%)	84	95	88	.60 *
Past or current smoker (%)	100	94	93	.34
Type of surgery (%)				
Bypass	47	58	81	.90 *
PVI	5	0	6	—
Endarterectomy	16	10	0	—
Endarterectomy + stent	32	32	13	—
Indication for surgery (%)				
Claudication	32	16	44	.63 *
Critical limb ischemia	58	74	50	—
Other	10	10	6	—
Length of stay mean, in hours (SD)	44 (26)	198 (382)	134 (166)	.09

SD, standard deviation; PVI, peripheral vascular insufficiency.

* Fisher's exact test result.