Effects of Computerized Decision Support Systems on Blood Glucose Regulation in Critically Ill Surgical Patients

Sandy L Fogel, MD, FACS, Christopher C Baker, MD, FACS

BACKGROUND: The use of computerized decision support systems (CDSS) in glucose control for critically ill surgical patients has been reported in both diabetic and nondiabetic patients. Prospective studies evaluating its effect on glucose control are, however, lacking. The objective of this study was to evaluate patient-specific computerized IV insulin dosing on blood glucose levels (BGLs) by comparing patients treated pre-CDSS with those treated post-CDSS.

STUDY DESIGN: A prospective study was performed in 4 surgical ICUs and 1 progressive care unit comparing patient data pre- and post-implementation of CDSS. The primary outcomes measures were the impact of the CDSS on glycemic control in this population and on reducing the incidence of severe hypoglycemia.

RESULTS: Data on 1,682 patient admissions were evaluated, which corresponded to 73,290 BGLs post-CDSS compared with 44,972 BGLs pre-CDSS. The percentage of hyperglycemic events improved, with BGLs of >150 mg/dL decreasing by 50% compared with 6-month historical controls during the 18-month study period from July 2010 through December 2011. This was true for all 5 units individually ($p < 0.0001$, by one sample sign test). In addition, severe hypoglycemia (defined as BGL <40 mg/dL) decreased from 1% to 0.05% after implementing CDSS ($p < 0.0001$ by 2-sided binomial test).

CONCLUSIONS: Patients whose BGLs were managed using CDSS were statistically significantly more likely to have a glucose reading under control (<150 mg/dL) than in the 6-month historical controls and to avoid serious hypoglycemia ($p < 0.0001$). (J Am Coll Surg 2013;216:828–835. © 2013 by the American College of Surgeons)

Hyperglycemia on admission or at any time during a patient hospital stay is common and is associated with poor clinical outcomes and mortality in patients with and without a history of diabetes.[1] Research has demonstrated that inpatients with newly diagnosed hyperglycemia have a significantly higher mortality rate and lower functional outcomes than patients with a known history of diabetes or normoglycemia.[1] Patients with medium, high, worsening, and highly variable hyperglycemia have significantly increased ICU length of stay, hospital length of stay, ventilator days, infection rate, and mortality compared with patients with controlled glucose levels ($p < 0.01$).[2]

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From the Department of Surgery, Virginia Tech Carilion School of Medicine, Roanoke, VA.

Correspondence address: Sandy L Fogel, MD, FACS, Department of Surgery, Virginia Tech Carilion School of Medicine, Roanoke, VA 24033. email: slfogel@carilionclinic.org

Narrowing the range of target blood glucose levels (BGLs) has been shown to decrease morbidity and mortality in the critically ill[3] and is now recommended by numerous organizations, including the American Diabetes Association[4] and the Institute for Healthcare Improvement.[5] These studies have used protocols requiring intensive monitoring of glucose levels (ie, initially every 30 to 60 minutes until BGL stabilizes and then every 4 hours) and numerous IV insulin infusion dose calculations and adjustments.[5] Although tighter glycemic control is becoming the standard of care, it might be associated with hypoglycemia and increased workloads for those managing the blood glucose.[6,7]

In 2011, the American College of Physicians released practice guidelines that stated that the use of intensive insulin therapy (IIT) was associated with excess risk for hypoglycemia in almost all clinical trials; critically ill patients receiving IIT aimed at achieving normoglycemia had the highest occurrence of hypoglycemia (relative rate = 5.32; 95% CI, 4.21–6.73).[8] Although the consequences of hypoglycemia in hospitalized patients are

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Abbreviations and Acronyms
BGL = blood glucose level
CDSS = computerized decision support systems
CMS = Centers for Medicare and Medicaid Services
HAI = health care–associated infection
IIT = intensive insulin therapy
VAP = ventilator-associated pneumonia

unclear, there is some evidence for excess mortality or extended length of stay among patients in the medical ICU experiencing one or more episodes of severe hypoglycemia (BGL <40 mg/dL) related to IIT.[8] Additional studies have suggested that hypoglycemia is associated with an increased risk for dementia in patients with type 2 diabetes and a 2-fold increase in risk for mortality, and that it can induce transient ischemia and catecholamine surges.[8]

In addition to the importance of controlling hyperglycemia on quality of patient care and outcomes, financial considerations are catapulting the control of blood sugars to the forefront in clinical care. According to the Centers for Medicare and Medicaid Services (CMS), poor control of blood sugar for patients with diabetes is considered a potentially preventable complication of care and has been named a targeted measure. In addition, CMS has stressed that poor control of blood sugar could reasonably be prevented through the use of evidence-based guidelines for appropriate hospital inpatient care.[9] Therefore, it seems likely that, in the future, CMS might not provide reimbursement for management of uncontrolled blood sugars, forcing health systems to shoulder the financial burden of extended lengths of stay, infections, etc. Standardized protocols for controlling hyperglycemia are recommended by CMS because they have been found to reduce variation, to increase adherence to evidence-based practices, and to improve clinical outcomes.[10-12] Unfortunately, IV insulin protocols for glycemic control are often complicated, requiring frequent bedside glucose monitoring and repeated complex calculations to titrate insulin doses.[10,13-15] Standardized, nurse-managed paper-based IV insulin protocols are not always associated with optimal results.[10,16] Several studies have reported the successful implementation of clinical computerized decision support systems (CDSS), computer programs that are intended to help health care workers in making decisions.[12,17,18]

In this prospective study, we sought to evaluate the impact of implementing a CDSS on the management of blood glucose in our critically ill surgical patients. The end points of this study of glycemic control before and after implementation of a CDSS were 3-fold. First, we analyzed the effect of the CDSS on glycemic control in this population as a whole and, secondly, the incidence of severe hypoglycemia before and after CDSS. Finally, we evaluated measures of health care–associated infection (HAI) during the study period.

METHODS

Study location and patient population

Carilion Clinic is a not-for-profit health care organization serving nearly 1 million people in southwest Virginia through 7 hospitals, as well as multiple outpatient specialty centers and advanced primary care and specialty practices. The study site is Carilion Roanoke Memorial Hospital, a 763-bed hospital affiliated with Virginia Tech Carilion School of Medicine and Research Institute in Roanoke, VA. Collection of data was prospectively performed in 5 units at Carilion Roanoke Memorial Hospital, including the surgical ICU, the neurotrauma ICU, the thoracic ICU, the cardiac surgical ICU, and the cardiac surgical progressive care unit.

Pre–computerized decision support systems glucose control protocols

On starting the glucose control project, 7 different protocols were identified that could be used in these units. The cardiac surgical ICU routinely used the Portland protocol, a well-accepted and common protocol in use in many cardiac surgical units around the country.[18] Another available method was the standard basal/bolus method of glucose control using a combination of short- and long-acting insulins. The other 5 paper protocols used IV insulin and were managed by the nursing staff. The choice of protocol was at the discretion of the admitting physician. On starting the CDSS, the medical directors of each of the units designated CDSS the standard of practice for any patient needing IV insulin in their unit.

Post–computerized decision support systems

The CDSS (EndoTool; Hospira) that was implemented is a software system designed specifically to customize the insulin dosing to the individual patient, including those with frequently changing requirements. Using mathematical modeling, trends of glucose readings are analyzed to formulate a patient-specific physiologic insulin-dosing curve. Adjustments are automatically made in the dosing curve to minimize episodes of hypoglycemia and to control hyperglycemia. It required a dedicated Citrix server in each unit with an interface with the electronic medical record. On receiving an order for the CDSS, the patient's name and medical record number, along with the patient's weight, creatinine, and initial glucose are entered. It then generates a bolus dose, an infusion rate, and a time to the next blood glucose measurement. There is a built-in

alarm as a reminder of this time. The initial time intervals might be very short, but once the glucose was within range they spread out significantly. Once within range, the glucose seldom left. The information was automatically shared with the electronic medical record.

Data

Blood glucose levels for all patients on IV insulin using the CDSS in the 5 surgical units (ie, surgical ICU, neurotrauma ICU, thoracic ICU, cardiac surgical progressive care unit, and cardiac surgical ICU) for an 18-month period between July 2010 and December 2011 were captured. Specific data variables included hospital unit, initial BGL, time to goal, number of in-range BGLs, total number of BGLs, and time (month, year). Data for the 6-month historical control period were collected from the same units from July 2009 through December 2009, before any of the units in our institution implemented the CDSS.

Statistical analysis

The biostatistician was provided with the summary 6-month control data for each unit, as well as the summary blood glucose levels for each patient during the 18-month post-CDSS period. Each patient had multiple BGLs. Initially, for each unit, logistic regression was used to calculate the predicted proportion of adequately controlled BGLs (70–150 mg/dL) for each patient, adjusted for initial BGL reading and time of measurement. Using the derived predicted data, separate analyses were performed for each unit. The 6-month control values for the corresponding units were subtracted from the logistic regression data and the differences were analyzed using a one sample sign test. The null hypothesis was that the median of the 18-month predicted data minus the 6-month control value was equal to zero. The alternative hypothesis was that the difference between the CDSS and the control values was significant.

As a sensitivity analysis, a second analysis was performed. Although this analysis used the same methodology as the primary analysis (one sample sign test), the sensitivity analysis was based on the summary data for each unit and excluded the 2 covariates of initial BGL and time. The results of these analyses were identical to the first analysis. A 2-sided binomial test was used to compare the 18-month study period to the 6-month historical control period with respect to the frequency of serious hypoglycemia (BGL <40 mg/dL).

RESULTS

There were a total of 1,682 patient admissions during the 18-month study period requiring IV insulin for which the CDSS was used. The number of patients in each unit varied from a high of 887 in the cardiac surgical ICU to a low of 67 in the thoracic ICU. There were a total of 449 patient admissions in which the patients were on IV insulin during the 6-month historical control period. Table 1 represents a breakdown of the number of glucose measurements in those patients for the 18-month study period compared with the number of BGL measurements in the 6-month historical control period. It also shows the number of BGL measurements per month in each unit. As can be seen by comparing the 18-month study period with 6-month historical controls, the frequency of BGL measurements by month went down substantially when using the CDSS. There were 7,495 total BGL measurements per month in the aggregate before implementation of the CDSS, compared with 4,072 per month after implementation of CDSS. Each unit was considered separately in the statistical analysis because of the variability in frequency of use of the CDSS.

Table 1. Total and per Month Blood Glucose Levels Measurements in Control vs Computerized Decision Support Systems

	BGL: historical control		BGL: CDSS	
Unit	6 mo, n	Per mo, n	18 mo, n	Per mo, n
SICU	9,196	1,533	14,413	801
NTICU	11,113	1,852	12,960	720
TICU	2,241	374	3,834	213
CSICU	19,406	3,234	36,441	2,025
CSPCU	3,016	503	5,642	313
Total	44,972	7,496	73,290	4,072

BGL, blood glucose level; CDSS, computerized decision support systems; CSICU, cardiac surgical ICU; CSPCU, cardiac surgical progressive care unit; NTICU, neurotrauma ICU; SICU, surgical ICU; TICU, thoracic ICU.

For each unit, the median of the difference between the proportion of readings controlled when using the CDSS and the historical controls was statistically significantly greater than zero ($p < 0.0001$). Table 2 displays 18 months of data showing the results of the BGL measurements in each of the units using CDSS compared with 6-month historical controls rounded to the nearest percent. Also shown is the mean percent decrease in the frequency of hyperglycemia as defined as a BGL >150 mg/dL.

Figure 1 represents the decrease in the frequency of hypoglycemia, as defined by a BGL <40 mg/dL, for each individual unit and in aggregate. The aggregate decrease from 1.0% to 0.05% was statistically significant ($p < 0.0001$) by 2-sided binomial analysis.

Table 3 represents the data on HAIs seen in the units at two points in time expressed as a 12-month rolling average. The first is December 2009 and represents the

Table 2. Blood Glucose Levels Measurements per Unit, Computerized Decision Support Systems Compared with Historical Control

Unit	Glucose range, mg/dL	6-mo historical control, mean, %	18-mo CDSS, mean, %	Decrease, %	p Value
SICU	>150	34	17	50	<0.0001
NTICU	>150	27	15	45	<0.0001
CSPCU	>150	36	18	50	<0.0001
TSCU	>150	44	19	57	<0.0001
CSICU	>150	28	15	48	<0.0001

CDSS, computerized decision support systems; CSICU, cardiac surgical ICU; CSPCU, cardiac surgical progressive care unit; NTICU, neurotrauma ICU; SICU, surgical ICU; TICU, thoracic ICU.

rates of HAIs before implementation of the CDSS. The second point in time is December 2011, eighteen months after implementing the CDSS. During this time, several interventions were implemented to decrease the infection rates. These included an increased effort in all units to follow the recommendation of "best practice" more closely as defined in the ventilator-associated pneumonia (VAP) bundle, the catheter-associated urinary tract infection bundle, and the central line–associated bloodstream infection bundle.[19] Although statistical analyses were not performed, there have been some definite improvements, especially in VAPs and catheter-associated urinary tract infections between the 2 time periods.

DISCUSSION

Based on a 2-month pilot feasibility study, we reached several conclusions. First, the learning curve for the nursing staff was very short. By the second or third patient, most of the nurses were comfortable and confident with the technology. Second, a time/work study of nursing before and after implementation of the pilot found that the total minutes of time spent by nurses on glucose control went down for every shift, including the first shift of initiating CDSS, where the work is most intense and time consuming. In subsequent shifts, the time spent on glucose control decreased substantially. As can be seen from the comparison of the total number of BGL measurements in Table 1, the 6-month historical controls had substantially more BGL measurements per month, on fewer patients, compared with the 18-month study period.

We began to institute the CDSS in early 2010, going live in one unit at a time to allow training to take place sequentially. The onset of data collection for this report began when all units were activated in July 2010. In addition to the ease of use of CDSS, the data demonstrated that the degree of glucose control was more effective than had been seen before implementation of the CDSS, including in the cardiac units that had been using the Portland protocol.[18] The degree of improvement in the glucose control (with 45% to 57% decrease in hyperglycemia) was similar across all units, as seen in Table 2.

The other primary end point studied was the degree of serious hypoglycemia, as defined by a BGL <40 mg/dL. Again, we found a large decrease in all units individually and in aggregate, as shown in Figure 1. There was

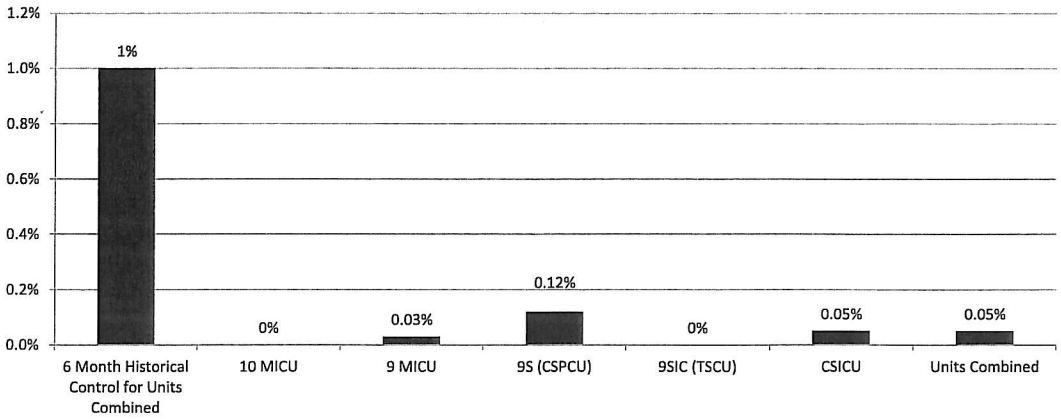

Figure 1. Rates of serious hypoglycemia (0–39 mg/dL) July 2010 through December 2011 in each of the surgical units in which the computerized decision support systems was used compared with 6-month historical controls. CSICU, cardiac surgical ICU; CSPCU, cardiac surgical progressive care unit.

Table 3. Health Care–Associated Infections per Unit Expressed as a 12-Month Rolling Mean, Pre- and Post-Computerized Decision Support Systems

Unit	HAI	December 2009	December 2011	NHSN pooled mean[21]
SICU	VAP	5	0.7	2.5
	CAUTI	5.1	0.4	1.5
	CLABSI	1.8	2.9	1
NTICU	VAP	12.5	2	6
	CAUTI	3.2	2.8	0.5
	CLABSI	2.3	4.3	1.9
TICU	VAP	6	0	1.6
	CAUTI	1.1	0	1.6
	CLABSI	0	0	0.9
CSICU	VAP	24.9	0.7	1.6
	CAUTI	2.1	0.3	1.6
	CLABSI	1.2	0.8	1.5
CSPCU	VAP	0	0	NA
	CAUTI	2.8	0	NA
	CLABSI	0	0	NA

CAUTI, catheter-related urinary tract infections per 1,000 drain days; CLABSI, central line–associated blood stream infections per 1,000 line days; CSICU, cardiac surgical ICU; CSPCU, cardiac surgical progressive care unit; HAI, health care–associated infection; NHSN, National Healthcare Safety Network; NTICU, neurotrauma ICU; SICU, surgical ICU; TICU, thoracic ICU; VAP, ventilator-associated pneumonia per 1,000 ventilator days.

a decrease from 1% in the pre-CDSS 6-month historical control group to 0.05% in the post-CDSS 18-month study period. This represents a 95% decrease in serious hypoglycemia ($p < 0.0001$).

During this same period, we have been tracking rates of HAIs, including VAPs, catheter-associated urinary tract infection, and central line–associated bloodstream infections, as well as surgical site infections. The trend for all of these has been downward. We have also instituted several other process improvements that will affect these rates. All that we can say is that the contribution of better glucose control was temporally associated with the trends of HAIs. A prospective study controlling for other variables would be required to assess this relationship. The CDSS certainly provided better glucose control than our historical controls, which were handled by other forms of IV insulin protocols.

With the increasing importance of cost controls in the health care landscape, the implementation of CDSS has the potential to limit expenditures. In our experience, it resulted in fewer blood glucose determinations and saved nursing time. The association of adequate glucose control and its possible effect on HAIs, however, has the potential for additional savings. There have been several methods used to estimate the cost to the system of such an HAI. The "return on investment calculator" from NSQIP can give one such estimate.[20] A single VAP is estimated to cost $40,000 and a single surgical site infection to average $27,000. If even a few infections are prevented, the cost of implementing the CDSS in an ICU setting in large hospitals can be offset by the cost savings listed here.

CONCLUSIONS

Implementation of this CDSS is feasible, has a short learning curve, and has a positive impact on nursing workload by decreasing the total number of BGL measurements and eliminating the need for calculations from a paper protocol. In addition, ICU patients in the study experienced half of the episodes of hyperglycemia (BGL >150 mg/dL) compared with patients in the 6-month historical control period who were managed by other methods of IV insulin administration ($p < 0.0001$). There was also a 95% reduction in episodes of serious hypoglycemia (BGL <40 mg/dL) compared with the same controls ($p < 0.0001$). Although the implementation of this system was temporally associated with a decrease in the HAIs, causality cannot be assessed in this study.

Author Contributions

Study conception and design: Fogel
Acquisition of data: Fogel
Analysis and interpretation of data: Fogel, Baker
Drafting of manuscript: Fogel, Baker
Critical revision: Fogel, Baker

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Discussion

DR DAVID HERNDON (Galveston, TX): I congratulate the authors on demonstrating that computer-directed insulin delivery in an ICU, in this case, a variety of ICUs, can be safer and more effective than current paper-driven insulin delivery protocols.

The computer decision support system (CDSS) described here decreased the number of blood glucose levels above 150 mg/dL a lot, and reduced the incidence, perhaps even more importantly, of severe hypoglycemia (blood glucose < 40 mg/dL), in half. Many authors have demonstrated that hyperglycemia in the ICU can lead to a marked increase in morbidity and mortality. Vandenberg showed this in a randomized prospective controlled study most effectively. And insulin-delivered protocols that treat hyperglycemia to maintain serum glucose levels between 90 and 150 mg/dL throughout a hospital stay can decrease not only mortality, as Vandenberg showed, but length of hospital stay and the time to wound healing in burns, as we have previously shown.

However, the reason these types of glucose control systems have been shied away from recently is because of a multi-institutional randomized trial around the world that showed that hypoglycemia was increased when you tried to obtain tight euglycemic control in the ICU, the Normoglycemia in Intensive Care Evaluation-Survival Using Glucose Algorithm Regulation (NICE-SUGAR) trial.

Hypoglycemia in the ICU increases mortality a huge amount, up to about 5-fold. And in multiple randomized trials, it increases mortality. It increased morbidity in the NICE trial.

The important issue, then, in this study, is that this computer support system decreased hypoglycemia. And if that can be done across the world by using computer support systems, we may have a winner. We may be able to maintain tight euglycemic control safely. And that's the crux of this paper.

In light of the findings of those randomized controlled studies, I would like to ask a few questions. First of all, I would like to know a little more about this black box, because it's a really good computer support system. I would like to have it myself. How exactly it achieves what it does was not entirely clear in the manuscript, and I think the methods could be fleshed out a little better there to help us by the time that gets to the *Journal of the American College of Surgeons.*

Your study brought about a great decrease in the number of blood glucose levels that were over 150 mg/dL. You also reduced the number of glucose levels that had to be drawn massively over those in paper protocols. And that's huge. But could the reduced surveillance skew the decrease in hyper- and hypoglycemia that you have shown in this patient population? You decreased the amount of glucose levels so much; does that in itself affect the results?

Reductions in infections acquired in the hospital were shown in this paper, but not greatly emphasized by Dr Baker. This is a historical control group, and there are limitations to comparing with a historical control group. One of the things that they dramatically showed was a huge decrease in hospital-acquired infections during their study period vs the control period. And that is certainly to be applauded.