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ORIGINAL ARTICLE

Hyperglycemia Control of the *Nil Per Os* Patient in the Intensive Care Unit: Introduction of a Simple Subcutaneous Insulin Algorithm

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Abstract

Background:

Diabetes patients in the intensive care unit (ICU) and either *nil per os*, on enteral feedings, or on total parenteral nutrition are often treated with sliding-scale insulin (despite lack of evidence showing benefit) or intravenous insulin (IVI) infusion, a nursing intensive procedure requiring hourly glucose measurements, and insulin rate adjustments. We introduced a subcutaneous insulin algorithm (SQIA) that would equal the glucose goals for IVI but have the simplicity of q4 hour adjustable sliding-scale insulin.

Methods:

As part of a quality improvement project, we developed a simple SQIA that titrates insulin to the requirements of the individual patient. Glucoses were monitored q4 h and SQ rapid-acting insulin administered based on both the previous insulin dose and current glucose level. Fourteen consecutive hyperglycemic patients admitted to ICU-A were placed on the SQIA. Glucose and insulin data were also obtained on 18 patients in an identical ICU-B who were treated with the usual IVI protocol, which is q1–2 h.

Results:

Duration on the SQIA was 4.5 ± 0.6 days (range 0.8–7) and on IVI 1.9 ± 0.6 days (range 0.25–9). Due to difference in length on protocols, only data for the first 3 days could be statistically compared. During this time, the mean ± standard error of glucoses for the SQ and IV groups were 157.3 ± 3.8 and 157.0 ± 2.2 (not significant). No differences were seen in hypoglycemia rates.

Conclusions:

A simple SQIA allows insulin doses to be adjusted to the individual patient's needs and meet current ICU goals for glycemic control. Its adoption may reduce the workload of nurses.

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Abbreviations: (BG) blood glucose, (ICU) intensive care unit, (IV) intravenous, (IVI) intravenous insulin, (NPO) *nil per os*, (SQ) subcutaneous, (SQIA) subcutaneous insulin algorithm

Keywords: hospital diabetes, inpatient diabetes, intensive care unit insulin, intravenous insulin, *nil per os* diabetes

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Introduction

Hyperglycemia is common in the critically ill patient and is associated with poor hospital-related outcomes.[1] Initial clinical trials in critically ill patients suggested that controlling glucose levels to near-normal levels in hyperglycemic patients improved these outcomes.[2–4] Intravenous insulin (IVI) infusions became the standard method to achieve this "tight" glucose control. Later trials of "tight" control in critically ill patients failed to replicate this improvement in mortality[5,6] and/or have shown increased mortality risk.[6] Although the ideal target range for glucose levels in intensive care unit (ICU) patients remains controversial because of the risk of hypoglycemia with intensive insulin protocols,[7] it is generally accepted that frank hyperglycemia [blood glucose (BG) greater than 180 mg/dl] in all hospitalized patients should be avoided because of the increased risk of nosocomial infection in patients with modest hyperglycemia.[8–11] Nevertheless, the American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control[12] suggests that IVI infusion is the preferred route of insulin administration in critically ill patients, though a few studies indicate that subcutaneous (SQ) insulin protocols using rapid-acting analogs may be equally efficacious and result in less hypoglycemia.[13–15] Furthermore, from the nursing perspective, IVI protocols are labor intensive. It is estimated that 2–3 h per day of direct nursing time is required for hourly glucose monitoring and IVI adjustments,[16,17] and insulin infusion protocols can be viewed as too complex by even experienced nurses.[18]

In order to address both the need for adequate glycemic control in the ICU and the goals of reducing nursing burden with far fewer glucose checks and less frequent insulin dosing than our traditional IVI protocol, we resurrected and adapted a previously published[19] simple SQ insulin algorithm (SQIA). That initial protocol was designed to deliver regular insulin subcutaneously every 4 h with the dose of insulin being determined by factoring in the current capillary glucose level and the prior insulin dose. The authors showed that, perioperatively, this simple SQIA allowed insulin to be adjusted to the needs of the patients and achieve results equal to IVI infusions. A SQ protocol similar to Pezzarosa's was used at Mount Zion Hospital in San Francisco in the early 1990s. At that time, the regular insulin that was used in the protocol appeared to stack, or build up over time, resulting in hypoglycemia, and thus, the protocol was replaced by an intravenous (IV) infusion protocol.[20] For the purposes of this quality improvement intervention, we modified Pezzarosa's protocol to use a shorter-acting insulin analog, with the aim of alleviating this problem.

Methods

Subcutaneous Insulin Protocol Design and Implementation

This algorithm is a variation on a simple protocol that was developed in Italy in 1988.[19] For the purposes of this quality improvement intervention, we modified the protocol to use a shorter-acting insulin analog, aspart (NovoLog, Novo Nordisk Pharmaceuticals Inc.). The order form utilized is shown in **Figure 1**. Of note, the key section of the order form relating to the ongoing insulin adjustments is in number 6.

The SQ protocol was made available in an adult medical–surgical ICU (ICU-A) at a teaching hospital. In a similar ICU on a different floor of the hospital (ICU-B), the SQ protocol was not used, and the usual insulin infusion protocol continued to be used (ICU IVI infusion protocol available at http://ucsfinpatientdiabetes.pbworks.com/f/ICU+iv+insulin+2011.pdf). All nurses in ICU-A were instructed on how to use the protocol through an interactive online module with test questions. In both ICUs, patients had any previously administered oral antidiabetic agents and/or noninsulin injectable hypoglycemic agents discontinued. In addition, all insulins, with the exception of insulin glargine, in those on the pilot algorithm were discontinued. In our institution, insulin glargine is the formulary basal insulin. Levemir is not used, and neutral protamine Hagedorn rarely used. Patients could be on basal insulin if the physician ordered, but it was not mandatory. Hypoglycemic events were treated per standard protocol similarly in both ICUs.

Subjects

Patients in ICU-A, who were *nil per os* (NPO) and would ordinarily be placed on an insulin infusion due to hyperglycemia, were placed on the SQ protocol. Patients deemed inappropriate for the protocol included those aged <18 years, those who were pregnant, or those with anasarca, where SQ insulin may have poor absorption.[21]

1 ☑ D/C all previous insulin orders.
2. ☑ D/C _____ (*oral antidiabetic agent*).
3. ☐ Give Glargine (lantus)_____units SQ ☐ qam ☐ qbedtime (*If currently on glargine, consider using 80% of previous dose*)
4. **Maintenance IV FLUIDS:** *IV dextrose infusion or Tube feeding or TPN* must be maintained while the patient is on insulin
☐ D5 NS at _____ mL/hr
☐ D5 1/2 NS at _____ mL/hr
☐ D10 W at _____ mL/hr (for patients with fluid restrictions or renal failure)
☐ D10 NS at _____ mL/hr (eg. fluid restricted with Na wasting, Neurosurgery or Neurology patients)
☐ Other at _____ mL/hr
☐ Add KCl _____ mEq/L (generally 20 mEq/L)

5. ☑ **Initial Aspart insulin dose.**

BG <120 mg/dl: Administer no insulin. Recheck BG in 4 hours and initiate protocol - use "0 units" as initial base dose (*see #6*)

BG 120-180 mg/dl:

☐ 4 units SQ Now (*consider for patients previously diet controlled, taking oral antidiabetic medications or on <30 units insulin/day*)
☐ 6 units SQ Now (*consider for patients on >30 units insulin/day*)
☐ Other: _____ units SQ Now (*for example, for patient currently on IV insulin drip, take current rate, multiply x4 and use that as dose*)

BG >180 mg/dl:

☐ 6 units SQ Now. Use 6 units SQ as base dose for insulin adjustment in 4 hours
(*consider for patients previously diet controlled, taking oral antidiabetic medications or on <30 units insulin/day*)
☐ 8 units SQ Now. Use 6 units SQ as base dose for insulin adjustment in 4 hours (*consider for patients on >30 units insulin/day*)
☐ Other: _____ units SQ Now. Use_____ units SQ as base dose for insulin adjustment in 4 hours

6. ☑ **Check BG q4hr (06, 10, 14, 18, 22, 02). Adjust Insulin Aspart dose q4hr as follows:**

BG <80 mg/dl	a. Do not administer insulin. b. Treat for hypoglycemia per protocol (*see #7 Below*). c. Continue to check glucose q4 hours d. when glucose is >120 mg/dl, give insulin at 50% of dose administered prior to glucose being <80 mg/dl, then restart protocol
BG 80-120	• Give same amount of insulin as given 4 hours earlier ***less 2 units***
BG 121-180	• Give same amount of insulin as given 4 hours earlier
BG 181-240	• Give same amount of insulin as given 4 hours earlier ***plus 2 units***
BG >240	a. Give same amount of insulin as given 4 hours earlier ***plus 2 units.*** **AND** b. Give additional 4 units X 1 NOW (may be given as single injection combined with scheduled dose). **Do not include this extra 4 units in determination of next insulin dose.**

7. ☑ **For a BG <80 mg/dl--Hypoglycemia Protocol**
- BG <80 mg/dl but >60 mg/dl, do not give insulin; give 25 ml D50 IV push.
Check BG q15 minutes and repeat treatment until BG >100 mg/dl, then continue with orders 6c and 6d, above.
- BG < 60 mg/dl, do not give insulin; give 50 ml D50 IV push.
Check BG q15 minutes and repeat treatment until BG >100 mg/dl, then continue with orders 6c and 6d, above.
- If BG remains <80 mg/dl for >1hour, page Primary Service Provider

8. Note: If patient is receiving Extraneal, Gamimune N 5%,Octogam, D-xylose, WinrhoD SDF Liquid,Hepatgam, Adept adhesion reduction solution or Orencia, do not use glucose meter for BG checks. All BGs must be sent to the laboratory.

9. ☑ **For a BG >400 mg/dl:** page Primary Service Provider

10. ☑ **Contact Endocrinology with any questions - pager: 415-443-9125**

Figure 1. Order form for the SQIA.

Patients in ICU-B who were NPO and hyperglycemic were placed on the usual ICU insulin infusion protocol.

Glucose Monitoring

Glucose measurements were made using a point-of-care glucose meter. Blood samples obtained were either capillary (from finger sticks) or arterial (from arterial lines), if an arterial line was available.

Statistical Methods

The normality test was performed to assess that BG levels were normally distributed. Because the BG levels were found to be normally distributed, the general linear model repeated-measures procedure available in SPSS v16.0 was used to calculate the difference in glucose values between ICU-A and ICU-B.

On inquiry, it was determined that institutional review board approval was not required, as these data were obtained as part of a quality improvement project for reintroduction of a modified insulin protocol.

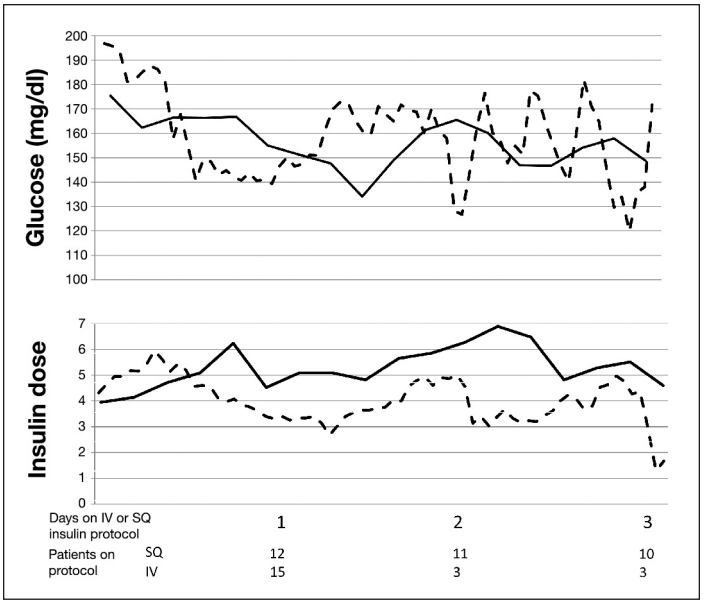

Figure 2. Comparison of glucose levels and insulin dosing in patients on SQ or IVI algorithms. Solid line, SQ protocol; dashed line, IV protocol. The insulin for SQ protocol is "units given every 4 h"; insulin for IV protocol is "units infused per hour."

Results

Subjects

Over the period of 22 days, 14 patients in ICU-A who would have routinely been placed on IVI were placed on the SQ algorithm protocol. During this same time period, data were collected on 18 patients in ICU-B who required and were placed on an ICU IVI infusion. Baseline characteristics for these patients were similar and described in **Table 1**.

Glucose Results

The glucoses levels and insulin doses for the patients in ICU-A and ICU-B are shown in **Figure 2**. While the average duration on the SQ protocol for patients in ICU-A was 4.5 ± 0.6 days (range 0.8–7), yielding a total of 339 glucose checks, the patients in ICU-B were only on the IVI protocol for an average of 1.9 ± 0.6 days (range 0.25–9), with a total of 814 glucose checks. Due to this difference in length on protocols, only data for the first 3 days could be statistically compared. During this time, the mean ± standard error (mg/dl) of glucoses for the SQ and IV groups were 157.3 ± 3.8 and 157.0 ± 2.2. For these 3 days (**Figure 2**), utilizing the repeated measures procedure, there was no significant difference in glucose levels between the patients on IVI and SQ insulin algorithm protocols.

The glucoses and insulin doses for patients who were on the SQ algorithm for 7 days are shown in **Figure 3**. Including the initial titration period, 75% of BGs in the SQ group and 79% of those in the IV group were within

Table 1.
Baseline Characteristics of Patients Treated with Intravenous and Subcutaneous Insulin Algorithms

Group	Mean age	Male	Female	Primary diagnoses	% with previous diabetes	Previous diabetes medications
SQ	62.4 ± 3.2 range 44–84	6 (43%)	8 (57%)	Sepsis (3), neck, surgery, gastrointestinal bleed (2) post-diabetic ketoacidosis cardiac arrest pneumonia, intestinal perforation peritonitis, fulminant hepatitis, hip surgery, bowel obstruction	57%	Total 6 (43%) oral 3 (21%) insulin 3 (21%)
IV	59.6 ± 2.9 range 39–80	8 (44%)	10 (66%)	Liver transplant (3), respiratory failure (2), aortic dissection, sepsis, pneumonia (3), altered mental status, gastrointestinal bleed (2), vascular surgery (2), multisystem failure, hepatic failure, abdominal abscess	66%	Total 10 (66%) oral 7 (39%) insulin 5 (28%)

the 100–200 mg/dl range. A total of 0.6% (SQ) and 0.3% (IV) of all glucoses were <60 mg/dl, with none resulting in an adverse event.

There were nine protocol administration errors (rate of 2.6%; **Table 2**).

Discussion

Diabetes is a growing epidemic in the United States and currently affects approximately 11.3% of adults.[22] Statistics indicate that 22% of all inpatient hospital days in the United States are utilized by people with diabetes, and 13% are directly due to diabetes itself.[23] These figures indicate that hyperglycemia is and will continue to be a significant problem in the inpatient setting. Intravenous insulin infusions have been the preferred method for maintaining glycemic control in the ICU, where the nurse-to-patient ratios are smaller. However, ICU nurses deal with a heavy cognitive workload, often multitasking in the face of continual interruptions to their work.[24]

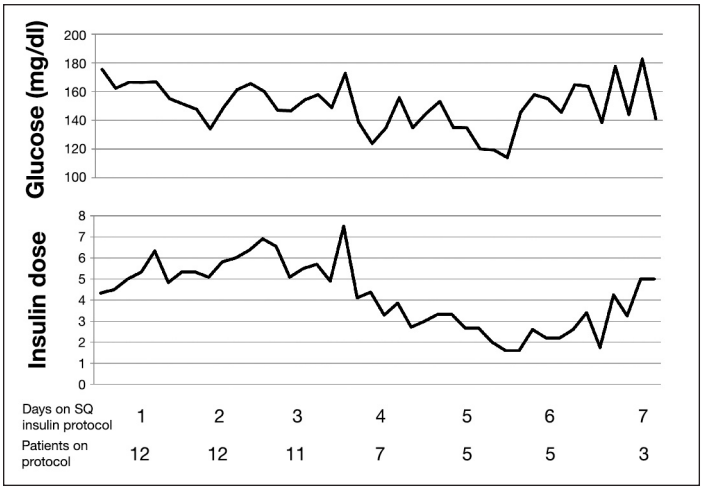

Figure 3. Glucose levels and insulin dosing in patients on SQIA. Blood glucose levels and insulin doses for the total time patients were on the protocol in the ICU. The insulin for SQ protocol is "units given every 4 h."

Table 2.
Types of Error Made Using the Subcutaneous Insulin Algorithm in the Intensive Care Unit

Description of errors	#
Following hypoglycemia, next insulin dose was not reduced by 50%	3
Insulin administered 2 h early	2
In response to BG 181–240 mg/dl, insulin dose was not increased by 2 U	2
In response to BG 81–120 mg/dl, insulin dose was not decreased by 2 U	2

A time–motion study of ICU nurses demonstrated that the time required by a nurse to perform a glucose check and respond according to an insulin infusion protocol ranges from 20–50 min, 10 min of which is spent reviewing the protocol alone.[25] Despite the time spent, 70% of glucose checks were associated with a protocol deviation, a third of which involved incorrect insulin dosing. Given the complexity of insulin infusion protocols, developing methods such as our SQ insulin protocol to reduce both nursing workload and potential errors is important as hyperglycemia in the inpatient setting becomes an increasingly common problem.

Our SQIA for NPO hyperglycemic patients allows insulin doses to be adjusted to the patient's needs and resulted in glucose control that was not significantly different from the control in patients who were on IVI. The SQ protocol resulted in a low rate of hypoglycemia with few errors and was effective in patients with and without diabetes as well as in both surgical and medical patients. Despite the success of this protocol, we made minor modifications to reduce the already low risk of hypoglycemia. As our institution has just transitioned from paper-based order sets to computer-based order entry, only protocols that were active at a time prior to reintroduction of the SQIA could be utilized. We anticipate adding this algorithm once the transition to computer-based orders is complete and changes are once again allowed.

When sliding-scale insulin is used for inpatient diabetes management, a fixed dose of insulin is given based on the current glucose level and can lead to a "rollercoaster" effect on glucose levels. When the glucose is at goal, no insulin is given, then the glucose increases and insulin is given, lowering the glucose, and the cycle begins again. With an algorithm, whether for IVI infusion or, as in this study, with SQ insulin, the insulin dose is titrated over time to the actual requirements of the patient, eliminating the rollercoaster effect. Indeed, the insulin infusion rates or SQ dosing to maintain glucose level at our target range were 0–17.2 U/h and 0–24 U every 4 h, reflecting how different the requirements are in each person, how insulin requirements change over time, and why algorithms are necessary.

Of note, prior to introduction into ICU-A, the insulin algorithm was initially piloted on a non-ICU surgical unit. All nurses were instructed on how to use the protocol by a 15 min orientation to the protocol followed by a competency test. Eleven patients who were NPO following complex abdominal or pelvic surgery were

placed on the SQIA. Results were nearly identical to those shown for the group in ICU-A. The average duration on the SQ protocol was 2.7 ± 0.5 days (range 0.8–6), 88% of BGs were within 100–200 range (79% within 100–180 range). No mistakes in insulin dosing adjustments were made.

Although not formally quantified, the time spent managing BGs with the SQIA was likely reduced at our institution, given that it requires dosing every 4 h as opposed to dosing every 1 to 2 h with our standard IV protocol. The time savings with the SQIA may not be as large compared with IV protocols in other institutions that allow for less frequent BG monitoring. Other advantages of the SQIA are that it does not require IV access and can be used in non-ICU settings, where, in many institutions, IVI infusions are often prohibited. Indeed, when this protocol was introduced for trial in a non-ICU surgical unit, there was quick acceptance by the nursing staff. In addition, because of its need for less nursing attention, when compared with IVI, this SQIA is likely to be cost saving.

Limitations

This was not a randomized study. Patients in each of the two ICUs on IV or SQ insulin protocols were not matched, but in general, similar patients are admitted to each unit. This protocol was not tested in post-coronary artery bypass patents, and it is unknown if current Surgical Care Improvement Project goals would be met. In addition, as we specifically designed the protocol to keep it simple, the tested algorithm did not take into account any rate of change in the glucose level. However, we believe that future versions of this algorithm may need to take into account single large decreases in glucose levels (even though still in an acceptable range) in order to further reduce the risk of hypoglycemia. As noted, patients were on the IV protocol for a shorter time than the SQ protocol. For the multiple reasons detailed here, patients are generally rapidly moved off of IVI. Finally, as with any IV or SQ protocol, as the clinical situation changes with alterations in enteral feedings or IV glucose rates or use of glucocorticoids, overriding the protocol orders and resetting the SQ insulin dose may be required.

Conclusions

A simple SQIA allows insulin doses to be adjusted to the individual patient's needs and meet current ICU goals for glycemic control. Primarily due to the decreased frequency of required glucose monitoring, its adoption may significantly reduce the workload of nurses. In addition, this algorithm can be utilized on medical and surgical units, locations where IVI infusions are often not allowed.

Disclosures:

Robert Rushakoff has been a speaker for Merck Pharmaceuticals.

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