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OUTCOMES OF THE IMPLEMENTATION OF LESS INTENSIVE GLYCEMIC TARGET FOR A SUBCUTANEOUS INSULIN PROTOCOL IN HOSPITALIZED PATIENTS

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Abstract

Background—This study looked at the effect of replacing an intensive subcutaneous insulin correction protocol (OP) with a less intensive protocol (NP) in a tertiary hospital with the hypothesis that using the NP will result in less hypoglycemia and improved hospital outcomes.

Methods—The charts for 200 hospitalized patients managed with the OP (glycemic target 90 – 116 mg/dL for intensive care and 90 – 130 mg/dL for non-intensive care patients) and 200 with the NP (glycemic target 150 – 200 mg/dL) were reviewed. Data were collected and were analyzed using Fisher's exact test and Student's t-test. The primary outcome was the difference in hypoglycemia rates between the two protocols. Hypothesis test p-values of $p < 0.05$ were deemed significant.

Results—There was no statistically significant difference in age, gender, ethnicity, BMI, level of hospital care or use of scheduled insulin for the two groups ($p > 0.05$ for all). Average blood glucose values were 160.45 and 169.98 mg/dL for the OP and NP, respectively ($p = 0.063$). There were 14 readings ≥ 40 mg/dL in the OP compared to 6 in the NP ($p = 0.046$). With the OP, 27 patients required dextrose treatment compared to 11 with the NP ($p = 0.0097$). The average length of hospitalization was longer for the NP compared to the OP (13.16 vs. 6.56 days, $p = 0.00085$).

Conclusions—A less intensive subcutaneous insulin correction protocol in hospitalized patients resulted in similar glucose values with less severe hypoglycemia. However, it was associated with longer length of hospitalization.

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Keywords

Subcutaneous insulin protocol; Glycemic targets; Inpatient hypoglycemia

Introduction

The 2014 National Diabetes Statistics Report published by the Centers for Disease Control and Prevention estimates that in the United States, 29.1 million people (9.3% of the population) have diabetes¹. Besides the long term complications of diabetes, more acute complication like hypoglycemia have also been linked to significant morbidity and mortality²⁻⁵. Intensive glycemic control in hospitalized patients with diabetes has been shown to increase the risk for hypoglycemia^{6,7}. Results from several large studies like the NICE SUGAR trial have led to recommendations for less intense glycemic targets in hospitalized patients with diabetes⁸⁻¹².

Subcutaneous insulin protocols are important tools designed to guide healthcare providers achieve appropriate and safe glycemic goals. These protocols are often implemented by nursing staff that provide direct care to patients. The effectiveness and safety of these protocols is a direct consequence of predetermined parameters including blood glucose correction targets and insulin sensitivities used in their design.

High rates of hypoglycemic events (blood glucose < 70 mg/dL) were noted while using a previous subcutaneous insulin correction protocol (OP) that targeted intensive glucose control at the site of the study. With the change in paradigm, a new subcutaneous insulin correction protocol (NP) with less strict glycemic targets was designed and implemented. This report is a summary of the results of the chart review done to determine the safety and effectiveness of the NP compared to the OP.

Methods

This was a retrospective chart review with primary outcome being the difference in hypoglycemia rates between the OP and NP. The study was conducted at a 450 bed county hospital in Las Vegas, Nevada. A list of all patients managed with a subcutaneous insulin protocol during the study period (April 2011 to September 2011) was generated from pharmacy medication administration database. The charts of 915 patients were reviewed to identify 400 that were eligible for the study. Starting from the time of introduction of the NP, the last 200 consecutive patients managed with the OP before it was discontinued in June 2011 and the first 200 consecutive patients managed with the NP after its introduction were identified and selected for the study. All included patients were managed with either the OP or NP exclusively (with or without fixed pre-meal or basal insulin). The study was approved by the institutional review board of the participating hospital.

Study Exclusion Criteria

1. Age less than 18 years.
2. Treatment with only intravenous insulin during hospitalization.

3. Patients taking oral hypoglycemic agents.
4. Patients with less than four consecutive blood glucose readings.
5. All pregnant patients.

Protocol Description

The NP was developed with input from internist, emergency room physicians, endocrinologists, nursing staff and pharmacy staff. Prior to implementation, the NP was reviewed and approved by the hospital Medical Executive Committee. Various initiatives were undertaken to educate staff physicians, residents, pharmacists and the nursing staff about the changes in the NP. The two protocols were used by the same group of providers but were not used concurrently. Insulin lispro was the only insulin used for blood glucose correction in both protocols.

The OP only had recommendations for the correction of elevated blood glucose with the aim of achieving tight glycemic target of 90 – 116 mg/dL for ICU and 90 – 130 mg/dL for non-ICU patients with insulin sensitivity factors of 5 and 10 (Appendix 1). The OP did not have provision or guidance for scheduled insulin use. In contrast, the NP had a less aggressive glycemic correction target of 150 – 200 mg/dL with insulin sensitivity factors of 20, 30, 40 and 50 plus suggestions for use in individuals with varying degrees of insulin resistance (Appendix 2). Unlike the OP, the glycemic correction target was not announced in the NP but was incorporated in the design of the protocol. The NP also had provision for basal and fixed pre-meal bolus insulin doses but without specific guidance on scheduled insulin dose adjustment. This was intended to serve as a reminder for providers to consider a basal/bolus regimen that mimicked a more physiologic insulin delivery which has been shown to improve inpatient glycemic control when compared to insulin corrections alone¹³. Both protocols had provisions for providers to create a correction scale based on customized blood glucose correction targets and insulin sensitivities.

Data Collection

Data were collected from the pharmacy electronic database and by reviewing the individual patient charts and was done by one individual (GK). Abstracted data included patient age, gender, BMI, ethnic group, level of care (i.e. general medical floor, intermediate care unit, ICU, etc.), type of diabetes, blood glucose values while on protocol, number of days on protocol, total number of blood glucose readings while on protocol, need for intravenous glucose or glucagon and length of hospital stay during a single hospitalization. After collection, all data were de-identified and stored securely prior to analysis.

Statistical analysis

With an anticipated 20 – 40% reduction in incidence of hypoglycemia following the introduction of the NP, inclusion of 100 – 200 charts for patients treated with each of the protocols was estimated to achieve 80% power with a significance level of $\alpha = 0.05$.

Differences in hypoglycemia rates and other variable rates between the two groups were measured with a Fisher's exact test or a simple test for proportions for statistical

significance. Differences in quantitative measurements such as glucose levels and length of hospital stay were evaluated using a Student's t-test.

Results

A total of 915 charts were reviewed to enroll the first 400 patients that met study inclusion criteria. Mean age was 65 ± 14.8 years. Out of the 400 patients, 180 (45%) were women, 50.5% were Caucasian, 20% were Hispanic and 18% were African American. There were 280 patients managed on the general floor, 48 patients (12%) in ICU and the rest in intermediate care unit. There were 287 patients who had documented diabetes (11 with type 1 diabetes, 176 with type 2 diabetes and 100 with unspecified type of diabetes). (Table 1)

There was no statistically significant difference found in age, gender, ethnicity, BMI, level of care, type of diabetes and the number of patients managed with either insulin glargine, NPH or scheduled pre-meal lispro (Table 2) between the two groups ($p > 0.05$ for all). A total of 2,635 blood glucose readings (mean number of readings 13.2 per patient) was collected in the OP compared to 2,913 (mean number of readings 14.7 per patient) in the NP ($p = 0.238$). The average blood glucose values were 160.45 and 169.98 mg/dL for the OP and NP, respectively ($p=0.063$). There were 6 unique patients with 14 blood glucose readings > 40 mg/dL in the OP compared to 4 unique patients with 6 blood glucose readings > 40 mg/dL in the NP ($p = 0.046$) (Figure 1). There were 36 unique patients with 81 blood glucose readings < 70 mg/dL in the OP compared to 26 unique patients with 65 readings in the NP ($p = 0.053$). The proportion of patients requiring treatment with dextrose on the OP was statistically significantly higher than the proportion in the NP (27 vs. 11, $p = 0.01$). Overall, the average length of hospital stay was longer for those treated with the NP compared to the OP (13.16 vs. 6.56 days, $p = 0.001$) (Table 3). There were 5 patients with LOS > 100 days in the NP (104, 112, 124, 159 and 173 days) compared to only 1 patient in the OP (202 days). Individual chart review for these 6 patients revealed that the reasons for their prolonged hospitalization were for chronic conditions including motor vehicle trauma, malignancy, severe burns, sepsis, *pneumocystis carinii* pneumonia and respiratory failure.

Subgroup analysis

Subgroup analysis that looked at patients with length of stay ≥ 14 days and < 14 days revealed that 16 out of 200 patients (8%) had length of stay ≥ 14 days in the OP compared to 48 out of 200 patients (24%) in the NP ($p = 0.00002$). There was no significant difference in either of the length of stay subgroups (≥ 14 days or < 14 days) for outcome measures (average glucose, incidence of hypoglycemia and severe hypoglycemia) when comparing those managed with the OP to those managed with the NP.

Another subgroup analysis evaluating patients managed in the ICU setting revealed that 25 out of 200 patients (15%) were managed in the ICU using the OP compared to 23 out of 200 patients (12.5%) managed using the NP ($p = 0.88$). There was no significant difference in age, BMI, total number of blood glucose readings, average blood glucose value, and incidence of hypoglycemia or severe hypoglycemia. However, there was a significantly longer length of stay for patients managed with the NP compared to the OP (24.48 vs. 6.36 days, $p = 0.0041$). (Table 4)

Discussion

With recent change in paradigm, the use of less intensive glucose correction targets and the adoption of more physiologic basal bolus insulin treatment regimens in hospitalized patients has been recommended as strategies to improve hospital outcomes⁷¹⁴. However, these outcomes have not been adequately studied. Several studies have reported increased length of hospitalization associated with hypoglycemia^{15–17}. Kim et al found a negative correlation between LOS and hypoglycemia in non-critically ill patients¹⁵ while Kasirye et al reported increased hospital complications and LOS in patients hospitalized with chronic obstructive pulmonary disease (COPD) exacerbation that had hypoglycemia¹⁶. Other studies have reported increase in adverse outcomes and prolonged hospital LOS associated with hyperglycemia^{17–19}. Lipton et al looked at outcomes in cardiac patients and found that every 1 mmol/L (18 mg/dL) increase in glucose was associated with a 10% increase in all-cause mortality¹⁸. Burt et al also looked at glucose values in COPD patients and found a 10% increase in LOS for every 1 mmol/L (18 mg/dL) increase in blood glucose¹⁹. Based on these reports, the ideal goal for a hospital glucose correction protocol therefore should be to maintain normal glucose while avoiding hypoglycemia or hyperglycemia. This study looked retrospectively at outcomes following implementation of a less intensive glucose correction protocol in a tertiary hospital with the goals of avoiding hypoglycemia while maintaining good glucose control.

There were only 6 episodes of severe hypoglycemia in the NP compared to 14 in the OP ($p=0.046$). More patients had blood glucose < 70 mg/dl in the OP compared to the NP (81 vs. 65 respectively, $p = 0.053$). There was a correspondingly higher number of patients requiring dextrose administration (26 in the OP compared to 11 in the NP, $p = 0.01$). This significant reduction in the incidence of severe hypoglycemia occurred without a difference in basal or scheduled pre-meal insulin use between the OP and NP and suggests an additional benefit of a less stringent glucose correction target.

The finding of slightly higher average blood glucose with the NP was not surprising because of its higher glucose correction targets. This difference was not statistically significant at the 0.05 significance level ($p=0.06$) and is similar to other published reports with less intensive glycemic targets²⁰²¹.

The use of standardized protocols for administering insulin has been shown to result in improvement in outcomes and are recommended as a strategy for reducing the rate of hypoglycemia in hospitalized patients¹⁴²⁰²²²³. Chen et al demonstrated that use of a basal/bolus insulin protocol resulted in less hypoglycemic events but led to higher mean blood glucose values in non-ICU hospitalized patients with diabetes or hyperglycemia²⁰. Another recent inpatient study conducted in non-critically ill patients in Ottawa, Canada demonstrated reduced hypoglycemia and less use of correctional scales as the only form of insulin therapy for managing hyperglycemia²².

Although poor glycemic control is associated with increased macro vascular and micro vascular complications, several large trials have suggested that intensive control could result in adverse cardiovascular outcomes²²⁴²⁵. The NICE SUGAR trial found increased risk of

death in critically ill patients who developed moderate to severe hypoglycemia as a result of intensive glucose control⁹. The ACCORD trial which was conducted in ambulatory patients failed to show benefit of intensive glycemic control but also demonstrated an association between tight glycemic control and increased all cause mortality²²⁴.

Present emphasis is shifting away from tight control towards less intensive control with less hypoglycemia and glycemic excursions. Current treatment guidelines for hospitalized patients recommend blood glucose target of 140 – 180 mg/dL for most critically ill, hospitalized patients and for non-critically ill patients, pre-meal blood glucose of <140 mg/dL and random blood glucose of <180 mg/dL¹¹¹⁴²⁶. The results of this study demonstrated that these targets can be achieved safely using the NP with a lower incidence of hypoglycemia.

An unexpected finding in this study was the significantly longer length of hospitalization for patients managed with the NP compared to the OP despite having comparable average blood glucose values and a lower rate of severe hypoglycemia in the NP. There were more patients with extended hospitalization (>100 days) for chronic conditions in the NP compared to the OP which likely contributed to the longer average LOS in the NP. There were no significant differences in outcome measures between the OP and NP in subgroup of patients with hospitalization 14 days and those with hospitalization <14 days. Because the major difference between the OP and NP was their glycemic targets, hyperglycemia in the NP may have delayed their recovery and contributed to their prolonged length of hospital stay, similar to other published reports^{17–19}.

In conclusion, the use of a less intensive subcutaneous insulin correction protocol in this study resulted in similar glucose values and a lower incidence of severe hypoglycemia compared to a more intensive subcutaneous insulin correction protocol. Contrary to other published results⁵¹³, the average length of stay in this study was longer with the NP despite having fewer episodes of severe hypoglycemia. It is possible that a less intensive glucose correction target resulted in poorer glycemic control and delayed hospital discharge similar to previous reports^{17–19}. The difference in length of stay could also be the result of other patient factors that could not be controlled for in this study. However, the exact causal relationship between higher glucose readings and longer length of hospitalization observed in the NP cannot be determined from this retrospective study and will be better explored prospectively.

Hospital protocols designed to address the glycemic variability in various groups of patients are expected to improve outcomes through minimizing the risk of errors and increasing compliance to evidence based recommendations²⁷²⁸. However, successful application of these protocols is often difficult to achieve²⁹. This study will contribute towards documenting the effectiveness of these protocols which will help increase awareness of their utility with wider acceptance and ultimately better patient outcomes.

Study Limitations

This is a retrospective chart review and some of the outcomes observed may have resulted from unrelated factors that were not accounted for in the analysis. Although the sample size

estimation was based on a power calculation relying on expected changes in hypoglycemia rates, the small sample size of this study may not adequately assess changes in other relevant outcome measures. A prospective trial will be ideal to further evaluate the findings of this study especially the longer length of hospitalization in patients treated with the NP. This is particularly important given the known increase in cost associated with prolonged hospitalization resulting from hyperglycemia³⁰. Finally, this study included patients managed in the ICU and non-ICU settings, and patients with and without diabetes. This approach may result in limited generalization of the study results. However, there was no difference between the OP and NP in their composition of ICU vs. non-ICU or diabetes vs. no diabetes patients. This approach was chosen to capture patients in a real-world clinical setting that can be applied to the study location.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

OP	Old subcutaneous insulin correction protocol
NPm	New subcutaneous insulin correction protocol
ICU	Intensive care unit
BMI	Body mass index

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Figure 1. Incidence of hypoglycemia and severe hypoglycemia in patients managed with the old protocol (black bars) and new protocol (white bars).

Table 1

Baseline characteristics of study cohorts

Parameter	Old Protocol (n=200)				New Protocol (n=200)				p-value
Average Age (years)	55.6				57				0.34
BMI (kg/m ²)	29.69				30.16				0.62
Sex	Male		Female		Male		Female		0.27
Type of Diabetes	116		84		104		96		0.07
	Type 1	Type 2	Unspecified	Unknown	Type 1	Type 2	Unspecified	Unknown	
	6	77	57	60	5	99	43	53	

Table 2

Number of patients treated with basal and scheduled pre-meal insulin.

Type of Insulin	Old Protocol (patients)	New Protocol (patients)	p-value
Glargine	80	66	0.18
NPH	3	11	0.53
Pre-meal Lispro *	43	41	0.9

* Includes only patients treated with scheduled pre-meal lispro.

Table 3

Study results showing outcome measures for patients treated with the two protocols.

Parameter	Old Protocol	New Protocol	p-value
Number of Blood Glucose Readings	2635	2913	0.238
Average Blood Glucose (mg/dl)	160.45	169.98	0.063
Blood Glucose readings ≥ 40 mg/dl (patients) *	14 (6)	6 (4)	0.046
Blood Glucose readings < 70 mg/dl (patients) #	81 (36)	65 (26)	0.053
Dextrose Administration (number of patients)	26	11	0.009
Average Length of Stay (days)	6.56	13.16	0.001

* There were 14 blood glucose reading in 6 patients in the OP compared to 6 blood glucose readings in 4 patients in the NP that were ≥ 40 mg/dl.

There were 81 blood glucose reading in 36 patients in the OP compared to 65 blood glucose readings in 26 patients in the NP that were < 70 mg/dl.

Table 4

Patient characteristics and study results showing outcome measures for subgroup of patients managed in the intensive care unit using the old and new protocols.

Parameter	Old Protocol	New Protocol	p-value
Number of Patients	25	23	0.88
Average Age (years)	56.8	57.6	0.85
Average BMI (kg/m ²)	31.84	26.46	0.078
Number of Blood Glucose readings	336	444	0.2
Average Blood Glucose (mg/dl)	143.85	170.39	0.056
Blood Glucose readings < 70 mg/dl (patients)	15 (3)	13 (5)	0.58
Blood Glucose readings ≥ 40 mg/dl (patients)	4 (1)	3 (2)	–
Average length of Hospital Stay (days)	6.36	24.48	0.0041