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ORIGINAL RESEARCH

Application of the PDCA Cycle for Managing Hyperglycemia in Critically Ill Patients

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ABSTRACT

Introduction: Stress hyperglycemia is a common symptom in critically ill patients, and is not only a marker indicating the severity of illness but is also related to worsening outcomes. Managing stress hyperglycemia without increasing the likelihood of hypoglycemia is one of the most pressing challenges to be urgently addressed in clinics. The Plan–Do–-Check–Act (PDCA) cycle management has been put forward in various surgical management scenarios, and has proven to be effective in the diagnosis and treatment of different diseases. It possesses dynamic characteristics and can be updated according to the results of glycemic control and feedback. This study focused on the use of PDCA to manage glucose levels in critically ill patients.

Methods: Based on the glucose level of 1003 critically ill patients admitted to the emergency intensive care unit (EICU) from 1 October 2019 to 31 December 2020, we collected and matched the prevalence of hyperglycemia, hypoglycemia, and glucose variability on a quarterly basis. According to the PDCA management method, we analyzed the possible causes, supervised the implementation of measures, summarized the feedback on improvements, and then proposed new improvement measures for implementation in the next quarter.

Results: Three measures were proposed and applied to enhance the management of hyperglycemia: (I) Updating and formulating three editions of the insulin infusion protocol and increasing the initial and maintenance doses of insulin on a case-by-case basis; (II) reducing the use of parenteral nutrition and ensuring that enteral nutrition is consumed at a uniform and slow rate; and (III) forming a training method during the COVID-19 pandemic and improving implementation of the insulin infusion protocol. Following PDCA management, the prevalence of hyperglycemia fell from 43.18% to 32.61%, the incidence of hypoglycemia was below 1.00%, and there was no significant fluctuation in blood glucose variability.

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Conclusion: The PDCA method is helpful in developing a superior insulin infusion protocol for critically ill patients and lowering the prevalence of hyperglycemia in critically ill patients.

Keywords: Hyperglycemia; Plan–Do–Check–Act cycle; Insulin infusion protocol; Critically ill

Key Summary Points
Stress hyperglycemia is not only a common symptom in critically ill patients but also the difficulty of treatment
Quarterly summarizing of the proportion of hyperglycemia, hypoglycemia, and glucose variability, leading to improvement and summary according to PDCA management methods
Updating and formulating three editions of the insulin infusion protocol, improving the use of enteral and parenteral nutrient solution, and adapting the training methods during the COVID-19 pandemic
The PDCA method is helpful in developing a superior insulin infusion protocol for critically ill patients and reducing the proportion of hyperglycemia in critically ill patients

INTRODUCTION

The American Diabetes Association (ADA) recommends a target glucose range of 140–180 mg/dL (7.8–10.0 mmol/L) for the majority of critically ill patients [1]. It is well documented that hyperglycemia, hypoglycemia, and glucose variability are independent risk factors for mortality of dysglycemic patients in the intensive care unit [2]. Stress hyperglycemia and diabetes are common conditions in the inpatient setting, with an estimated combined prevalence of 40% and an even higher prevalence in the critically ill. Stress hyperglycemia develops in up to 50% of patients during the first 48 h following admission [3, 4]. In 2011, a survey conducted in 575 intensive care units (ICU) in the USA reported that the prevalence of hyperglycemia (> 180 mg/dL) was 32.2% of patient-days for ICU patients, while that of hypoglycemia (< 70 mg/dL) was 6.3% of patient-days, and the prevalence of severe hypoglycemia (< 40 mg/dL) was 1.1% of patient-days [5]. In 2017, results from nine sites showed the percent of patient-days with severe hyperglycemia [any blood glucose (BG) > 299 mg/dL] was 7.2%, while the percent of patient- days with hypoglycemia (any BG < 70 mg/dL) was 4.1% [3].

Current research suggests that hyperglycemia is not only a marker for the severity of illness but also for adverse outcomes; even marginal increases in mean glucose levels in ICU patients are associated with an increased risk of in-hospital mortality. Hyperglycemia increases the risk of further complications, such as severe infection, myocardial infarction, polyneuropathy, and multiple-organ failure [6, 7]. It can result from multiple factors, including increased levels of cortisol, catecholamines, glucagon, growth hormone, tumor necrosis factor-alpha (TNF-α), interleukin (IL) 1, and IL-6. These factors promote glucogenesis, glycogenolysis, and insulin resistance, especially hepatic insulin resistance [8]. Earlier studies have signaled that strict glycemic control lowered both morbidity and mortality in ICU patients, but recent studies have suggested potential harm related to the development of hypoglycemia [7]. Therefore, regulating stress hyperglycemia without increasing the risk of hypoglycemia is the crux of the problem that needs to be promptly resolved in clinics.

In intensive care units, continuous intravenous short-acting insulin for management of dysglycemia is recommend by guidelines. Intravenous insulin protocols should be administered based on human calculation or computerized protocols [1]. Automated computer insulin calculators have demonstrated tighter glycemic control than achieved by paper protocols, which could reach the glucose target

faster and improve the ability of nursing staff to adjust insulin doses. However, computer-based insulin infusions are not widely available because of commercial licensing fees, and the algorithms do not typically move beyond the pilot phase [9].

The Plan–Do–Check–Act (PDCA) cycle, also known as the Daiming cycle, is a repetitive four-phase model for continuous improvement in quality management such as surgical or standardized nursing management. In recent years, many studies have suggested that PDCA cycle management plays an effective role in the diagnosis and management of numerous diseases [10].

Given the high prevalence of hyperglycemia and the lack of standardized insulin infusion protocols, this study aimed to establish a project to address glycemic control in critically ill patients to formulate an insulin infusion protocol to lower the prevalence of hyperglycemia without increasing the incidence of hypoglycemia. The use of PDCA to manage glucose levels in critically ill patients has dynamic characteristics that could be adjusted based on the results of glycemic control and feedback. Furthermore, it can take into account improvements in other aspects, such as raising the protocol execution rate or adjusting the nutritional approach. It would be more comprehensive and continuous to improve glucose management in critically ill patients by PDCA.

METHODS

With 30 beds, roughly 850 patients admitted annually, and a nurse to bed ratio of 2.8:1, the emergency intensive care unit (EICU) of Ruian People's Hospital chiefly admits patients with cerebral injuries and severe infections. The formal glucose management working group comprises two doctors and four nurses. This study was approved by the ethics committee of Ruian People's Hospital.

Based on the glucose level of all patients admitted to the EICU from 1 October 2019 to 31 December 2019, the prevalence of hyperglycemia was 43.18%, far above what has been reported in the literature [5], and the objective was to lower it to 35.00%. The Pareto principle was utilized to identify and analyze the causes of hyperglycemia. Then, a fishbone diagram of the primary causes was constructed. Lastly, we followed the PDCA management approach for glycemic control based on the three main causes.

Plan

(I) Insufficient insulin dosage in infusion protocol: increasing the loading and maintenance doses of insulin can lower the prevalence of hyperglycemia, but it is necessary to ensure that the incidence of hypoglycemia does not increase, which is the most challenging point of this technique. The countermeasure was to understand the insulin infusion protocol from the literature, increase the insulin dose, examine the cause of hypoglycemia in each case, and comprehensively consider adjustments in insulin doses.

(II) Inadequate nutritional support: hyperglycemia can be caused by parenteral nutrition, excessive carbohydrate content, or rapid enteral nutrition. The countermeasure was to cooperate with the nutrition management team, draw on the nutrition guidelines, limit parenteral nutrition, control excessive enteral nutrition intake, and evenly and slowly infuse enteral nutrition.

(III) Low implementation rate of the insulin infusion protocol: after the insulin infusion protocol was updated, the training of medical staff was incomplete. Thus, the working group members were unaware of the real causes for the implementation errors, which contributed to the low implementation rate, particularly after the outbreak of COVID-19 in November 2019 when personnel training was restricted. The countermeasure was to revise the training mode of insulin infusion protocol from centralized training mode to online + offline combination training. The updates were to read the protocol online, and the new protocol

was delivered to each nurse's workstation. The working group members were accountable for responding to daily doubts, and the group leader was in charge of summarizing common questions and answering them online. The working group members had one-on-one meetings with those who implemented the incorrect procedures, summarized the common causes, and abdicated from publicly penalizing those who implemented the wrong procedures to avoid resentment.

Do

(I) The working group collected data on the prevalence of hyperglycemia, hypoglycemia, and glucose variability on a monthly basis, identified the causes of hyperglycemia, analyzed the reasons behind each case of hypoglycemia, formulated corresponding measures, and implemented them the following month.
(II) The working group was in charge of training, interpretation, and response following the protocol update, as well as talking to the individuals who executed the incorrect procedures.
(III) The working group assisted the nutrition working group in implementing the nutrition protocol.
(IV) The working group reviewed the data every quarter, compiled the effect of the measures, and further proposed solutions based on the problems. They identified and solved problems using a step-by-step approach to reach the target.

Check

(I) Quarterly data summary and corresponding countermeasures were reported to the EICU quality management team.
(II) Monthly spot checks of measure implementation were conducted by the director and head nurse.

Act

(I) Updated and formulated three editions of the insulin infusion protocol.
(II) Formulated the training method under COVID-19 restrictions.
(III) Promoted the implementation of auxiliary nutrition.

Statistical Methods

All statistical analyses were performed using SPSS 25.0 (IBM Corporation, Armonk, NY, USA). The measurement data were analyzed by variance analysis. $P < 0.05$ was considered statistically significant, and Dunnett's *t*-test was used to compare the means between the different groups. The chi-square test was used to compare enumeration data. If $P < 0.05$, the Bonferroni partition of the chi-square method was used for pairwise comparison with the basic control group, with an adjusted $P < 0.00625$ indicating statistical significance. Hypoglycemia was summarized as the percent of patient days with at least one blood glucose value less than 4.0 mmol/L.

Compliance with Ethics Guidelines

The study protocol was approved by the institutional review board of Third Affiliated Hospital, Wenzhou Medical University. A copy of the written consent is available for review by the Editor of this journal.

RESULTS

The research time was divided into five stages from 1 October 2019 to 31 December 2020 on a quarterly basis. The control stage lasted from 1 October 2019 to 31 December 2019, and the subsequent stages were the first to the fourth stage in turn. During these stages, 1003 patients were included in the study, leading to 10,610 patient days and 102,392 blood glucose time points. There were no significant differences in

Table 1 Baseline information and characteristics of patients

	Control stage	Stage 1	Stage 2	Stage 3	Stage 4	Statistics
Number of patients	244	169	192	194	204	
Men/women	162/82	110/59	127/65	124/70	140/64	NS
Age (years)	59.70 ± 16.41	61.60 ± 17.45	60.80 ± 16.70	60.10 ± 17.20	60.77 ± 17.34	NS
BMI (kg/m^2)	23.28 ± 3.92	23.63 ± 4.42	23.08 ± 3.64	22.93 ± 3.72	23.69 ± 3.78	NS
Diabetes(yes/no)	59/185	39/130	40/152	45/149	47/157	NS
HbA1c (%)	6.18 ± 1.47	6.23 ± 1.80	6.62 ± 3.27	6.31 ± 1.58	6.20 ± 1.31	NS
APACHE-II score	18.84 ± 7.44	19.25 ± 7.44	17.59 ± 7.16	18.78 ± 7.33	18.68 ± 7.22	NS
No/enteral feeding/total parenteral	81/157/6	58/107/4	65/119/8	61/126/7	81/115/8	NS
Mechanical ventilation	212	137	153	158	173	NS
Vasopressor therapy	112	90	98	102	90	NS
Hemodialysis	10	10	8	8	10	NS

Data are presented as numbers as mean ± SD
BMI body mass index, *APACHE-II* acute physiology and chronic health evaluation II

Table 2 Prevalence of hyperglycemia (> 10.0 mmol/L)

	Control stage	Stage 1	Stage 2	Stage 3	Stage 4
≥ 10.0 (mmol/L)	8751 (43.18%)	9367 (42.48%)	7206 (35.54%)	6913 (33.96%)	6342 (32.61%)
< 10.0 (mmol/L)	11,515	12,682	13,068	13,442	13,106
Statistics		NS	$P < 0.001$	$P < 0.001$	$P < 0.001$

the baseline demographics of patients, including basic information, disease severity, and important interventional measures, as presented in Table 1.

Using the PDCA cycle, the prevalence of hyperglycemia gradually decreased from 43.18% to 32.61% (Table 2). However, with an increase in insulin dose, the prevalence of hypoglycemia significantly progressively increased in the first three stages and reached 1.76%. It was lowered to 0.78% in the fourth stage, which was similar to the control stage (Table 3). In the last stage, the occurrence of hypoglycemia did not increase: the prevalence of hyperglycemia declined.

Our protocol had no significant impact on the variability of glucose levels; in each stage, there was no significant alteration in the concentration trend (median and quartile values of mean blood glucose levels in individual patients) and dispersion of glucose (calculate the standard deviation for each patient, and then report the median and interquartile range of standard deviations for the population), as outlined in Table 4.

DISCUSSION

The Plan–Do–Check–Act (PDCA) Cycle, also referred to as the "Quality Cycle," is a general

Table 3 Prevalence of hypoglycemia (< 4.0 mmol/L)

	Control stage	Stage 1	Stage 2	Stage 3	Stage 4
< 4.0 (mmol/L)	16 (0.75%)	21 (0.91%)	23 (1.12%)	36 (1.76%)	16 (0.78%)
≥ 4.0 (mmol/L)	2128	2283	2032	2009	2046
Statistics		NS	NS	$P = 0.0032$	NS

Table 4 Blood glucose variability, central tendency, and measures of dispersion

	Control stage	Stage 1	Stage 2	Stage 3	Stage 4	Statistics
Glucose variability (%)	21.67 (16.37–26.93)	21.42 (17.33–26.71)	20.55 (16.63–27.17)	21.93 (16.77–26.50)	22.00 (17.46–27.00)	NS
IQR (mmol/L)	8.97 (7.82–10.75)	8.98 (7.75–10.70)	8.62 (7.71–10.31)	8.53 (7.61–9.85)	8.74 (7.61–10.25)	NS
SD (mmoL/L)	1.94 (1.31–2.84)	1.88 (1.39–2.81)	1.84 (1.31–2.63)	1.85 (1.27–2.62)	1.90 (1.34–2.71)	NS

Data are presented as median (25th–75th percentile)
IQR interquartile range, *SD* standard deviation

management model dating back to the 1920s. It was initially used in total quality management, and then expanded to various areas of work in many industries. It has been extensively employed in clinical practice as a pivotal approach to improving the quality of clinical nursing. The management system of the entire organization constitutes a large cycle, and each phase of PDCA has its own smaller cycle, resulting in a large-scale, small-ring, interrelated, and mutually restricted scientific cyclic system [11, 12].

According to guidelines, insulin intravenous injection is the gold standard for managing hyperglycemia in critically ill patients. [1]. Therefore, the main measure to lower the prevalence of hyperglycemia is the rational and accurate use of intravenous insulin doses. Although there are multiple international insulin protocols for glycemic control, there is no recognized standard recommendation for insulin dose selection. The most widely used protocol is the Yale protocol. A study comparing the Yale protocol to the one used in the Leuven studies revealed that patients treated under the Yale protocol had superior glycemic control with fewer hypoglycemic events [7]. Hence, our starting dose was modified according to the Yale protocol [13]. Compared with the insulin doses in the literature, we found that it was instrumental to increase the insulin dose in our study. There are many approaches to increasing insulin doses: (1) increasing the initial dose: if the patient's blood glucose is 10.1–12.0 mmol/L, the patient can be initiated on a 2.0 mg/h or 3.0 mg/h dose following a 2.0 mg loading dose; (2) increasing the maintenance dose: if the patient's glucose level reaches the recommended target of 7.8–-10.0 mmol/L, the insulin dose is halved rather than discontinued; and (3) delaying the timing of insulin withdrawal: if the glucose level is lower than 7.8 mmol/L, insulin will not be continued until it drops to 4.4 mmol/L. After repeatedly summarizing and validating the PDCA cycle, the following changes were made to increase the insulin dose compared with the original protocol: (I) pre-load insulin was used when initiating insulin therapy in patients with nutritional support and (II) when the glucose

level dropped < 1.5 mmol/L, the maintenance dose of insulin was increased. To avoid an increase in the incidence of hypoglycemia, the following improvement measures were applied: (I) insulin bolus was exclusively administered to patients on nutritional support; (II) when the glucose level reached 7.8–10.0 mmol/L, insulin was withdrawn if there was no nutritional support; (III) when parenteral nutrition support was discontinued, insulin was withdrawn regardless of the glucose level; and (IV) the insulin dose was halved when the glucose level reached 4.0 mmol/L rather 5.5 mmol/L.

Moderate and uniform intake of carbohydrates is also essential for glycemic control. According to the recommendations of the 2019 ESPEN guidelines, we chose to attain the target energy calories within 3–7 days without exceeding 70.00% in the early stage (48 h) to avoid early use of parenteral nutrition and minimize the excess supplementation of parenteral nutrition [14]. The incidence of hyperglycemia during parenteral nutrition infusion was observed to be high, and the glucose level fluctuated considerably. Discontinuing parenteral nutrition could easily lead to hypoglycemia using the initial insulin regimen. Therefore, we proposed that insulin be withdrawn when discontinuing parenteral nutrition. In addition, the infusion speed of the nutrient solution is an important factor. Herein, the enteral nutrient solution infusion pump was employed to control the infusion speed, allowing for improved insulin dose adjustment.

The insulin infusion protocol formulated by our working group still requires timely and correct implementation by the medical personnel, given that a high implementation rate is a crucial factor. Previous studies have reported the benefits of electronic protocols, but they are also related to the increased workload associated with more frequent measurements and a lower implementation rate [8]. We adopted a simple paper-based approach without relying on special measurement devices, which facilitated the implementation of the protocol. Through the sampling survey, we found that the correct implementation rate during the control stage was 92.32%. However, the outbreak of COVID-19 at the end of 2019 has limited centralized training, discussion, and feedback, resulting in a temporary drop to 91.99%. Through recording videos, training the nursing director, individual conversations, etc., as well as the use of online and offline approaches to encourage the correct implementation process by medical staff, the implementation rate increased to 97.82%.

CONCLUSIONS

In summary, the adjustment in insulin dose, the uniform and reasonable intake of carbohydrates, and the high implementation rate of the insulin infusion protocol have achieved the goal of reducing the prevalence of hyperglycemia without increasing the incidence of hypoglycemia. To the best of our knowledge, this is the first report on using the PDCA cycle to manage and control glucose levels in critically ill patients. The application of effective management methods will aid in standardizing the glycemic control of critically ill patients. We further posit that if the PDCA cycle is adhered to, for example, the insulin regimen is updated according to the amount of carbohydrates in the nutrient solution and the infusion rate, the prevalence of hyperglycemia will keep declining.

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Author Contributions. ZWR and RC and JC were responsible for the study design, literature searched manuscript drafting. JC and WCC and FL and XCC were responsible for the data collection and statistical analysis. ZWR and JC were mainly responsible for the data interpretation. ZWR and RC and JC were responsible for the study concept and critical revision. All authors contributed to the discussion, writing and reviewing the manuscript and all authors have approved the final manuscript.

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Compliance with Ethics Guidelines. The study protocol was approved by the Institutional Review Board of Third Affiliated Hospital, Wenzhou Medical University. The study is conducted in accordance with the Declaration of Helsinki. A copy of the written consent is available for review by the Editor of this journal.

Data Availability. Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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