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Comparative Study of Intravenous Insulin Protocols: Paper-based versus Computer-based

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Abstract

Background: Scientific evidence exists to demonstrate that glycemic control produces a positive outcome for critically ill patients by decreasing mortality and morbidity. Results of published research have revealed a reduction of mortality in critically ill patients when serum blood glucose levels are maintained at a level of less than 150mg/dL. Recommendations from the Surviving Sepsis Campaign for treatment of patients in septic shock include use of intravenous insulin therapy to control hyperglycemia via the use of a validated protocol for insulin dose adjustment. **Purpose:** The purpose of this study was to determine whether glycemic control (less than 150mg/dL) was attained more effectively using an existing Rochester General Hospital Surgical Intensive Care Unit (RGH SICU) paper-based standardized insulin infusion protocol or a computer-based insulin infusion protocol. A secondary purpose was to determine how the use of each protocol affects the incidence of hypoglycemia. **Research Questions:** Is there a difference in the incidence of hypoglycemia (<60mg/dL) between the paper-based protocol and the computer-based protocol? Is there a difference between the paper-based protocol and the computer-based protocol in attaining glycemic control (<150mg/dL)? Is there a relationship between clinician adherence and correct insulin dosage? **Hypotheses:** There will be no relationship between time required to attain glycemic control and protocol used to achieve control. There will be no relationship between the incidence of hypoglycemia and protocol. There will be no relationship between clinician adherence and correct insulin dosage. **Method:** A quantitative, combined retrospective and prospective design was used to review medical records of 60 patients admitted to the SICU at RGH. For the retrospective part of the study, 30 charts were reviewed from 2006, which was prior to the development of the computerized insulin infusion protocol. The prospective part of the study began after the StatStrip Xpress Glucose Hospital Meters had been implemented by RGH. For the retrospective data collection, patients' blood glucose measurements were monitored via the use of the Roche Advantage Accu-Chek Glucometers and Accu-Chek Comfort Curve test strips. The Pharmacy Department supplied the medical record numbers of these patients (n ~ 30). Data collected included age, gender, weight, prior history of diabetes, presenting illness/surgery, serum glucose on admission to SICU, use of vasopressors, use of corticosteroids, use of total parenteral nutrition (TPN) or gastric tube feedings, use of mechanical ventilation and Acute Physiology and Chronic Health Evaluation (Apache II) scores related to illness severity. **Analysis:** Using SPSS 18.0, descriptive statistics were calculated, including measures of central tendency, shape of distributions, and measures of variability. Spearman's correlations were used to determine the relationships between time required to attain glycemic control and protocol used to achieve control, incidence of hypoglycemia. **Results:** The rate of hypoglycemia for patients receiving the paper-based protocol was 10% and 3% for patients receiving the computer-based protocol. Both protocols achieved glycemic control within six hours of initiation of the intravenous insulin protocol. There was a moderately strong relationship (Spearman's rho ~ .667, p ~ 0.01) between clinician adherence and correct insulin dosage with the computer-based protocol, and a moderate relationship (Spearman's rho ~ .424, p ~ 0.05) between clinician adherence and correct insulin dosage with the paper-based protocol. **Conclusions:** The findings of this study did not support the hypothesis that a computer-based protocol is more effective at attaining glycemic control than a paper-based protocol. Although the difference in rate of hypoglycemia was not statistically significant between the paper-based protocol and the computer-based protocol, it was thought to be clinically significant for individual patients' glycemic control. **Dissemination:** Study outcomes were presented to the faculty and students at Wegman's School of Nursing at St. John Fisher College, the Nursing Research and Evidence-Based Practice Department, and the staff and management of the SICU at RGH. **Potential use/impact at RGH:** Both the Pharmacy and Nursing Departments at RGH held stakes in adopting an insulin infusion protocol as a standard of practice. Positive outcomes of this study includes improved glucose monitoring, improved patient outcomes, and decreased SICU length of stay (LOS). **Potential National Contribution:**

Outcomes of this study may reinforce existing evidence related to glycemic control. Hospitals and insurers may benefit financially from improved patient outcomes and decreased LOS.

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Comparative Study of Intravenous Insulin Protocols: Paper-based versus Computer-based

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Submitted in partial fulfillment of the requirements for the degree

M.S. in Advanced Practice Nursing

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Fall 2010

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Abstract

Background: Scientific evidence exists to demonstrate that glycemic control produces a positive outcome for critically ill patients by decreasing mortality and morbidity. Results of published research have revealed a reduction of mortality in critically ill patients when serum blood glucose levels are maintained at a level of less than 150mg/dL. Recommendations from the Surviving Sepsis Campaign for treatment of patients in septic shock include use of intravenous insulin therapy to control hyperglycemia via the use of a validated protocol for insulin dose adjustment.

Purpose: The purpose of this study was to determine whether glycemic control (less than 150mg/dL) was attained more effectively using an existing Rochester General Hospital Surgical Intensive Care Unit (RGH SICU) paper-based standardized insulin infusion protocol or a computer-based insulin infusion protocol. A secondary purpose was to determine how the use of each protocol affects the incidence of hypoglycemia.

Research Questions: Is there a difference in the incidence of hypoglycemia (<60mg/dL) between the paper-based protocol and the computer-based protocol? Is there a difference between the paper-based protocol and the computer-based protocol in attaining glycemic control (<150mg/dL)? Is there a relationship between clinician adherence and correct insulin dosage?

Hypotheses: There will be no relationship between time required to attain glycemic control and protocol used to achieve control. There will be no relationship between the incidence of hypoglycemia and protocol. There will be no relationship between clinician adherence and correct insulin dosage.

Method: A quantitative, combined retrospective and prospective design was used to review medical records of 60 patients admitted to the SICU at RGH. For the retrospective part

of the study, 30 charts were reviewed from 2006, which was prior to the development of the computerized insulin infusion protocol.

The prospective part of the study began after the StatStrip Xpress Glucose Hospital Meters had been implemented by RGH. For the retrospective data collection, patients' blood glucose measurements were monitored via the use of the Roche Advantage Accu-Chek Glucometers and Accu-Chek Comfort Curve test strips. The Pharmacy Department supplied the medical record numbers of these patients ($n = 30$). Data collected included age, gender, weight, prior history of diabetes, presenting illness/surgery, serum glucose on admission to SICU, use of vasopressors, use of corticosteroids, use of total parenteral nutrition (TPN) or gastric tube feedings, use of mechanical ventilation and Acute Physiology and Chronic Health Evaluation (Apache II) scores related to illness severity.

Analysis: Using SPSS 18.0, descriptive statistics were calculated, including measures of central tendency, shape of distributions, and measures of variability. Spearman's correlations were used to determine the relationships between time required to attain glycemic control and protocol used to achieve control, incidence of hypoglycemia.

Results: The rate of hypoglycemia for patients receiving the paper-based protocol was 10% and 3% for patients receiving the computer-based protocol. Both protocols achieved glycemic control within six hours of initiation of the intravenous insulin protocol. There was a moderately strong relationship (Spearman's $\rho = .667$, $p = 0.01$) between clinician adherence and correct insulin dosage with the computer-based protocol, and a moderate relationship (Spearman's $\rho = .424$, $p = 0.05$) between clinician adherence and correct insulin dosage with the paper-based protocol.

Conclusions: The findings of this study did not support the hypothesis that a computer-based protocol is more effective at attaining glycemic control than a paper-based protocol. Although the difference in rate of hypoglycemia was not statistically significant between the paper-based protocol and the computer-based protocol, it was thought to be clinically significant for individual patients' glycemic control.

Dissemination: Study outcomes were presented to the faculty and students at Wegman's School of Nursing at St. John Fisher College, the Nursing Research and Evidence-Based Practice Department, and the staff and management of the SICU at RGH.

Potential use/impact at RGH: Both the Pharmacy and Nursing Departments at RGH held stakes in adopting an insulin infusion protocol as a standard of practice. Positive outcomes of this study includes improved glucose monitoring, improved patient outcomes, and decreased SICU length of stay (LOS).

Potential National Contribution: Outcomes of this study may reinforce existing evidence related to glycemic control. Hospitals and insurers may benefit financially from improved patient outcomes and decreased LOS.

Chapter I

Introduction

A 2001 study by Van den Berghe et al. concluded that intensive insulin therapy in critically ill patients decreases morbidity and mortality. This large (N= 1548) prospective, randomized, controlled study was conducted in a surgical intensive care unit. Findings demonstrated a reduction of mortality from 8% with conventional therapy to 4.6% with intensive insulin therapy. Evidence-based recommendations derived from the Surviving Sepsis Campaign (Dellinger, et al., 2004) included use of intravenous insulin therapy to control hyperglycemia for patients in septic shock. The authors stated that the goal of therapy is to keep blood glucose below 150 mg/dl via the use of a validated protocol for insulin dose adjustment (Dellinger et al., 2004).

Stress Theory was described in the 1930s by Hans Selye. Stress was defined as the sum of all non-specifically induced changes in a biologic system. By the 1970s, according to Viner (1999), science redefined stress as “an accepted element of common human experience that promised new methods of understanding and fighting disease elements” (p.392). The concept of stress allows man a scientific way to explain failure and disease. Stress Theory identifies three phases of stress: the alarm phase (or “fight or flight” response), the adaptation phase (resistance), and the exhaustion phase. During the alarm phase, the sympathetic nervous system is activated, and natural fats and sugars are actively produced to supply the body with extra energy. This reaction results in an upward shift of serum glucose levels. Stress causes physiological responses in the human body and, if these responses are not mediated and continue for prolonged periods, they will cause permanent damage or death (Viner, 1999).

Recently, the healthcare community has studied two types of insulin protocols, paper-based and computer-based, to determine which provides superior glycemic control for intensive care (ICU) patients. The operationalization of paper-based protocols has a human factor that computer-based protocols do not have. Using the computer-based protocol, data are entered into a computer program that calculates the rate of the insulin drip. With paper-based protocols, the nurse adjusts the insulin drip according to written protocol. It is believed that nurses use personal judgment in adjusting the insulin drip (Rood, Bosman, Van Der Spoel, Taylor & Zandstra, 2005). In this study, the researcher determined which protocol, paper-based, or computer-based, was more effective for rapidly attaining glycemic control, with a lower incidence of hypoglycemia.

Background

Scientific evidence exists to demonstrate that glycemic control has the potential to produce a positive outcome for critically ill patients by decreasing the risk for mortality and morbidity. Results of published research have revealed a reduction of mortality in critically ill patients when serum blood glucose levels are maintained at a level of less than 150mg/dL. Recommendations from the Surviving Sepsis Campaign for treatment of patients in septic shock include use of intravenous insulin therapy to control hyperglycemia via the use of a validated protocol for insulin dose adjustment (Dellinger, et al., 2004).

In 2006, the American Association of Critical Care Nurses (AACN) published a practice alert for severe sepsis. The practice alert is divided into five sections: expected practice, supporting evidence, education, AACN grading of evidence system (Level I to VI) and references. Maintaining glucose levels less than 150mg/dL for patients with severe sepsis is a Level V recommendation.

Recommendations were supported by evidence-based results in clinical studies involving more than one or two patient populations and situations.

Theoretical Framework

A patient's admission to the SICU during hospitalization, whether due to a complex surgical procedure or complications following a surgical procedure, renders the patient unable to care for himself. Orem's Self-Care Deficit Nursing Theory proposes that there are many internal and external sources in a patient's health status that would limit the patient's ability to care for himself (Parker, 2006).

The profession of nursing is based upon the ability to plan and provide this care when patients are unable to provide it for themselves. Indeed, the very definition of nursing, according to the American Nurses Association (ANA), includes the "optimization of health and abilities, prevention of illness and injury..." (ANA, 2004). Findings from evidence-based research have demonstrated that serum blood glucose levels maintained below 150mg/dL result in decreased patient mortality and morbidity in the SICU. In critically ill patients, the use of insulin infusions and frequent monitoring of serum blood glucose is imperative to achieving this goal. In this research project, an examination was undertaken to determine which protocol, paper-based or computer-based, attained glycemic control (less than 150mg/dL) more rapidly, and how the use of each protocol affected the incidence of hypoglycemia.

Purpose Statement

The purpose of this study was to determine whether glycemic control (less than 150mg/dL) was attained more effectively using an existing Rochester General Hospital Surgical Intensive Care Unit (RGH SICU) paper-based standardized insulin infusion protocol or a computer-based insulin infusion protocol. A secondary purpose was to determine how the use of each protocol affected the incidence of hypoglycemia.

Variables

The dependent variable for the proposed study was hyperglycemia. The operational definition for hyperglycemia was blood glucose greater than 150 mg/dL. The independent variables were computer-based insulin infusion protocol and paper-based insulin infusion protocol. The operational definition of a computer-based insulin infusion protocol was data entered into a computer program that calculated the rate for the insulin infusion. The operational definition of the paper-based insulin infusion protocol was a preprinted physician order sheet for the insulin infusion protocol to be administered by the nurse. Extraneous variables included nurse adherence to either protocol, timing of blood glucose testing, the type and extent of the patient's disease, and whether the patient was receiving total parenteral nutrition.

Summary

The goal of this study was to determine whether a difference exists between patient outcomes when a paper-based insulin infusion protocol or a computer-based insulin infusion protocol was used to attain glycemic control with less risk of hypoglycemia. Arguments can be made for and against each protocol. The paper-based insulin infusion protocol uses the nurse's judgment and human error may occur. Although computer software is believed by many to be more accurate, this may not always be true. In 2007, the National Institutes of Health (NIH) issued a statement regarding an article published in the New England Journal of Medicine regarding the use of Computer-Aided Detection (CAD), which is computer software for the interpretation of mammograms. Though the software was designed to aid radiologists in the interpretation of mammograms, it actually made readings less accurate. Researchers concluded that women who had undergone testing at centers with CAD devices were more likely to be given false positive results and to have undergone unnecessary biopsies. The authors of the

study concluded that more studies were needed prior to the widespread application of the software (Fenton, et al., 2007).

According to an abstract published in the program proceedings of the Society of Critical Care Medicine's 39th Critical Care Congress, a small study (N= 192) was conducted to test glucose variability in a surgical intensive care unit. Although 192 patients were enrolled, only 47 were assigned to the computer-assisted group. The authors concluded that, although the computer-assisted protocol led to minor improvements in glucose control and a decrease in glucose variability, the overall rate of severe hypoglycemia and response to insulin therapy was not improved. The authors suggested that further studies are needed to evaluate the full benefit of their findings (Barletta, et al., 2009). However, there appeared to be blatant sampling bias in this study which leads to questions concerning the existence of a Type II error, and the validity of the conclusions.

Findings from evidence-based research have demonstrated that achieving glycemic control is an important and necessary step in caring for critically ill patients. The most effective way to achieve glycemic control, though, is a matter that researchers continue to investigate.

Chapter II

Introduction

Research methods into glycemic control in critically ill patients have undergone many changes since the landmark study conducted by Van Den Berghe et al. in 2001. These investigators determined that tight glycemic control reduces mortality and morbidity in ICU patients. Other researchers questioned the recommendations for blood glucose levels in the Van Den Berghe study and proposed levels of less than 150mg/dL. As research efforts in this area have progressed, new areas of inquiry have emerged, including explanations for an increase in staff workload and lack of adherence due to difficulties in the interpretation of protocols. A frequent conclusion found in these studies is that most incidences of hypoglycemia and hyperglycemia result from clinicians' lack of adherence to insulin infusion protocols. These issues have led to a new area of study- the protocol itself. Will a computer-based insulin infusion protocol versus a paper-based insulin infusion protocol attain glycemic control more rapidly while promoting improved adherence by staff?

Literature Search

The databases used to search for literature were CINAHL, MEDLINE, SAGE, COCHRANE and OVID. Key words used in the literature search were “intensive care unit, insulin protocols and intensive insulin therapy.” The search was limited to full text, English language, research, and research conducted between the years of 2000 to 2010.

Literature Review

The landmark study by Van Den Berghe et al. (2001) was conducted on 1548 critically ill SICU patients. The investigators concluded that intensive protocol-based insulin therapy reduced mortality and morbidity by keeping serum glucose values between 80-110 mg/dL via

intravenous insulin infusions. A new set of practice standards was developed as a result of the findings of this study.

In 2005, a randomized, controlled trial with an off-on-off design was conducted by Rood, Bosman, Van Der Spoel, Taylor, and Zandstra. A paper-based glucose regulation guideline was developed in an intensive care unit during the first study period, which lasted for six weeks. During the second study period, which lasted ten weeks, the guideline was randomly applied to either the paper-based guideline or a computerized guideline. In the third and final study period, which lasted four weeks, only the paper-based guideline was applied. The authors stated that findings have demonstrated that adherence to guidelines is low, particularly with a paper-based guideline, despite evidence demonstrating that implementation of the guidelines improved the quality of care. A number of reasons were given for the lack of adherence: poor explanation of the guidelines, lack of agreement regarding the content of the guidelines, and low outcome expectancy by clinicians. On completion of the study, the authors concluded that adherence was considerably improved with the use of the computerized version of the guidelines, as significant improvement in adherence to the timing of glucose measurements and dosing of insulin was demonstrated, thereby improving glucose regulation.

In 2006, the New England Journal of Medicine published an article focusing on drug therapy in the management of sepsis, including intensive insulin therapy in critically ill patients (Russell, 2006). The author concluded that the appropriate glucose range and insulin dosage in septic patients remains uncertain, and emphasized that results of research have demonstrated that there is a difference between the insulin needs of critically ill surgical and medical patients. Questions also were raised regarding the correlation between the length of stay in the intensive

care units (ICU) and intensive insulin therapy. Russell cited the 2001 Van den Berghe study and concluded that mortality was decreased in patients with a length of stay in the ICU of less than three days, but that mortality actually increased in patients with length of stay greater than five days. In addition, a response editorial written by the authors of the Van den Berghe study addressed the conclusions reached by Russell, the article's author, and provided data that supported the Van den Berghe findings. Russell responded to the editorial by stating that the findings were hypothesis-generating, and indicated the need for further research to examine the association between lengths of stay in ICU and intensive insulin therapy in septic patients (Russell, 2006).

In an article by Rea et al. (2007), the authors discussed the implementation of three different insulin protocols in intensive care units at two community hospitals and one academic medical center. The authors concluded that, although studies have shown that tight glycemic controls have a positive effect on patient outcomes, there were obstacles encountered during the implementation of insulin protocols. These obstacles included increased staff workload, difficulties in interpretation of the algorithm, and lack of perceived benefits. They also compared the details of the insulin protocols at the two different types of institutions and concluded that the differences were influenced by the type of institution. These differences in the implementation of the protocols included initial physician response to the protocol, the details of the protocol, nursing staff autonomy, and the involvement of nursing staff at the early stage of protocol development. Two paper-based insulin protocols were used in the Rea et al. study. One protocol was detailed. The other protocol was less detailed, requiring the nurses to exercise more clinical judgment. The authors believed that experienced nurses would prefer the less detailed protocol while less experienced nurses would prefer more guidance.

Rea et al. compared their findings with the study conducted by Van Den Berghe, and concluded that the Van Den Berghe insulin infusion protocol allowed more autonomy for nurses in initiating insulin therapy. The authors believed that the institutions involved in their own study successfully implemented the insulin protocol, and that adherence by nurses and physicians was achieved. Factors that aided in the success of the implementation were multidisciplinary involvement, continuous education of the nursing staff, vigilant involvement of the pharmacist and flexibility in revising the protocol.

In a more recent study, Dortch et al. (2008) evaluated the degree of glucose control using manual paper-based versus a computer-based insulin protocol in a trauma intensive care unit. This cohort study involved 552 critically ill patients. Fisher's exact test was used to compare the two protocols and the glucose values in a target range of 80-110 mg/dL. The protocols also were compared related to incidence of hyperglycemia (greater than 150 mg/dL) and hypoglycemia (less than 40 mg/dL). The sample was divided into two groups: a group of 309 patients managed with the paper-based protocol, and a group of 243 patients managed with the computer-based protocol. The total number of blood glucose values obtained from both groups was 21,178. The authors concluded that, even though the admission blood glucose was higher in the computer-based group (170 vs. 152 mg/dL), glucose control was superior when the computer-based protocol was used. In the computer-based protocol, there was a higher percentage of glucose values in the 80- 110mg/dL range (41.8% vs. 34.0%), less hypoglycemia (0.2% vs. 0.5%), and less hyperglycemia (12.8% vs. 15.1%).

In 2006, Taylor et al. published a three-part study on the efficacy of utilizing an insulin protocol. The study was conducted over three nonconsecutive six month periods. The period between phases allowed the multidisciplinary team the time to develop the next phase of the

study. The first phase was pre-intervention, and patients (N = 71) received a physician-initiated insulin infusion without a protocol in place. In the second phase, patients (N= 95) received a nurse-driven insulin infusion protocol with a target blood glucose (BG) of 120 to 150mg/dL. During the third phase, patients (N= 119) also received a nurse-driven insulin infusion protocol, but the target BG was lowered to 80 to 110mg/dL. The authors explained that the study was designed with three phases to address concerns regarding increasing the risk of hypoglycemia. After phase two was completed without an increase in hypoglycemia, the target range of the protocol was tightened. Results showed a significant decrease in time to achieve the target BG, with a similar incidence of occurrences of severe hypoglycemia within all three phases. Protocol safety and compliance were evaluated during each phase. The authors noted that while insulin infusion protocols increase nursing workload, the incidence of hypoglycemia notably coincided with protocol nonadherence. The authors concluded that the protocols were successful in achieving rapid and effective BG control without an increase in complications (Briggs & Cornell, 2004).

Kanji, Singh, Tierney, Meggison, McIntyre, & Hebert (2004) conducted a combined retrospective-prospective before-after cohort study to evaluate the efficacy and safety of a nurse- managed insulin protocol in critically ill adults. The first control cohort (N=50) received insulin infusions titrated according to target BG ranges and sliding scales at the physician's discretion. Patients in the second cohort (N=50) received an adjusted insulin infusion, using a standardized protocol, with a goal BG of 81 to 110mg/dL. The authors determined efficacy by measuring the amount of time it took to reach the goal and the time spent within the target range. Safety was measured by comparing the incidences of severe hypoglycemia, though hypoglycemia was defined differently for each cohort. Results demonstrated that patients in the interventional cohort reached the target blood glucose faster and maintained their blood glucose

within the target range longer. The control cohort had four times more incidence of severe hypoglycemia that required treatment of rescue dextrose to correct. The authors found that the workload of the bedside nurse increased by 35% due to the increased frequency of glucose monitoring with the interventional protocol, although they stated that the nurses were less likely to deviate from the protocol in the interventional cohort than the prescribed titration levels in the control cohort. The authors concluded that the development of a standardized insulin infusion protocol improves the efficacy and safety of glycemic control in critically ill patients.

Oeyen, Hoste, Roosens, Decruyenaere, & Blot (2007) conducted a prospective observational study to evaluate the efficacy and safety of an insulin protocol developed to improve the care of critically ill patients (N =30). The investigators' aim was to determine factors linked with maintaining adequate glucose control and utilized a target range of 81 to 110 mg/dL. The authors did not develop their own protocol, but chose instead to utilize the protocol developed by Van den Berghe et al. The study began after a one hour lesson and a four week trial period of utilizing the protocol. Physicians were given clear instructions that this was to be nurse-driven and to refrain from interfering with decisions regarding insulin infusion rates. If physicians were consulted regarding severe hypoglycemia, they were to utilize the protocol to guide their answers. Both physicians and nurses were not made aware of the observational component of the study. Adherence to and safety and efficacy of the insulin protocol were evaluated and linear regression analysis was used to determine factors related to acceptable blood glucose control. The authors concluded that maintaining BG in the target range was positively associated with protocol adherence. Of the 1,749 deviations from the protocol, only 87 were for warranted reasons. The authors stated that many nurses voiced concerns about causing hypoglycemia. Sixty percent of patients experienced at least one hypoglycemic event, and the investigators concluded that target ranges of 81 to 110mg/dL may be too difficult to

maintain in critically ill patients, and thus, would not recommend this range. However, they did state that perhaps the use of a computerized protocol could improve adherence and efficacy.

Alm-Kruse, Bull and Laake (2007) conducted a study on a nurse-led implementation of an insulin infusion protocol in an adult combined medical/surgical intensive care unit. The objective of the study was to evaluate the present degree of glycemic control, and to implement and evaluate an intensive insulin protocol. The study was conducted over a 32-month period, and was composed of two parts. The first part (N=494) consisted of a retrospective data collection of all arterial BG results obtained over a 20-month period prior to the implementation of a insulin protocol. The second part (N=448), which lasted 12 months, began with the prospective implementation of an algorithm for intensive insulin therapy. Statistical analysis was used to assess performance of the protocol, provide feedback for improvements, and uncover any incidences of hypoglycemia.

The retrospective part of the study showed that a considerable amount of improvement in practice was needed. Following implementation of the algorithm, a 12.8% improvement was observed in achieving strict glycemic control. Although there was a significant increase in episodes of hypoglycemia, the authors believed that continued efforts to revise the protocol and educate staff to increase confidence in utilizing the protocol would improve glycemic control.

In a 1-month retrospective chart review of 72 patients, Cyrus, Szumita, Greenwood and Pendergrass (2009) assessed compliance with a paper-based, multiplication-factor, intravenous insulin protocol. The investigators examined compliance with the protocol, and its resultant safety and efficacy. Results demonstrated very low compliance with the protocol. The authors noted multiple factors which could have affected compliance, including varying degrees of comfort levels by nursing staff in adhering to the protocol. Although the protocol had been in

effect for eight months prior to the study, the institutional protocol in place was a fixed-dose protocol with a more liberal glucose range. The authors also questioned the accuracy and reliability of point-of-care testing and believed it also was a barrier to glycemic control. The authors stated that they did not take into consideration the daily workload of ICU nurses, who care for critically ill patients, and identified other obstacles to providing optimal glycemic control, such as the nurses level of comfort with the protocol and the reliability of point-of-care testing in critically ill patients. The authors recommended searching for solutions to the obstacles that prevent compliance with the use of a computerized intravenous insulin protocol, and concluded that “computerized protocols have shown to be a simple, safe, and effective way to provide glucose control in the ICU setting (p. 1417).”

Critique of studies

Based on the review of literature, the subject of strict glycemic control is a controversial topic. The 2001 Van den Bergh study was the first to raise questions about strict glycemic control and to demonstrate that strict glycemic control reduces mortality in the ICU. Further research challenged not the findings of reduced mortality, but rather 80 to 110mg/dL as the target range for BG. The authors of the Surviving Sepsis Campaign recommended using 150mg/dL or less as the target blood glucose. Evidence showed that use of this target would help to avoid an increased risk of prolonged hypoglycemia. There was no consensus among investigators in the reviewed studies that either the paper-based insulin infusion protocol or the computer-based insulin infusion protocol was better in controlling BG, although all agreed that glycemic control was essential in the care of critically ill patients.

Proposal for further research

A common topic in recent research literature is adherence to insulin infusion protocols by nursing staff and the increased nursing workload that accompanies the implementation of an

insulin infusion protocol. After becoming aware of the increased workload and the lack of adherence to the protocol, many physicians have included nurses in the development and revisions of insulin infusion protocols. In a 2008 interdisciplinary collaborative study by Holzinger, Feldbacher, Bachlechner, Kitzberger, Fuhrmann and Madl, investigators stated that “collaboration of physicians and nurses guaranteed that the protocol not only met the medical requirements, but was also practical (p. 155).” Findings from this review of literature suggest that the development of a computer-based insulin infusion protocol must involve collaboration between nurses and physicians.

Chapter III

Method

The purpose of this study was to determine whether glycemic control (less than 150mg/dL) was attained more effectively using an existing Rochester General Hospital Surgical Intensive Care Unit (RGH SICU) paper-based standardized insulin infusion protocol or a computer-based insulin infusion protocol. A secondary purpose was to determine how the use of each protocol affects the incidence of hypoglycemia.

Research Questions

Is there a difference in the incidence of hypoglycemia (<60mg/dL) between the paper-based protocol and the computer-based protocol? Is there a difference between the paper-based protocol and the computer-based protocol in attaining glycemic control (<150mg/dL)? Is there a relationship between clinician adherence and correct insulin dosage?

Hypotheses

There will be no relationship between time required to attain glycemic control and protocol used to achieve control. There will be no relationship between the incidence of hypoglycemia and protocol. There will be no relationship between clinician adherence and correct insulin dosage.

Design

A quantitative mixed retrospective and prospective design was used to review medical records of patients who had been admitted to the surgical intensive care unit (SICU) at Rochester General Hospital (RGH). A retrospective chart review was conducted on patients (N=30) admitted to the SICU at RGH in 2006, prior to the development of the computer-based insulin infusion protocol. Patients' blood glucose measurements were monitored via the use of the Roche Advantage Accu-Chek Glucometers and Accu-Chek Comfort Curve test strips. The

Pharmacy Department supplied the medical record numbers of these patients (n = 30). The prospective chart review was conducted on patients (n=30) admitted to the SICU at RGH after an institution- wide glucometer change to the Nova StatStrip Glucose Hospital Meter in April 2010, and the exclusive use of the computer-based insulin infusion protocol. A data abstraction tool (see Appendix I) was used to collect the following data: age, gender, weight, prior history of diabetes, presenting illness/surgery, serum glucose on admission to SICU, use of vasopressors, use of total parenteral nutrition (TPN) or gastric tube feedings, steroid use, use of mechanical ventilation and the APS of the Apache II scores related to illness severity between the two groups and statistically significant differences was sought.

Letters of support were obtained from the medical director of SICU, the Chief Nursing Officer of RGH, the nurse manager of SICU, the clinical pharmacist of SICU and the lead physician assistant of SICU (see Appendix II).

Sample/Setting

This study was a curriculum requirement towards a graduate degree in advanced practice nursing. Due to time constraints, a decision was made to keep the sample size at 30 for each protocol. Medical records (n=30) were reviewed, and data were abstracted from former patients of the SICU at RGH admitted during 2006, prior to the implementation of the computer-based insulin infusion protocol, who had been treated with an intravenous insulin infusion. Medical records for patients (n=30) who had been treated with an intravenous insulin infusion, admitted after the StatStrip Xpress Glucose Hospital Meters and the computer-based insulin infusion protocol have been implemented, were reviewed and similar data were abstracted,

Inclusion Criteria

For the retrospective review, patients (n=30) admitted to the SICU at RGH in 2006 who were treated with the paper-based intravenous insulin infusion protocol were included. For the

prospective review, patients (n=30) admitted to the SICU at RGH after April 2010 who were treated with a computer-based intravenous insulin infusion protocol were included.

Exclusion Criteria

Patients in the SICU at RGH who had not required an intravenous insulin infusion were excluded. Patients also were excluded when an order for an intravenous insulin infusion had been written, but discontinued prior to the start of the infusion.

Instruments

The Glucometer is a medical device used to determine the approximate concentration of glucose in the blood. Patients whose glucose is kept within the normal range of 80-110 mg/dl typically have a reduced risk of complications associated with diabetes. The Food and Drug Administration (FDA) requires that all glucometers have an error rate of less than 20%. The American Diabetes Association (ADA) prefers that the error rate be less than 10% at the same blood glucose levels (Briggs & Cornell, 2004).

The accuracy and reliability of point-of-care glucose testing and the impact of sample source was the subject of a study conducted by Karon et al. (2007). This study used the Roche Accu-Chek glucose monitoring system and the Accu-Chek Comfort Curve test strip. Evaluation and precision reports of the Accu-Chek Comfort Curve test strip and the Accu-Chek glucometers were obtained directly from Roche Diagnostics (2002), as were the Field Hematocrit Evaluation Protocol and the accuracy reports of the Accu-Chek Comfort Curve test strip, which used both capillary and arterial blood. In the study conducted by Karon et al. (2007), statistical analysis included use of generalized estimating equations (GEE), which adjusts for variances grouped within patients. The authors found little variation within patients. Although there was significant variation between patients, the authors believed that the GEE was the best way to account for this variation.

The authors also noted different results for plasma glucose measurement in each of the arterial, capillary and venipuncture glucose measurements, with $p \leq 0.2$, indicating the presence of significant bias. The authors also compared correlations among laboratory plasma glucose and capillary, arterial and venous whole blood glucose values by utilizing the Shrout-Fleiss fixed set intraclass correlation coefficient (ICC). The authors described ICC as similar to the Pearson correlation coefficient, with the exception that the ICC takes into account the systematic differences and multiple observations per patient and can be interpreted as a chance corrected index of agreement. Unlike the ICC, the Pearson correlation coefficient disregards the systematic differences and assumes that all observations are independent. The authors listed the ICC benchmarks described by Landis and Koch (1977), with 1.0 indicating a perfect agreement (as cited in Karon et al., 2007). Finally, a power analysis was performed prior to the study to show how many patients were needed to achieve 90% power to detect a difference of 10mg/dl. The power analysis assumed an overall type I error rate of 0.05 and a correlation of 0.8 among the glucose measurements (Karon et al., 2007).

In 2009, a decision was made by RGH to convert all handheld glucometers to the Nova StatStrip, and a system wide change was completed by April 2010. Mandatory classes were provided by the manufacturer for all staff who utilized the glucometers within their scope of practice, and each department had additional staff trained as “super users” to provide additional assistance once the system change took place.

Since the time of introduction of the Advantage AccuChek glucometers at RGH, manufacturers have attempted to make the handheld device more accurate and easier to use. Studies have been conducted to evaluate glucometers for performance and suitability for use in critical care areas. The AccuCheck and Nova StatStrip were similar in many categories that were tested, however, the Nova StatStrip was found to be superior when tested against common

agents including sample Hematocrit, which could interfere with the accuracy of the results. The authors of the studies believed that this would allow for better management of critically ill patients on glycemic control protocols (Scott, et al., 2007; Karon, et al., 2008; Chan, Rozmanc, Seiden-Long, & Kwan, 2008).

According to Polit and Beck (2004), validity is the degree by which an instrument measures what it is intended to measure. The glucometer was created to simplify the method for diabetics to test and treat their blood glucose. The glucometer is valid because it does, in fact, measure what it is intended to measure, i.e. serum blood glucose. Measurement of instrument reliability has been achieved in the following manner: when the glucometers were first introduced into the Rochester General Health System, a validation study was carried out by manufacturer field support personnel with the assistance of hospital laboratory and nursing staff. This study was conducted to examine the precision, linearity and accuracy of the glucometers and test strips. In the hospital, quality controls must be performed by the nursing staff every twenty-four hours on two levels, high and low, or the glucometers will not function. Annual staff competencies are performed on the use of the glucometers. Staff must be certified as competent, or they will be locked out of the system and unable to utilize the glucometers (Gretchen Smith, personal communication, 2007).

Procedures

Since this was both a retrospective and prospective review, no patient contact occurred. For the retrospective data collection, a list of identifiers was delivered by email to the PI by Kevin Silinskie, the clinical pharmacist for RGH SICU. Once the list of identifiers was obtained, copies of the list and the Clinical Investigation Committee (CIC) approval letter was given directly to the supervisor of Human Information Management (HIM). Once the charts were available, the supervisor called the PI, and the charts were placed on a separate shelf that

was labeled with the name of the PI. Charts remained in HIM until the chart review was completed and the PI placed the charts on the return shelf. Most charts have multiple volumes and were marked only with the identifiers name and were not always in the same stack. Requests had to be made to the supervisor if chart sections were missing and the chart was held until all sections were made available. All data were collected on an investigator-developed data abstraction sheet, and data abstraction was done within the HIM department. Depending on the volume of information, data abstraction took 15 to 30 minutes. Physician orders were reviewed first to ascertain the order for the intravenous insulin infusion and the date and time were noted. A log sheet was maintained on every chart that was reviewed and whether the chart was accepted or not accepted. Patients in the SICU at RGH who had not required an intravenous insulin infusion were excluded. Patients also were excluded when an order for an intravenous insulin infusion was written, but discontinued prior to the start of the infusion.

Human Subject Protection

All patient-related information was de-identified and aggregated to assure that no individual subject could be identified. Data were entered into computer files using a study-generated identification number. At the time of retrospective medical record review, each study subject was assigned a code number. No individual identifiable data were reported. Only the investigator had access to the study files and data. Data were maintained in a location separate from the master code number ID list. The computer files containing data was password protected. The investigator had been thoroughly trained in issues of confidentiality and had successfully completed the mandated St. John Fisher College IRB training concerning the ethical treatment of research subjects. IRB consent was obtained from St. John Fisher College, Department of Nursing Research and Evidence-Based Practice and the Rochester General health System Clinical Investigation Committee (see Appendix III).

Data Preparation

Data were abstracted from medical records and entered into Statistical Package for the Social Sciences (SPSS) 18.0 by the principal investigator (PI). Double entry was used to ensure a high level of accuracy.

Data Analysis

Descriptive statistics were calculated, including measures of central tendency, shape of distributions, and measures of variability. Spearman's correlations were used to determine the relationships between time required to attain glycemic control and protocol method used to achieve control, incidence of hypoglycemia and protocol method.

Conclusion

Although the definition of glycemic control still sparks debate, both the medical and nursing professions acknowledged its importance in decreasing mortality and morbidity in critically ill patients. Results of recent studies have demonstrated that the use of an intravenous insulin protocol is the most effective method for achieving this goal. Will the use of a computerized intravenous insulin protocol achieve this goal faster and with less risk of hypoglycemia than with the use of a paper-based insulin infusion protocol? Additionally, will the use of a computerized intravenous insulin protocol promote adherence by having an effect on the workload of nurses?

Chapter IV

Rochester General Hospital (RGH), part of the Rochester General Health System (RGHS), is a 528 bed, acute care teaching hospital. In 2004, RGH became a Magnet designated organization. Magnet designation is awarded by the American Nursing Credentialing Center (ANCC) and is the gold standard for nursing practice. RGH also is affiliated with the Cleveland Clinic and has developed partnerships with Roswell Park Cancer Institute and Rochester Institute of Technology. Through these affiliation and partnerships, RGH has wider access to research and programs that have allowed it to become a center of excellence in cardiology, cancer treatment, orthopedics and rehabilitation, women's and children's health, primary care, surgery and behavioral health.

RGH has three separate intensive care units, surgical/neurologic, cardiothoracic and medical/coronary care with a total of 52 beds. The staff of the surgical/neurologic intensive care unit (SICU) is comprised of a multi-professional team that includes a critical care Intensivist, nurse practitioners, physician assistants, registered nurses, a clinical pharmacist, a registered dietician and a respiratory therapist. Support staff includes physical therapy, occupational therapy, speech therapy, radiology, social work and pastoral care.

In 2007, the SICU was awarded the Excellence in Collaboration Award by the American Association of Critical Care Nurses (AACN) for the development and implementation of a daily patient care goals sheet. The goals sheet was developed by a multidisciplinary team to address high risk clinical concerns and to improve patient outcomes.

In 2008, Jonathan Scott, lead physician assistant (PA), was presented with the "Adjunct Staff Award for Clinical Excellence". His work was pivotal in the creation of the early goal directed sepsis bundle. At the 2010 Society of Critical Care Medicine 39th Congress, Jonathan

Scott and Kevin Silinskie, clinical pharmacist for SICU, presented “Before–After Study Evaluating the Impact of an Analgesia and Sedation Protocol in Critically Ill Surgical Patients.”

As well, the SICU nursing staff has developed an early mobility protocol to enhance patient care, and to improve patient satisfaction and outcomes. Their 2010 Patient Safety Project was designed to decrease the number of urinary tract infections (UTI).

Demographics

The Statistical Package for Social Sciences for Windows, Version 18.0 (SPSS, 18.0, Chicago, Il.) was utilized for data analysis. Demographic data collected for both protocols demonstrated consistencies in findings. These similarities were representative of demographic characteristics of the region and patients admitted to this SICU. The mean age for subjects in the computer-based protocol group was 63 years, (Figure 4.1) with men comprising 67% of the sample. In the paper-based protocol group, the mean age was 67 years, (Figure 4.2) with men comprising 53% of the sample (Figure 4.3).

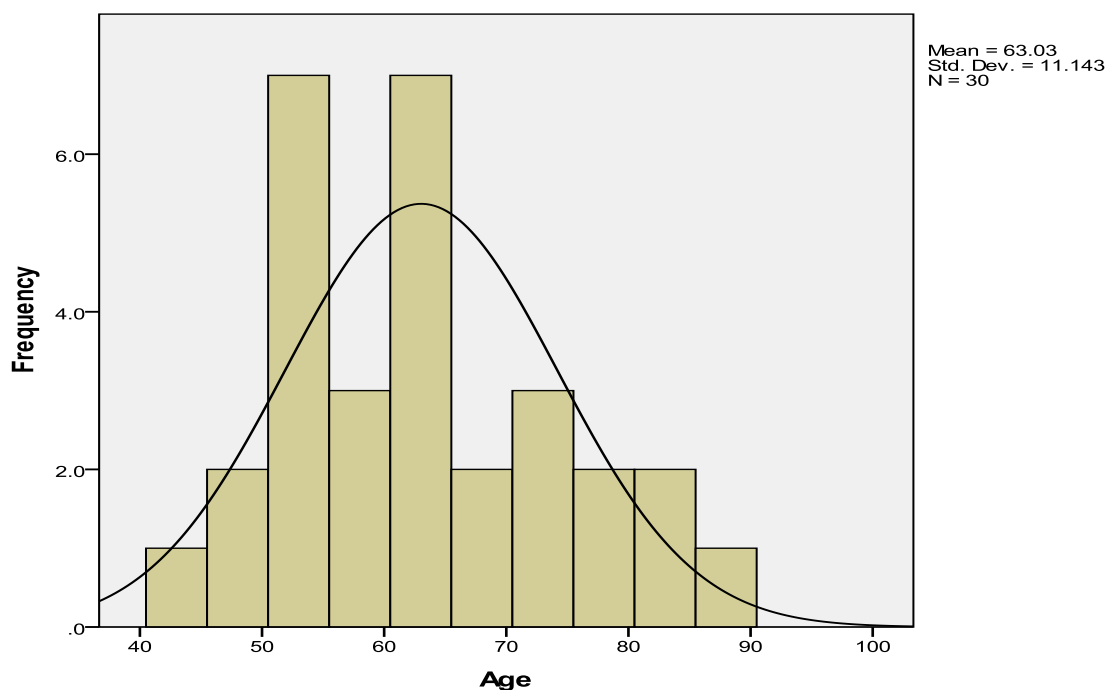


Figure 4.1 Distribution by Age (Computer-Based Protocol)

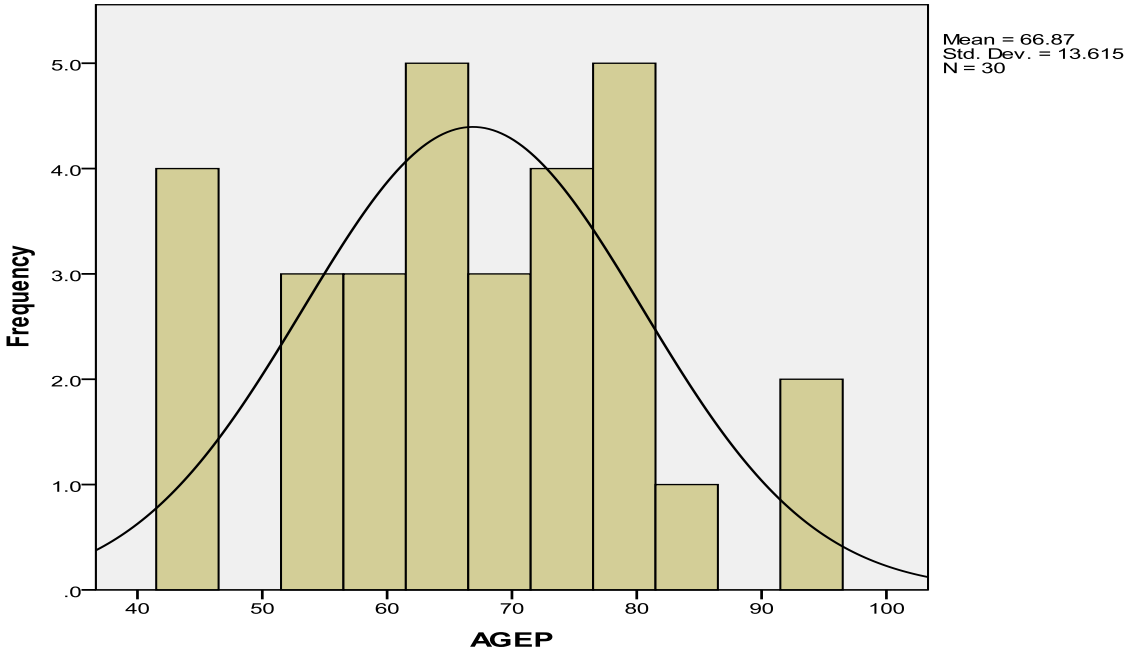
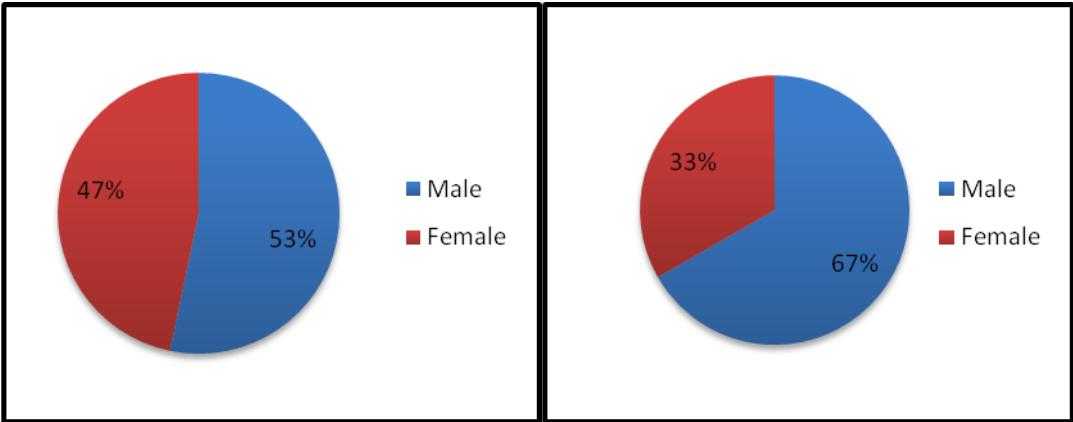


Figure 4.2 Distribution of Age (Paper-Based Protocol)



Computer-Based protocol

Paper-Based Protocol

Figure 4.3 Distribution by Gender

Parametric comparison of patients' weights between the computer-based group and the paper-based group revealed no statistically significant differences.

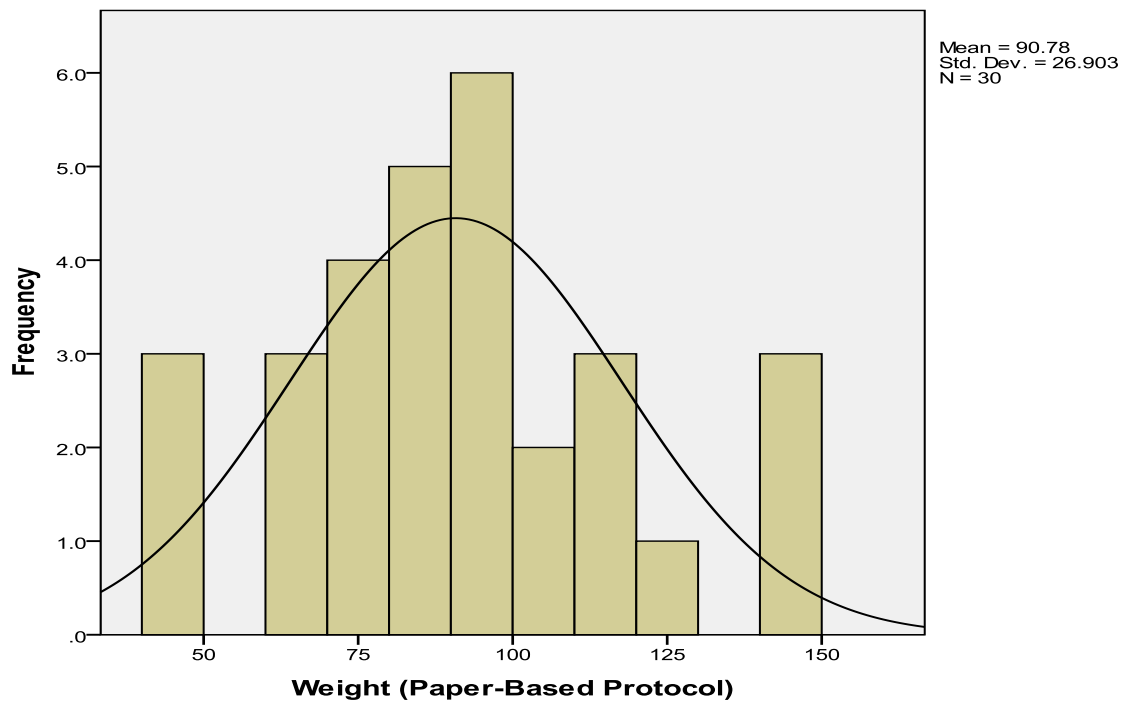
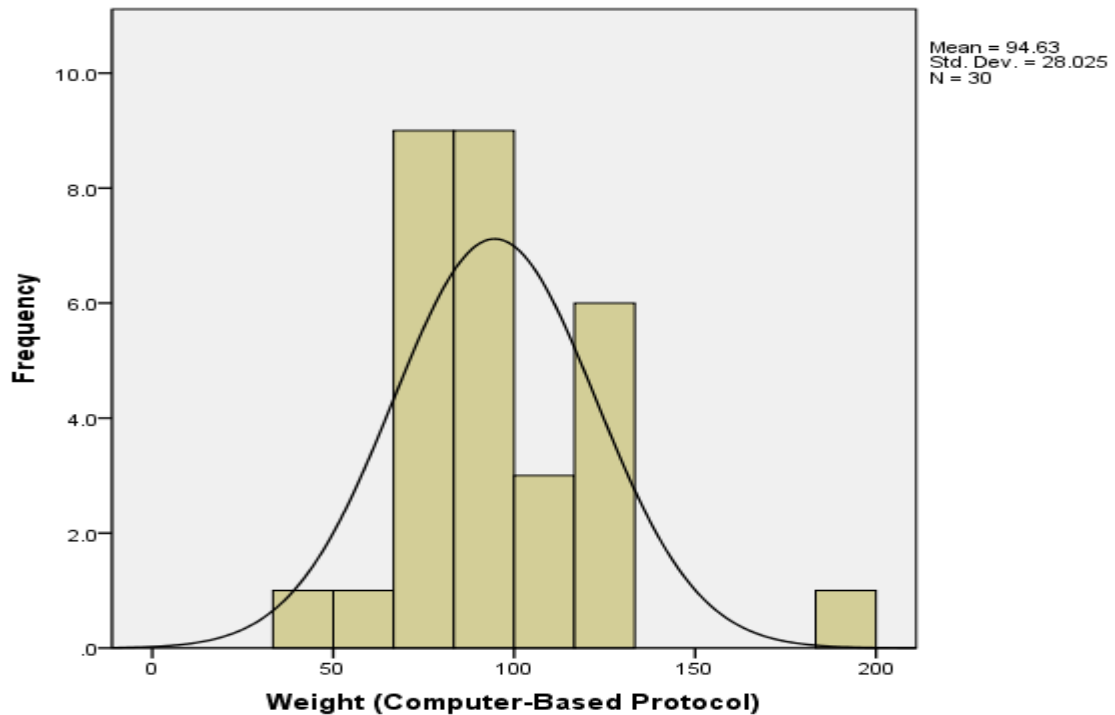


Figure 4.4 Distribution of Weight (in kilograms)

There were 32 different patient diagnoses between the two protocols, with the majority (n = 18) involving general surgery (Table 1). Other surgical services included neurosurgery (n = 6) and vascular (n = 5). At RGH, all thoracic and open heart surgeries are admitted to the cardiothoracic intensive care unit. These patients were excluded from this study.

Table 1

Distribution of Diagnoses for Patients on the Computer-Based Protocol

<u>Diagnosis</u>	<u>Frequency</u>	<u>Percentage</u>
Ruptured Abdominal Aortic Aneurysm	3	10%
Cholecystectomy with Sepsis	3	10%
Gastrectomy	3	10%
Hemicolectomy	2	6.7%
Cholecystectomy	2	6.7%
Transhiatal Esophagectomy	2	6.7%
Craniotomy	2	6.7%
Repair gastric fistula/ileostomy closure	2	6.7%
Fall with Splenic Rupture	1	3.3%
Tensynovitis	1	3.3%
Fall with Fractures	1	3.3%
Fall with Head injury	1	3.3%
Endovascular Abdominal Aortic Aneurysm	1	3.3%
Roux-en-Y	1	3.3%
Cecostomy	1	3.3%
Ex Lap with Small Bowel Resection	1	3.3%
Reversal of ostomy	1	3.3%
Hydrocephalus 2° to IVH	1	3.3%
Intracerebral Hemorrhage	1	3.3%

Distribution of Diagnoses for Patients on the Paper-Based Protocol

<u>Diagnosis</u>	<u>Frequency</u>	<u>Percentage</u>
Ruptured Abdominal Aortic Aneurysm	3	10%
Pancreatitis	3	10%
Cholecystectomy	2	6.7%
Reversal of Ostomy	2	6.7%
Femoral-peroneal Bypass Graft	2	6.7%
Bowel Resection d/t ischemic bowel	2	6.7%
Ex Lap Perforated Gastric Ulcer	2	6.7%
Fall with Head Injury	1	3.3%
Transhiatal Esophagectomy	1	3.3%
Craniotomy	1	3.3%
Aorta-bifemoral Bypass Graft	1	3.3%
Gastric Perforation	1	3.3%
Corpectomy	1	3.3%
Hemicolectomy with Sepsis	1	3.3%
Debridement & I/D of perirectal abscess	1	3.3%
Bowel Resection d/t diverticulitis	1	3.3%
Cholecystitis with Dehydration	1	3.3%
Ureteral Nephrolithiasis with ARF	1	3.3%
Peritonitis Sepsis	1	3.3%
Acute Resp Failure with multifactorial acidosis	1	3.3%
Colectomy	1	3.3%

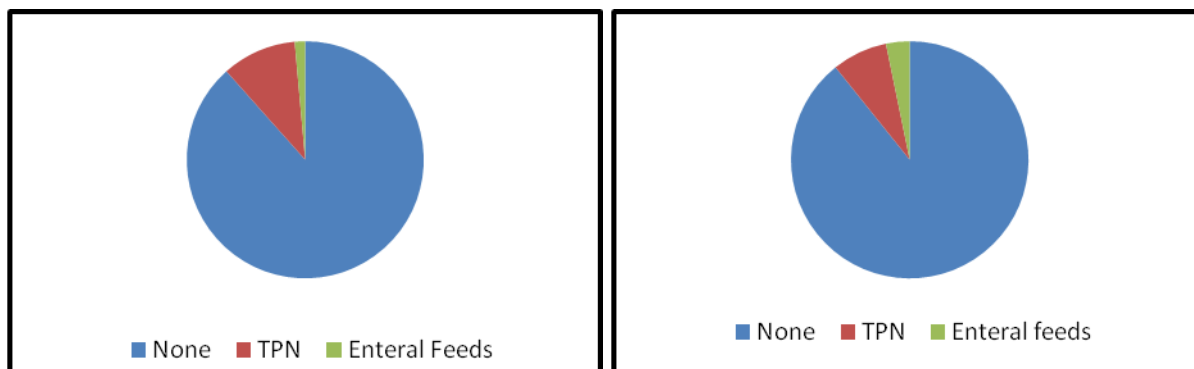
Review of demographic data for patients on either the paper-based and the computer-based protocols revealed that more than half of the patients included in the study had a history of diabetes (Table 2)

Computer-Based Protocol	63.3%
Paper-Based Protocol	53.3%

Table 2 Percentage of Diabetes Observed in Protocol Groups

Evidence based research has changed many practices policies in the SICU since 2006 when the paper-based protocol still was being utilized. The percentage of patients requiring ventilatory support declined from 70% observed via review of patients who had received care via the use of the paper-based protocol, to 53% of patients who received care via the use of the computer-based protocol. The use of corticosteroids also declined from 47% to 27%.

Since bowel surgery occupied the largest percentage observed among patient diagnoses, it is appropriate to infer that the practice of maintaining a fasting period after surgery has remained unchanged since 2006 (Figure 4.5). The use of total parental nutrition (TPN) and enteral feeding also remained essentially unchanged.



Computer-Based Protocol

Paper-Based Protocol

Figure 4.5 Percentage of Initial Nutrition

In the SICU, the most consistently used type of intravenous (IV) fluid used since 2006 has been Lactated Ringers (LR) (Figure 4.6). The intravenous insulin infusion protocol requires that a dextrose source, whether from IV fluids, TPN or enteral feedings, must be initiated to prevent episodes of hypoglycemia.

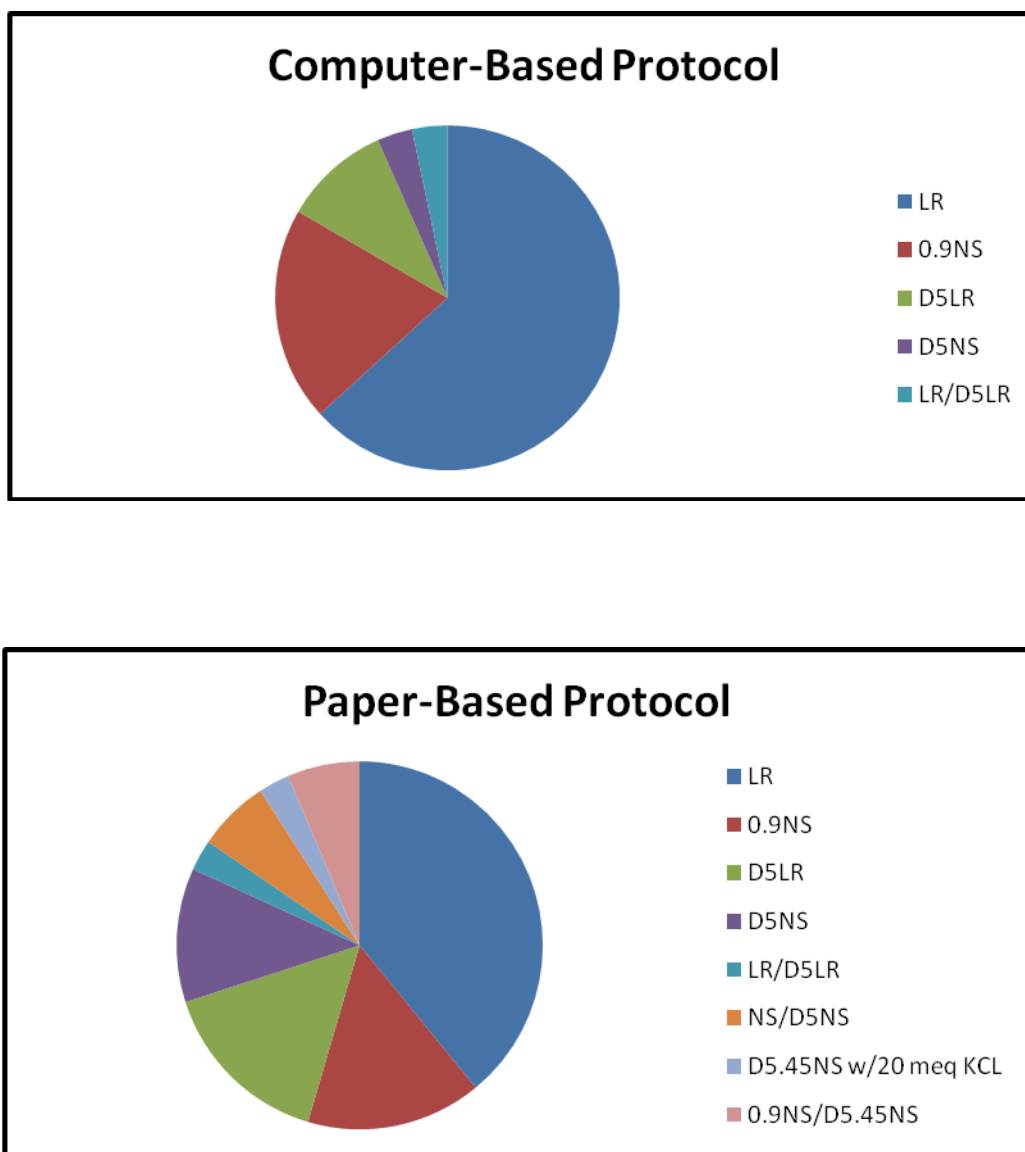


Figure 4.6 Type of Intravenous Fluid Used

The APACHE II score is a measure of disease severity in adults admitted to the ICU (Knaus, Draper, Wagner, & Zimmerman, 1985). Scores may range from zero to 71, and include different measurements, including age, oxygen requirements, history of chronic organ insufficiency, white blood cell count and acute renal failure. The more severe the disease process, the higher the scores, and the increased risk of death. Since 2006, the mean APACHE II scores among SICU patients requiring insulin therapy have remained unchanged. The mean APACHE II score for the computer-based protocol group was 22.4 (Figure 4.7) and the mean score for the paper-based protocol group was 24.5 (Figure 4.8).

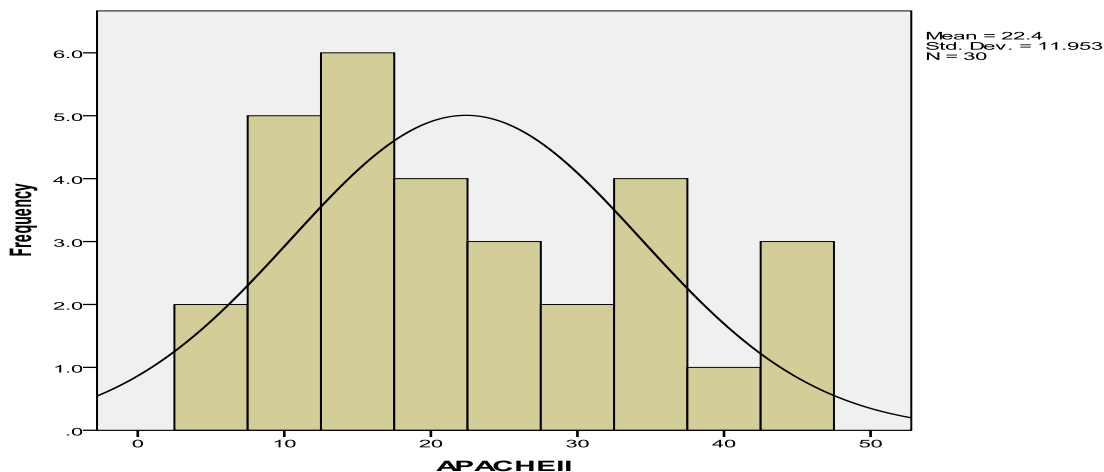


Figure 4.7 APACHE II Scores for Patients in the Computer-Based Group

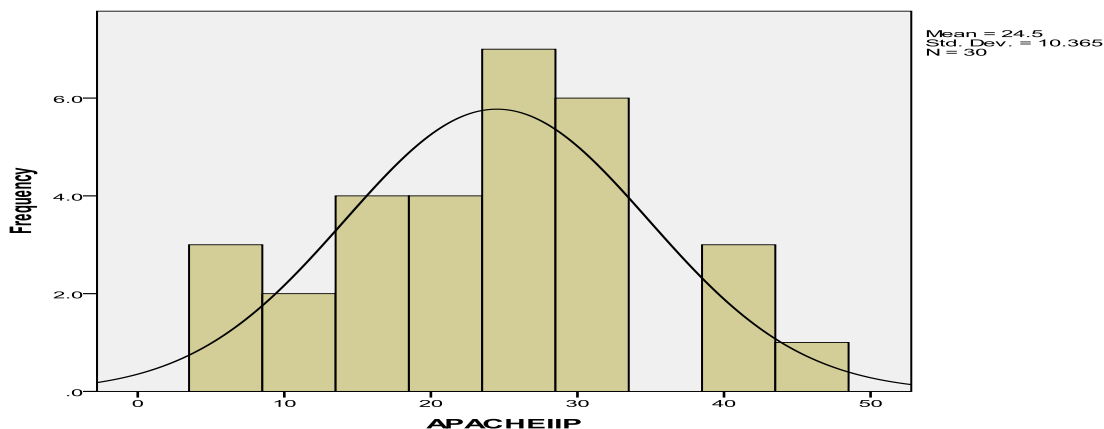


Figure 4.8 APACHE II Scores for Patients in the Paper-Based Group

When a critically ill patient experiences a sudden drop in blood pressure, medications are available to reverse this. Vasopressors are compounds that act on blood vessels causing them to constrict, which produces an increase in blood pressure. The hemodynamic effects of vasopressors differ according to their interactions with receptors in the vasculature and the heart. The use of vasopressor agents for RGH SICU patients who have required insulin therapy has been unchanged since 2006 (Figure 4.9).

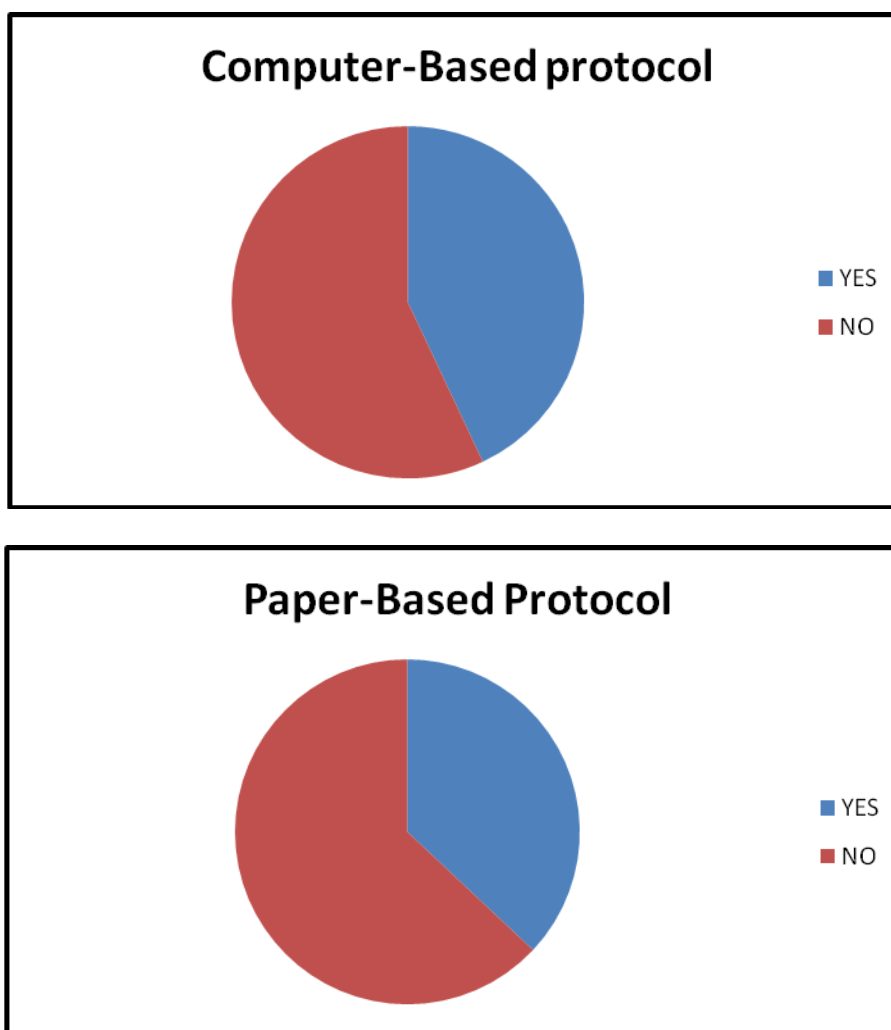


Figure 4.9 Vasopressor Usage

Findings Related to Glycemic Control

In this study, the following questions were posed:

1. Is there a difference in the incidence of hypoglycemia (<60mg/dL) between the paper-based protocol and the computer-based protocol?

The rate of hypoglycemia decreased from 10% with the use of the paper-based protocol to 3 % with the use of the computer-based protocol. While the differences between the protocols and incidence of hypoglycemia approached statistical significance ($p = .184$), the decrease in incidence of hypoglycemia was thought to be clinically significant for individual patients. Upon further examination of the data, it was noted that five out of five hypoglycemic episodes were associated with lack of adherence to the protocol.

2. Is there a difference between paper-based protocol and computer-based protocol in attaining glycemic control (<150mg/dL) ?

Both protocols achieved glycemic control by the fifth BG.

3. Is there a relationship between clinician adherence and correct insulin dosage?

Spearman's correlations demonstrated statistically significant differences in correct insulin dosages between the objective computer-based protocol ($p = 0.01$) and the subjective, or individual clinician judgement-derived, paper-based protocol ($p = 0.05$).

Chapter V

Discussion

The purpose of this study was to determine whether glycemic control (less than 150mg/dL) is attained more effectively using an existing RGH surgical intensive care unit (RGH SICU) paper-based standardized insulin infusion protocol or a computer-based insulin infusion protocol. A secondary purpose was to determine how the use of each protocol affects the incidence of hypoglycemia. The rationale was based on the assumption that a computer-based protocol would perform the mathematic calculations required for an adjustable intravenous insulin infusion and would eliminate the possibility of human error.

The study design was both retrospective and prospective. For the retrospective part of the study, 33 charts were examined, and 30 were found to be appropriate for inclusion. For the prospective part of the study, 34 patients' names were submitted, and 30 patient charts were found to be appropriate for inclusion, yielding a combined sample size of 60.

Results in General

Research Questions

Three relationships were proposed. First was the relationship between incidences of hypoglycemia with the use of the paper-based protocol versus the computer-based protocol. The rate of hypoglycemia was 10% for the patients who received insulin therapy based on the paper-based protocol, and 3% for the patients who received insulin therapy based on the computer-based protocol. Though the differences between the incidences of hypoglycemia approached statistical significance (Spearman's $\rho = .702$, $p = .184$), this decrease in the rate of hypoglycemia was clinically significant in that prolonged hypoglycemia can result in profound consequences to the patient, including death. Upon further investigation of the data, it was

noted that all five incidences of hypoglycemia were associated with clinician lack of adherence to the protocol.

The second relationship that was investigated compared which of the two protocols achieved glycemic control more rapidly. Both protocols resulted in patient achievement of glycemic control by the fifth blood glucose, or approximately six hours after the insulin infusion was initiated.

The final relationship that was investigated was a comparison of clinician adherence and correct insulin dosage. The relationship between clinician adherence and correct insulin dosage was found to be direct and strong (Spearman's $\rho = .677, p = 0.01$) for the computer-based protocol and moderate (Spearman's $\rho = .424, p = 0.05$) for the paper-based protocol.

Interpretation of Results in Relation to Literature

Van den Berghe et al. (2001) concluded that intensive insulin therapy recommended for critically ill patients in a surgical intensive care unit decreased morbidity and mortality. Since then, investigators who have replicated the Van den Berghe study have questioned the feasibility of safely attaining glycemic control, as defined by Van den Berghe, without risking severe hypoglycemia. In 2004, evidence-based recommendations from the Surviving Sepsis Campaign by Dellinger et al. redefined glycemic control as below 150mg/dL, and recommended the development of a validated protocol for insulin dose adjustment. This recommendation served to endorse a new area of investigation related to the risks and benefits of an intravenous insulin protocol. As researchers continued to study intensive insulin therapy (IIT) in critically ill patients, numerous studies (Rood, Bosman, Van Der Spoel, Taylor and Zandstra, 2005; Taylor et al., 2006; Oeyen, Hoste, Roosens, Decruyenaere and Blot, 2007; Alm-Kruse, Bull and Lake, 2007) included clinician adherence as a factor when examining prolonged episodes of hypoglycemia and failure to attain glycemic control.

It was presumed that the computer-based protocol would achieve glycemic control faster than the paper-based protocol due to the elimination of mathematical calculations performed by the nurse. However, both protocols achieved glycemic control within six hours of initiating the insulin infusion. It was not surprising that there was a stronger relationship between clinician adherence and correct insulin dosage with the computer-based protocol.

It was immediately obvious while collecting data for the paper-based protocol that clinician adherence was, at times, poor, and it was assumed that the use of the computer-based protocol would show improved adherence. Though clinician adherence was improved with the use of the computer-based protocol, adherence still remained an area for improvement.

Conclusions

The findings of this study did not support the hypothesis that a computer-based protocol is more effective at attaining glycemic control than a paper-based protocol. Use of either protocol was found to result in achievement of glycemic control (less than 150mg/dL) within six hours. Use of the computer-based protocol resulted in fewer incidences of hypoglycemia (less than 60mg/dL). While this finding was not statistically significant, it was clinically significant in that prolonged hypoglycemia can result in profound consequences, including permanent neurologic deficits and death. No incidences of severe hypoglycemia (less than 40 mg/dL) were associated with use of either protocol, as had been observed in other studies.

There was a stronger relationship (Spearman's $\rho = .677$, $p = 0.01$) between clinician adherence and correct insulin dosage with use of the computer-based protocol. This finding is explained by the fact that all insulin calculations were completed via computer algorithm, so that human error was avoided.

Results in Relation to Theories

When patients require complex nursing care due to a life threatening illness or complications associated with a surgical procedure, they are admitted to an intensive care unit. Orem's Self-Care Deficit Theory (1971) stated that a "wholly compensatory nursing system" is necessary to provide for a patient's lack of ability to engage in self-care activities. In the wholly compensatory system, nurses must "support and protect" the patient by continually assessing and providing the therapeutic self-care demands of the patient (Eben, Gashti, Hayes, Marriner-Tomey, Nation, & Nordmeyer, 1994).

Orem described a "nursing system" as a continuous series of actions which are linked together by nurses, and are directed to meet the self-care demands of the patient. When the demands of the patient are not met by either omission or lack of adherence to protocols, the system is disrupted and the self-care demands of the patient are not met (Eben, Gashti, Hayes, Marriner-Tomey, Nation, & Nordmeyer, 1994).

Limitations

Generalizability of these findings is limited to intensive care units where close frequent monitoring of serum glucose can occur. In addition, these results cannot be generalized to the pediatric population. There are differences of opinion regarding glycemic control for patients admitted into the medical intensive care unit (MICU). In a second study conducted by Van den Berghe et al. (2006), 1200 patients in a MICU were treated with intensive insulin therapy. The authors concluded that maintenance of blood glucose levels below 110mg/dL prevented morbidity, but did not decrease mortality, as had been observed in the surgical intensive care unit in an earlier study.

The present study had several limitations. First among these was clinician adherence to the protocol. Although the paper-based protocol was implemented in 2005 and the computer-based protocol in 2007, many nurses believed that the protocol was a guideline, rather than an order set, to assist with the determination of intravenous insulin dosages. Educational in-services were conducted three months prior to the start of this study, so that the staff would have time to become familiar with the computer-based protocol and the new glucometers. However, because patients and their families in the ICU have multiple complex needs, nurses must prioritize their care and complete critical tasks during their shift. Learning and then adopting new processes may take low priority. Moreover, the amount of experience and time management skills a nurse possesses can have an impact on his or her adherence to the protocol.

In a study conducted by Oeyen, Hoste, Roosens, Decruyenaere & Stijn (2007), non-adherence was listed as one of the study limitations and the main cause of hypoglycemia. The authors suggested lack of training and fear of causing severe hypoglycemia as reasons for clinician non-adherence. In a more recent study to evaluate compliance with a paper-based intravenous insulin protocol, Cyrus, Szumita, Greenwood & Pendergrass (2009) observed a low level of compliance with the protocol. The authors did suggest that the use of a computerized protocol could improve adherence and efficacy.

Second, compared to other studies, the sample for this study was small (N = 60). Time constraints for this study prohibited a longer period for inclusion of subjects into the prospective arm of the study, thus sampling bias was a risk. Van den Berghe's study enrolled more than 1500 subjects over a 12- month period. This was one of the largest samples participating in research on this topic. Most studies enrolled less than 100 patients, and researchers were careful to maintain equivalent sample sizes in their groups. According to information contained in an abstract submitted by Barletta et al. (2009) to the Society of Critical Care Medicine's 39th

Critical Care Congress, 192 patients were enrolled in a before – after study to compare the quality of glucose control utilizing a paper-based insulin protocol or a computer-assisted insulin protocol, but only 47 were assigned to the computer-based protocol. Though their findings were similar to findings from this study, the lack of equivalence of group sizes leads to questions related to sampling bias, and to further questions regarding the existence of a Type II error, and the validity of findings.

Finally, the researcher for this study was a graduate student at St. John Fisher College and a staff member in the SICU at RGH. Every effort was made to avoid the mention of the thesis requirements related to this study to avoid the possibility of the Hawthorne effect.

Implications for Nursing

Recommendations

Results of prior research have demonstrated that morbidity and mortality in critically ill patients is reduced when glycemic control is maintained. The use of an intravenous insulin protocol has been demonstrated, in other studies, to be successful at achieving this goal. Other researchers have concluded that the development of a standardized insulin infusion protocol improves the efficacy and safety of glycemic control in critically ill patients. However, clinician nonadherence has been found to be an obstacle to glycemic control.

Nurse researchers need to investigate factors related to clinician nonadherence and how to minimize or eliminate this problem. Future study designs may include before - after studies to evaluate the effect of education on clinician adherence. As suggested by Holzinger, Feldbacher, Bachlechner, Kitzberger, Fuhrmann and Madl, in a 2008 interdisciplinary collaborative study, “collaboration of physicians and nurses guaranteed that the protocol not only met the medical requirements, but was also practical (p. 155).”

Paper-based protocols also are utilized for calculating heparin infusion dosages. One of the 2010 Joint Commission National Patient Safety Goals (NPSG Chapter Outline and Overview Hospital, 2009) is to reduce the possibility of patient harm with the use of anticoagulant therapy. Anticoagulation therapy has one of the highest risks for patient harm due to the complexity of dosing. Would the use of a computer-based algorithm decrease the risk of miscalculation, thus preventing patient harm?

At times, clinical practice standards are updated and modified on the basis of evidence-based research without having taken nursing workload into consideration. Investigation of ICU nursing workload is warranted, with potential for subsequent workload regulation to accommodate the pace of technology. The overall goals are to develop protocols that will be safe for the patient in achieving its goal and practical for the nurse.

Dissemination

Results of this study will be shared with the Department of Nursing Research and Evidence-Based Practice and the SICU nurse manager at RGH. Based on study findings, interdisciplinary discussions will take place related to whether a change in the standard of practice is warranted. In collaboration with the SICU clinical resource nurse, who is responsible for education, competencies and orientation of the SICU nursing staff, education regarding the findings of this study and ways to address clinician adherence will be provided. Submission of an abstract of study findings is planned for the 41st Scientific Sessions of the Society of Critical Care Medicine (SCCM).

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Appendix I

Computer/Paper

Data Abstraction Tool

Patient # _____ ICU Admission Date _____ Male/Female
 Age _____ Weight _____ kg Initial Nutrition _____ None _____ TPN _____ TF
 Diagnosis _____
 History of DM: _____ Yes _____ No
 Nutrition started on _____ Type: _____
 IV Fluids _____ @ _____ mL/Hr Ventilator: _____ Yes _____ No
 Vasopressors: _____ Yes _____ No Type _____
 Corticosteroids: _____ Yes _____ No Apache II score: _____
 SICU Admission Blood Glucose _____ Date/Time Insulin drip Started: _____ BG _____
 Hypoglycemic Episodes _____ D50% required: _____ Yes _____ No
 Time to achieve normal BG: _____ Hrs
 Date Insulin drip D/C: _____
 Started on: _____ Sliding Scale _____ Lantus _____ No Insulin

* **Expected time:** When BG was actually performed

Actual time: When BG was required to be performed

Insulin Drip Data

Time *	Time <input checked="" type="checkbox"/>	BG	Correct Insulin dose	Time *	Time <input checked="" type="checkbox"/>	BG	Correct Insulin dose
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No
			Yes No				Yes No

Appendix II



October 26, 2009

Arleen B. Miller RN BSN CCRN

Dear Ms. Miller:

I am pleased to support your study titled "Paper versus Computerized Insulin Protocol". This project is an important one and I view this initiative as complementary to Rochester General Health System's missions of practice, education and research.

The number of critically ill and vulnerable patients we see increases each year and I am fully supportive of efforts to assure that the services provided are cost effective and of high quality.

You can sure that the many resources of Rochester General Health Systems will be available to you and that I will offer my enthusiastic support of this project. I envision the collaborative relationships established in this project as foundational to the expansion of the practice, education and research opportunities we plan for the future. The individuals and departments that are involved in the project will assure its success. Please do not hesitate to call upon me for assistance in moving this project forward.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kevin Silinskie'.

Kevin Silinskie Pharm D

Clinical Pharmacist SICU

Rochester General Hospital

585-922-3860

1425 Portland Avenue, Rochester, NY 14621 585.922.4000 www.rochestergeneral.org



October 26, 2009

Arleen B. Miller RN BSN CCRN

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Sincerely,

A handwritten signature in black ink, appearing to read "R. Stephan".

Rabie Stephan MD

Medical Director SICU

Rochester General Hospital

585-922-3860

1425 Portland Avenue, Rochester, NY 14621 585.922.4000 www.rochestergeneral.org



October 26, 2009

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Sincerely,

A handwritten signature in dark ink, appearing to read 'Jonathan Scott PA'. The signature is written in a cursive style with some initials that look like 'JS'.

Jonathan Scott PA

Head Physician Assistant SICU

Rochester General Hospital

585-922-3860



October 26, 2009

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Sincerely,

A handwritten signature in cursive script that reads 'Diana Blauw'.

Diana Blauw RN

Nurse Manager SICU

Rochester General Hospital

585-922-3862

1425 Portland Avenue, Rochester, NY 14621 585.922.4000 www.rochestergeneral.org



October 26, 2009

Arleen B. Miller RN BSN CCRN

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Sincerely,

Cheryl Sheridan

Cheryl Sheridan RN

Chief Nursing Officer

Rochester General Hospital

585-922-2448

1425 Portland Avenue, Rochester, NY 14621 585.922.4000 www.rochestergeneral.org

Appendix III

ST JOHN FISHER COLLEGE

November 12, 2009

Arleen Miller
6207 Holly Creek Drive
Ontario, NY 14519

File No: 1044-111909-07

Dear Ms. Miller:

Thank you for submitting your research proposal to the Institutional Review Board. I am pleased to inform you that the Board has approved the proposal entitled, "Comparative Study of Intravenous Insulin Protocols Computer-based vs. Paper-based." Following federal guidelines, research related records should be maintained in a secure area for three years following the completion of the project at which time they may be destroyed.

Should you have any questions about this process or your responsibilities, please contact me at 385-5262 or by-mail to emerges@sjfc.edu.

Sincerely,

Eileen M. Merges, Ph.D.
Chair, Institutional Review Board

EM:jlm

Copy: OAA IRB
IRB: Approve exempt.doc

3690 East Ave. Rochester, NY 14618 585-385-8000 www.sjfc.edu

Rochester General Health System

April 8, 2010

Lynda Dimitroff, PhD, BSN, RN, CHES

Nursing Research Department

RE: 1218-8-10-1 Comparative study of intravenous insulin protocols: Paper based vs. computer based

Expedited Approval New Study Minimal Risk

Effective Date of Approval: April 7, 2010 -April 6, 2011

Dear Dr Dimitroff.:

The Chair for the Rochester General Health System Clinical Investigation Committee has reviewed the information you have submitted, including the protocol regarding this study and has given its approval until April 7, 2011. Continuation of this study beyond this time will require submission of a study progress report and re-approval of the study by the Clinical Investigation Committee. The next progress report and request for re-approval for this study will be due, April 1, 2011.

Any modifications in the proposal as originally submitted which affect the subjects of the study, or in the risk to subjects will necessitate re-review of the proposal by the committee. Proposed modifications must be sent to the Committee Chair before they are implemented so that proper review can occur.

Any adverse reaction to biologicals, drugs, radioisotopes, or medical devices must be reported to the Clinical Investigation Committee for evaluation. Adverse reactions reported by other investigators involving any substance used in this study should also be reported to the Rochester General Health System Clinical Investigation Committee.

Sincerely,

John R. Cronmiller, MA

Chair, Rochester General Health System

Clinical Investigation Committee

1425 Portland Avenue, Rochester, NY 14621 585.922.4000 www.rochestergeneral.org