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Effect of a program to control perioperative blood glucose on the incidence of nosocomial infections in patients with diabetes: A pilot study*

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ABSTRACT

Aim: To evaluate the safety and effectiveness of a pilot program to control perioperative blood glucose in patients with diabetes. Methods: A pre-post intervention study was conducted in a 280-bed hospital in Spain. In the year 2008 we implemented perioperative insulin protocols aimed at blood glucose values from 80 to 180 mg/dL. Surgical patients with diabetes admitted on year 2009 (intervention group) were compared with a control group of patients with diabetes admitted for surgery on year 2007, matched 1:1 by traditional wound class. Results: We analyzed 96 patients. Implemented protocols were followed in 48% of patients intra-operatively and 75% of patients postoperatively. Patients in the intervention group had reductions in blood glucose at surgery 150 +/− 61 mg/dL vs. 172 +/− 53 mg/dL; *p* = 0.05), greater proportion of target glucose values throughout hospitalization (67% vs. 55%; *p* = 0.07), and reductions in the incidence of nosocomial infections after controlling for confounders (Odds Ratio: 0.20; 95% Confidence Intervals: 0.06 - 0.72; *p* = 0.014) when they were compared with the control group: The incidence of hypoglycemia was similar between two groups (0.12% vs. 0.10%, *p* = 0.867), respectively. Conclusion: Although our protocol needs improvements to increase implementation it was useful to control blood glucose safely and for reducing nosocomial infections.

Keywords: Diabetes; Insulin/Administration and Dosage/Therapeutic Use; Surgical Site Infection; Nosocomial Infection

*Conflict of interest: The authors declare that they have not conflict of interest.

1. INTRODUCTION

The association between diabetes mellitus and greater risk of suffering from surgical site infections has been recognized for many years [1-3]. Hyperglycemia impairs granulocyte functions including adherence, chemotaxis, phagocytois, and bactericidal activity [4]. Improving glycemic control in the preoperative period can reduce wound complications and nosocomial infections in patients with coronary artery by-pass graft [5,6]. The Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee recommends that preoperative blood glucose should be held to less than 200 mg/dL [7]. The recently published standards for diabetes care in hospitalized patients admitted to general medicine or surgical wards recommended maintaining blood glucose values below 180 mg/dL if they can be achieved safely [8]. Most experience of controlling diabetes in the operative period has been reported for patients undergoing cardiac surgery. There is insufficient evidence that strict blood glucose control prevents surgical site infections in patients undergoing abdominal or orthopedic surgery; moreover, the relative risk of infection compared to the risk of hypoglycemia has not been established.

In the present study we evaluated the impact of a glycemic control protocol aimed at achieving blood glucose levels between 80 - 180 mg/dL on the perioperative period in patients undergoing abdominal and orthopedic surgery. Specifically we evaluated the proportion of patients with an appropriate glucose control, the risk of hypoglycemia, the incidence of surgical site infections and other nosocomial infections, all-cause related mortality and the hospital length of stay after implementing a specific protocol for controlling blood glucose intra- and postoperatively.

2. METHODS

2.1. Setting

Hospital Marina Baixa is a 280-bed center belonging to the National Health System providing care for 210,000 inhabitants in the East coast of Spain. The General Surgery Department and the Orthopedics Department have assigned a total of 68 beds.

2.2. Type of Study

We carried out a quasi-experimental before and after study. Strict blood glucose control was aimed at fasting values between 80 and 180 mg/dL. To assess the impact of strict glucose control on morbidity and mortality we compared outcome variables before and after implementing a protocol for intra- and postoperative blood glucose control. A prospective group of patients with strict blood glucose control was compared with an historical control group matched by wound contamination class. The study was approved by the institutional review board of the Hospital Marina Baixa.

2.3. Intervention

The proposed perioperative glucose control protocol was presented and discussed with anesthetists, general surgeons, orthopedic surgeons, and nurses. The protocol included the following steps: 1) Stopping oral hypoglycemic agents in all patients on admission; 2) Starting a intra- and postoperative insulin regimen with two algorithms depending on patients´ preoperative blood glucose control and type of diabetes treatment (Addendum); 3) Starting a postoperative basal-bolus-correction insulin regimen [9]; 4) Assessment of diabetes treatment at discharge according to hemoglobin$_{A1c}$ values on admission. Under usual care patients hospitalized with diabetes had capillary glucose readings every 6-hour if fasting or before breakfast, lunch and dinner if they are not fasting. Every patient had a capillary blood glucose reading at 06:00 h. on the day of surgical intervention.

Patients on oral hypoglycemic agents with preadmission appropriate blood glucose control, had discontinuation of oral drugs, and before the induction of anesthesia they received an infusion consisting of 2500 mL of 5% dextrose in water with 60 mEq of potassium chloride, and corrections with subcutaneous injections of regular human insulin every 4 hour guided by capillary blood glucose.

Patients on treatment with insulin or showing poor preadmission blood glucose control (glucose > 200 mg/dL or Hb$_{A1c}$ > 8%) received before the induction of anesthesia an infusion consisting of 1500 of 10% dextrose in water with 60 mEq of ClK and continuous intravenous insulin (50 units of regular human insulin in 500 mL of 0.9% saline solution) at an infusion rate according to hourly capillary blood glucose and individual requirements (Addendum). Pre- and intra-operative treatment was typically started at 06.00 h. AM on the day of surgery, and maintained throughout patients' fasting state. Thereafter, subcutaneous insulin was administered according a basal-bolus correction regimen. Insulin glargine was used as basal insulin, and insulin aspart was used as bolus and correction dosages according to our institution protocol [9]. Adherence to glucose control protocols was assessed by reviewing clinical records.

2.4. Patients

In the present study we included adult patients with type 2 diabetes undergoing elective abdominal or orthopedic surgery (hip replacement), with no active infection up to the date of surgery, and hospitalized for at least 3 days. We collected the following information from the clinical record: age, sex, type of diabetes therapy, recent haemoglobin$_{A1c}$, comorbidities (Charlson scale) [10], Acute Physiologic and Chronic Health Evaluation (APACHE-II) score [11], American Society of Anesthesiologists physical status classification (ASA score) [12], most recent blood glucose before surgery, duration of surgical intervention, wound class (clean, clean-contaminated or contaminated surgery classification) [13], National Nosocomial Infections Surveillance System (NNIS) classification [14], and presence of laparoscopic or open surgery. As outcome variables we collected: adherence to pre- and postoperative glycemic control protocols, capillary glucose readings during hospitalization, presence of hospital acquired infection diagnosed according to Centers for Disease Control and Prevention (CDC) criteria [15,16], rate of severe hypoglycemia (blood glucose < 60 mg/dL), hospitalization length, and all cause mortality at 30-day. Surveillance was extended to 30 days after hospital discharge to detect hospital infections clinically developed at home. Post-discharge surveillance was achieved by reviewing all of the emergency department forms and by telephone.

2.5. Statistical Analysis

Data is presented in absolute numbers and proportions for nominal variables. Mean ± standard deviation (SD) is use for continuous variables. Outcomes were analyzed with the use of a Student's *t*-test and the Pearson chi-square or Fisher exact test for proportions. To assess the independent contribution of the glycemic control program on the incidence of nosocomial infections we carried out a logistic regression analysis using as control variables NNIS classification, use of laparoscopic surgery and length of hospitalization. *P* values less than 0.05 were considered statistically significant. Data analysis was performed using SPSS/PC v. 15 as statistical package (SPSS inc. Chicago, IL, USA)

3. RESULTS

From January through December 2009 (post-intervention group), 1051 patients were admitted to the Department of Surgery of whom 161 (15%) had type 2 diabetes as secondary diagnosis. In the same period, 997 patients were admitted to the Department of Orthopedics and Traumatology of whom 61 (6%) had type 2 diabetes as secondary diagnosis. A total of 61 consecutive discharge clinical records were analyzed for inclusion in the study, being 13 excluded due to lack of surgical intervention (n = 3), presence of active infection on admission (n = 4), and urgent surgery (n = 4). From our institutional database registry we selected for inclusion from January through December 2007 (control group) an eligible patient with type 2 diabetes matched by wound class with those included in the post-intervention group.

3.1. Patient Characteristics

We analyzed 48 patients from the post-intervention group, and 48 patients from the control group (**Table 1**). The clinical and demographic characteristics were similar

Table 1. Characteristics of patients entering the study.

	Post-Intervention Group (N = 48)	Control Group (N = 48)	P
Age, years (mean +/− SD)	70.69 ± 10.73	69.10 ± 10.39	0.465
Gender, male (%)	28 (58)	25 (52)	0.682
Diabetes duration, years (mean+/− SD)	15.46 ± 10.65	9.80 ± 6.15	0.108
Hemoglobin$_{A1c}$ (%)	7.21 ± 2.10	7.06 ± 1.56	0.791
Diabetes treatment (%)			0.192
Diet	4 (8)	1 (2)	
Oral hypoglycemic agents	25 (53)	34 (71)	
Insulin	16 (32)	12 (25)	
Oral hypoglycemic agents + insulin	3 (7)	1 (2)	
Charlson score (mean +/− SD)	2.46 ± 1.47	2.23 ± 1.65	0.475
APACHE II score (points)	7.46 ± 1.92	8.40 ± 3.08	0.077
ASA classification (%)			0.189
I	1 (2)	0 (0)	
II	17 (44)	15 (33)	
III	17 (44)	28 (63)	
IV	4 (10)	1 (2)	
V	0 (0)	1 (2)	
Wound class (%)			1.000
Clean	9 (19)	9 (19)	
Clean-contaminated	25 (52)	25 (52)	
Contaminated	14 (29)	14 (29)	
NNSI index (%)			0.161
0	5 (10)	6 (12)	
1	13 (27)	21 (44)	
2	21 (44)	11 (23)	
3	9 (19)	10 (21)	
Laparoscopic surgery (%)	24 (50)	19 (40)	0.305
Length of surgical intervention (min)	185.25 ± 77.96	135.96 ± 64.59	0.001

Data are no [%] or mean values [standards deviation]; ASA American Society for Anesthesiology; NNSI National Nosocomial Infection Surveillance (NNIS) classification: The NNIS basic surgical site risk index is composed of the following criteria: American Society of Anesthesiologists score of 3, 4, or 5 (1 point); wound contamination degree contaminatd or dirty (1 point); and duration of surgery greater than 120 min (1 point).

between two groups except for APACHE II score (7.46 vs. 8.40, $p = 0.07$) and duration of surgical intervention (185.25 ± 77.96 min vs. 135.96 ± 64.59 min; $p = 0.001$) between post-intervention and control group, respectively.

3.2. Process-of-Care and Outcome Measures

Our pre-operative and operative glycemic control was followed in the post-intervention group in 48% patients, and in the control group in 2% of patients ($p = 0.000$). Use of basal-bolus-correction insulin dosage was observed in 75% of patients in the post-intervention group compared with 40% of patients in the control group ($p = 0.008$). Hemoglobin$_{A1c}$ blood test orders did not change significantly between two periods (50% vs. 48%; $p = 0.412$) (**Table 2**).

Regarding laboratory indicators, there was an almost significant reduction in the mean glucose values prior to surgery in the post-intervention group compared to the control group (150.50 +/− 61.60 vs. 172.54 +/− 53.55; $p = 0.05$). The proportion of glucose values prior surgery that were within the target range in the two groups were 73% vs. 52%; $p = 0.038$. However, after surgery the use of insulin in basal-bolus correction regimen increased the proportion of target glucose values in the post-intervention group compared with the control group, respectively (65% vs. 59%; $p = 0.000$). The rates of severe hypoglycemia were similar between two groups (0.12% vs. 0.10%; $p = 0.894$), respectively.

The post-intervention group had borderline significant reductions in the incidence of surgical site infections (17% vs. 33%, $p = 0.06$), and not so in other nosocomial acquired infections (15% vs. 21%, $p = 0.594$) compared with the control group. However, there were significant differences between two groups in logistic regression analysis after controlling for confounders such as: NNIS classification, use of laparoscopic surgery and length of hospitalization (**Table 3**).

We did not find differences in other outcomes analyzed within three months such as deaths (4% vs. 13%, $p = 0.268$) and hospital readmissions (0% vs. 6%, $p = 0.242$) between post-intervention and control groups, respectively.

4. DISCUSSION

This pilot study shows that our perioperative protocol for blood glucose control is safe and reduces patient morbidity. The independent contribution of the protocol was 50 percent reduction in the rate of surgical site infections. Additionally, we observed a reduction in other nosocomial infections. Most importantly adverse events

Table 2. Process-of-care and outcomes evaluated.

	Post-intervention Group (N = 48)	Control Group (N = 48)	P
Recent haemoglobin$_{A1c}$ available (%)	24 (50)	20 (42)	0.422
Adherence to intra- and post-operative protocol (%)	23 (48)	2 (2)	0.001
Glucose (mg/dL) at surgery	150.50 ± 61.60	172.54 ± 53.55	0.396
Glucose (%) values between 80 and 180 mg/dL at surgery	35 (73)	25 (52)	0.038
Adherence to post-operative glucose control protocol (%)	36 (75)	19 (40)	0.008
Glucose (%) values between 80 and 180 mg/dL post-operative	1094/1683 (65)	1175/1988 (59)	0.000
Glucose (%) values below 60 mg/dL	2/1683 (0.12)	2/1988 (0.10)	0.894
Surgical site infection (%)	8 (17)	16 (33)	0.065
Other nosocomial infection (%)	7 (15)	10 (21)	0.439
Urinary tract infection	4 (8)	5 (10)	
Catheter-related infection	1 (2)	4 (8)	
Nosocomial bacteremia	1 (2)	1 (2)	
Nosocomial pneumonia	1 (2)	0 (0)	
Surgical site and other nosocomial infections (%)	15 (31)	26 (54)	0.025
Death (%)	2 (4)	6 (13)	0.145
Hospitalization (days)	13.67 ± 12.04	15.02 ± 15.90	0.390
Hospital readmission (%)	0 (0)	3 (6)	0.242

Table 3. Independent contribution of the program for perioperative glycemic control on the risk of nosocomial infections. Logistic regression analysis.

	Odds Ratio	95% Confidence Intervals	*P*
NNSI index (for every point)	3.148	1.412 - 7.016	0.005
Laparoscopic surgery (yes vs no)	0.814	0.245 - 2.699	0.736
Hospitalization length (per day)	1.163	1.060 - 1.276	0.001
Group (intervention vs control)	0.512	0.155 - 1.723	0.014

Addendum Intraoperative subcutaneous insulin protocol for patients treated with oral hypoglycemic agents with appropriate metabolic control defined by hemoglobin$_{A1c}$ less or equal to 8% or preoperative blood glucose values below than 200 mg/dL.

Glucose (mg/dL)	Insulin dosing (subcutaneous regular short acting insulin)
Less than 150	0 units
151 - 200	4 units
201 - 250	6 units
251 - 300	8 units
Greater than 300	10 units

Addendum Intraoperative intravenous insulin infusion (rate in mL per our) used for patients with inappropriate metabolic control defined by hemoglobin$_{A1c}$ greater than 8% or preoperative blood glucose values equal or greater than 200 mg/dL.

	Continuous intravenous insulin infusion 50 units of regular short acting insulin in 500 mL of 0.9% saline solution			
	Basal insulin requirement below 30 units per day	Basal insulin requirement between 30 and 50 units per day	Basal insulin requirement between 51 and 80 units per day	Basal insulin requirement greater then 80 units per day
Capillary blood glucose (mg/dL)	Rate (mL/hour)	Rate (mL/hour)	Rate (mL/hour)	Rate (mL/hour)
Less than 70	Stop infusion*	Stop infusion*	Stop infusion*	Stop infusion*
70 - 90	5	7	10	15
91 - 150	10	15	20	30
151 - 200	15	20	25	35
201 - 250	25	30	35	45
251 - 300	30	35	40	50
Greater than 300	40	45	50	60

(*) Insulin infusion is stopped until next glucose control.

related to strict blood glucose control occurred in a very small proportion of patients. It should be taken into account that compared to patients undergoing clean surgery, as coronary by-pass graft procedures, the population entering our study underwent clean-contaminated or contaminated surgical procedures and had significant underlying conditions defined by the Charlson score.

Most studies have evaluated the safety and efficacy of tight blood glucose control in patients with diabetes undergoing coronary artery bypass graft surgery [17-20]. These protocols included the administration of intravenous insulin and were aimed at obtaining perioperative blood glucose values below 200 mg/dL. The reduction in the rate of surgical site infections obtained was from 90% [19] to 50% [18,20]. However, the risk of hypoglycemia was not well described in these studies. A recent study evaluated an insulin infusion protocol aimed at obtaining blood glucose levels below 150 mg/dL for patients admitted in medical and surgical wards [21-22]. According this protocol, the mean time to achieve the target values was 9 hours but 10% of a total of 30 patients entering the study suffered from hypoglycemia. Hypoglycemia is a major fear since, as the NICE-SUGAR study demonstrated, when the target glucose control is in the range of 81 to 108 mg/dL compared to the conventional target values of less than 180 mg/dL, there is an increased risk of mortality and severe hypoglycemia. Using our insulin protocol, the mean preoperative glucose value obtained was 150 mg/dL, and along the postoperative period 65 percent of the capillary glucose readings were between 80 - 180 mg/dL, with a very low risk of hypoglycemia. These blood glucose values were associated with clinical benefits in terms of a significant reduction in nosocomial infections.

Out study had some limitations; First, intra-operative blood glucose values in the control group were appropriated in a high proportion of patients. Thus, there was small room for improvement. Second, the perioperative insulin protocol was not applied to every patient, therefore the risk of hypoglycaemia could have been underestimated. Specifically, the adherence to intraoperative use of intravenous insulin infusion was lower than expected; however, during hospitalization most patients received insulin as basal-bolus therapy according the proposed algorithm. Third, although for comparison purposes groups were matched by wound class, patients in the control group had lower proportion of laparoscopic surgery compared to the intervention group. It is well known that laparoscopic surgery decreases the risk of surgical site infection and prolongs the time in the operating room [23-25]. In addition, patients undergoing laparoscopic surgery have shorter length of stay in the hospital, which also have impact in the risk to acquire subsequent nosocomial infections. To overcome these potential confounders, we carried out a multivariate analysis taking into account most significant prognosis variables in order to demonstrate the independent contribution of our glucose control protocol for reducing the risk of nosocomial infections. Finally, there are some other prognosis variables not accounted for in our study. These are type of antiseptic preparation, appropriateness of antibiotic prophylaxis, perioperative oxygen inspired fraction, patient body temperature in the operating room, blood transfusion requirements, surgical safety checklists or other best practices that have improved surgical outcomes in recent years. However, in the study period there have not been modifications in the surgical and anaesthetics' protocols in our institution besides improvement in glucose control.

In conclusion, the present before and after study showed that a protocol targeting perioperative glucose values between 80 and 180 mg/dL with subcutaneous and intravenous insulin was safe and effective to reduce surgical site and other nosocomial infections. Improvements need to be done to implement fully the protocol intra-operatively and post-operatively. Perioperative glucose control should be added to the list of best practices for patients with diabetes undergoing surgery.

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Contributions: JE conceived and designed the study, collected data, undertook the statistical analysis and drafted the paper; RC assisted in study design, collected data and reviewed the paper; MJC assisted collecting the data and reviewing the paper. EL collected data and reviewed the paper. All authors reviewed and approved the final manuscript.

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ADDENDUM

ADA: American Diabetes Association;
APACHE-II: Acute Physiologic and Chronic Health Evaluation;
ASA: American Anesthetists Association;
CDC: Centers for Disease Control;
CI: Confidence intervals;
NNIS: National Nosocomial Infections Surveillance;
SD: Standard Deviation.

