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Differences in inpatient glycemic control and response to subcutaneous insulin therapy between medicine and surgery patients with type 2 diabetes^{☆,☆☆,★}

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Abstract

Objective—To determine differences in inpatient glycemic control and response to two different glargine-based insulin regimens in general medicine and surgery patients with type 2 diabetes (T2D).

Methods—This is a post-hoc analysis of a prospective, multicenter, randomized trial of 298 non-ICU medicine and surgery patients with T2D treated with Basal Bolus regimen with glargine once daily and glulisine before meals and with Basal Plus regimen with glargine once daily and supplemental doses of glulisine before meals for blood glucose (BG) > 140 mg/dl. Major study outcomes included differences in mean daily BG, frequency of treatment failures (defined as >2 consecutive BG > 240 mg/dl or a mean daily BG > 240 mg/dl), and hypoglycemia between the medicine and surgery cohorts.

[☆]Authors' Contributions: G.E.U. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. G.E.U. wrote the initial research proposal and manuscript. D.S., D.O., K.H., A.K., C.N., S.J., M.R., L.P., A.G., and V.F. reviewed/edited/revised the research proposal and manuscript and contributed to the discussion. G.E.U., D.S., D.R., I.P., D.O., M.F., V.H. and K.H. collected and researched the data.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.jdiacomp.2013.05.007>.

Results—Patients treated with Basal Bolus or with Basal Plus experienced similar improvement in mean daily BG after 1st day of therapy ($p = 0.16$), number of treatment failures ($p = 0.11$) and hypoglycemic events ($p = 0.50$). Compared to surgery patients ($n = 130$), medicine patients ($n = 168$) had higher admission BG ($p = 0.01$) and HbA1c levels ($p < 0.01$); however, they had similar response to either treatment regimen without differences in mean daily BG after 1st day of therapy ($p = 0.18$), number of treatment failures ($p = 0.58$), daily insulin requirements ($p = 0.36$), or in the frequency of hypoglycemia ($p = 0.79$).

Conclusion—The Basal Plus regimen with glargine once daily and correction doses with glulisine before meals resulted in similar glycemic control to basal bolus regimen. We observed no differences in response to either basal insulin regimen between medicine and surgery patients with type 2 diabetes.

Keywords

Type 2 diabetes; Medicine and surgery patients; Inpatient hyperglycemia; Glargine; Glulisine; Sliding scale insulin; Basal insulin; Hospital hyperglycemia

1. Introduction

Inpatient hyperglycemia is common and associated with poor outcomes including prolonged hospital stay, increased risk of hospital complications and disability after hospital discharge and death (Falciglia, Freyberg, Almenoff, D'Alessio, & Render, 2009; Frisch et al., 2010; Kosiborod et al., 2009; Umpierrez et al., 2002). The results of randomized clinical trials in general medicine and surgery patients with T2D have shown that the use of basal bolus insulin regimens result in better glycemic control and lower frequency of a composite of hospital complications including postoperative wound infection, pneumonia, bacteremia, and acute renal and respiratory failure compared to treatment with sliding scale regular insulin (SSI) (Korytkowski et al., 2009; McDonnell & Umpierrez, 2012; Umpierrez et al., 2007, 2011). Despite these benefits of basal bolus regimen, simplified basal insulin regimens are needed as many healthcare providers and hospitalist physicians may find it difficult to integrate this approach into their clinical practice, likely because of its perceived complexity and fear of hypoglycemia (Cook et al., 2007; Korytkowski, 2007; Kosiborod et al., 2009; Umpierrez & Maynard, 2006).

Worsening hyperglycemia during medical and surgical illness frequently occurs following the acute metabolic and hormonal changes associated with the response to injury and stress (McCowen, Malhotra, & Bistran, 2001; Umpierrez & A.E.K., 2004). Few observational studies have compared differences in inpatient glucose control between medicine and surgery patients (Umpierrez et al., 2002), and to the best of our knowledge, no previous randomized trials have investigated differences in the response to different basal insulin regimens in medicine and surgery patients with T2D. Identifying differences in glycemic control and response to insulin treatment should help in designing safe and effective insulin strategies, as well as in determining if a 'one-size-fits-all approach' is appropriate for the management of both medicine and surgery patients in non-ICU settings.

In the Basal Plus trial (Umpierrez et al., 2013) we randomized general medicine and surgery patients with T2D treated with diet, oral antidiabetic agents or low-dose insulin therapy (≤ 0.4 U/kg/day) to receive treatment with a basal bolus regimen with glargine once daily and glulisine before meals, a basal plus regimen with glargine once daily and supplemental doses of glulisine, or sliding scale regular insulin. In agreement with previous studies (Korytkowski et al., 2009; Rubin, Rybin, Doros, & McDonnell, 2011; Umpierrez et al., 2007, 2011), we found that treatment with sliding scale insulin was associated with higher mean daily BG and more treatment failures compared to treatment with basal bolus and basal plus regimens. Therefore, in this analysis we excluded patients treated with SSI and analyzed differences in glycemic control between general medicine and surgery patients during treatment with basal bolus and basal plus regimens.

2. Methods

In a recently completed multicenter, prospective, open-label randomized controlled study (Umpierrez et al., 2013), we enrolled patients with a BG level between 140 mg/dl and 400 mg/dL, a known history of T2D for > 3 months, ages 18 to 80 years old, and treated with diet alone, any combination of oral antidiabetic agents, or low-dose insulin therapy at a TDD ≤ 0.4 U/kg prior to admission. We recruited general medicine and surgery patients admitted for elective or emergency treatment and not expected to require ICU admission. We excluded patients with new hyperglycemia and without a known history of diabetes, admission to the ICU, cardiac surgery, clinically relevant hepatic disease or impaired renal function (serum creatinine ≥ 3.0 mg/dL), history of diabetic ketoacidosis (Kitabchi, Umpierrez, Murphy, & Kreisberg, 2006), pregnancy, and any mental condition rendering the subject unable to give informed consent.

This study was conducted at Grady Memorial Hospital, Emory University Hospital and the Veterans Administration Medical Center in Atlanta, Georgia; Medical University of South Carolina Medical Center in Charleston, SC and at Tulane Medical Center, New Orleans, LA. The institutional review boards at each participating institution approved the study protocol and consent.

Patients were randomly assigned to a basal bolus regimen with insulin glargine (Lantus®, Sanofi Aventis) once daily and insulin glulisine (Apidra®, Sanofi Aventis) before meals with correction doses of glulisine and to a basal plus regimen of a daily dose of glargine and correction doses of glulisine by sliding scale for BG > 140 mg/dl (Umpierrez et al., 2013). Patients treated with basal bolus were started at a total daily dose (TDD) of 0.5 U/kg divided half as insulin glargine once daily and the other half as scheduled insulin glulisine given before meals, plus correction doses of glulisine before meals when BG ≥ 140 mg/dl. The insulin TDD in the basal bolus group was reduced to 0.3 U/kg in patients ≥ 70 years of age and in those with a serum creatinine ≥ 2.0 mg/dL. Patients in the basal plus group received 0.25 U/kg of glargine once daily plus correction doses of glulisine before meals for BG ≥ 140 mg/dl. In the basal plus group, the glargine dose was reduced to 0.15 U/kg in patients ≥ 70 years of age and in those with a serum creatinine ≥ 2.0 mg/dL. The goal of insulin therapy was to maintain fasting and pre-meal glucose concentration between 100 mg/dl and 140 mg/dl. Blood glucose was measured before each meal and at bedtime (or every 6 h if a

patient was not eating) using an inpatient glucose meter. During treatment, treatment failure was arbitrarily defined as having two consecutive values > 240 mg/day or a mean daily BG level > 240 mg/dL (Umpierrez et al., 2007, 2011). If this occurred, patients in the basal plus regimen were switched to basal bolus starting at a TDD of 0.5 U/kg (Umpierrez et al., 2007, 2011).

2.1. Outcome measures

The primary outcome of this analysis was to determine differences in glycemic control, as measured by mean daily BG concentration in response to basal plus and basal bolus insulin regimens between medicine and surgery patients. Other outcomes included differences in any of the following measures: number of hypoglycemic events, number of hyperglycemic events, total daily dose of insulin, length of hospital stay, hospital complications, admission to the ICU, and death. In addition, we analyzed the importance of admission glucose and HbA1c in predicting the response to insulin therapy between treatment groups.

2.2. Statistical analysis

The primary goal of this post-hoc analysis was to assess the non-inferiority hypothesis for comparing basal plus and basal bolus, as no greater than 18 mg/dl (1 mmol/l) difference in mean daily glucose value among medicine and surgery patients (Umpierrez et al., 2007, 2011). We compared baseline and clinical characteristics and outcomes, such as mean daily BG after day one, occurrence of hypoglycemia among treatment groups and between medical and surgical patients. The comparisons were made with the use of Wilcoxon tests (or Kruskal–Wallis tests) for continuous variables and Chi-square tests (or Fisher's exact test) for discrete variables. Multivariate analysis was conducted based on a repeated measures linear model which accounted for within-subject BG correlation through a first-order autoregressive correlation structure (AR1). Statistical analyses were performed using SAS (v9.2). The data were generally presented as mean $\pm$ SD for continuous variables and count (percentage) for discrete variables.

3. Results

A total of 298 patients with T2D were consented (168 medicine and 130 surgery); of them, 19 patients were excluded (10 medicine and 9 surgery) from further analysis because they received < 24 h of insulin treatment, were transferred to the ICU or received high dose corticosteroid therapy. A total of 158 medicine and 121 surgery patients treated with basal bolus (n = 144) or with basal plus regimen (n = 133) were included in this secondary analysis. The clinical characteristics of study patients are shown in Table 1. There were no significant differences in age, racial distribution, body mass index, type of treatment prior to admission, or mean hospital length of stay (LOS) between treatment groups. The patients in the basal bolus arm had a longer duration of diabetes than those in the basal plus arm; however, there were no differences in the duration of diabetes between the medical and surgery cohorts (Table 2). The most common admitting diagnoses in medicine patients were cardiovascular (47%), renal (21%), infectious (18%), and pulmonary (16 %) disorders, while the most common types of surgery were orthopedic (35 %), abdominal (24 %), and urologic (13 %) procedures.

Treatment with basal bolus and basal plus regimens resulted in similar improvement in mean daily BG after 1st day of therapy ($p = 0.16$). Differences in mean daily BG concentration during the hospital stay in medicine and surgery patients treated with basal bolus and basal plus are shown in Fig. 1. The improvement in daily mean BG was similar in medicine (Fig. 1A) and surgery patients (Fig. 1B). There were no treatment differences in BG before breakfast, lunch, dinner and bedtime in surgery patients. However, basal bolus resulted in lower BG before lunch and at bedtime in medicine patients ($p < 0.05$) compared to basal plus group (Fig. 1C and D).

Comparisons between clinical characteristics, glycemic control and response to treatment between medicine and surgery patients are shown in Table 2. Medicine patients were younger ($p = 0.053$) and had longer length of hospital stay ($p = 0.003$), and had significantly higher admission BG ($p = 0.012$) and HbA1c than surgery patients ($p < 0.001$). During the hospital stay, both groups experienced a similar prompt and sustained improvement in glycemic control during insulin treatment. Medicine and surgery patients had similar mean daily BG after 1st day of treatment (161.4 ± 37 mg/dl vs. 156.7 ± 37 mg/dl, $p = 0.18$) and percent of BG levels within target range ($37\% \pm 29\%$ vs. $42\% \pm 31\%$, $p = 0.24$); however, the percent of BG ≥ 180 mg/dl ($33\% \pm 29\%$ vs. $26\% \pm 30\%$, $p = 0.041$) was higher in the medicine cohort. Despite this, the occurrence of treatment failures in the medicine patients was similar to surgery patients (1% vs. 2%, $p = 0.58$).

Information on insulin therapy is shown in Table 2. The total daily dose of insulin (units/day) was similar in medicine patients (31 ± 15 U/day) and surgery patients (28.3 ± 11 U/day), $p = 0.36$. There was no difference in the amount of glargine daily dose (17.7 ± 9 and 16.9 ± 7 U/day, $p = 0.78$) or glulisine (12.7 ± 10 and 10.8 ± 9 U/day, $p = 0.10$) between the basal bolus and basal plus, respectively.

There were no differences in the frequency of hospital complications in medicine and surgery patients (16% vs. 12%, $p = 0.42$), but surgery patients had a longer LOS compared to medicine patients (7.1 ± 6.3 vs. 5.4 ± 5.0 days; $p = 0.003$). In addition, we observed no differences in the frequency of hypoglycemia (<70 mg/dl) between medicine and surgical patients (15% vs. 14%, $p = 0.95$) during the hospital stay (Table 2). Severe hypoglycemia (<40 mg/dL) was rare and observed in one patient in each group. In all cases, hypoglycemia was corrected with oral dextrose, and none of these hypoglycemia episodes were associated with adverse outcomes. There was also no difference in outcome within medicine or surgery subgroups depending on whether they received treatment with basal bolus or basal plus regimens.

4. Discussion

This study determined differences in inpatient glycemic control between general medicine and surgery patients treated with a single daily dose of glargine plus correction doses with glulisine before meals and with a standard basal bolus regimen. We observed that treatment with basal plus and basal bolus regimens resulted in a similar improvement in glycemic control, and that medicine and surgery patients experienced a similar response to either

treatment regimen without differences in mean daily BG, insulin requirements, or in the frequency of hypoglycemia during the hospital stay.

Our study identifies differences on admission and response to insulin therapy in general medicine and surgery patients with T2D. Medicine patients were found to have significantly higher BG and HbA1c concentration compared to surgery patients. It is not known what explains this difference, but it may relate to severity of illness and stress in medicine patients, nutritional differences with lower caloric intake during the perioperative period, improved glycemic control prior to surgery in elective surgery patients (McDonnell & Umpierrez, 2012; Smiley & Umpierrez, 2011), or to more medical complications that might have led physicians to choose less stringent targets in the medical patients consistent with recent guidelines (Moghissi et al., 2009; Umpierrez et al., 2012). Despite differences on admission BG, medicine and surgery patients experienced a similar improvement in glycemic control in response to either treatment regimen. These results are in agreement with previous clinical trials that reported improvement in glycemic control with basal bolus therapy compared to sliding scale regular insulin, which was previously accompanied by significant reduction in the frequency of hospital complications including wound infection, pneumonia, bacteremia, and acute respiratory and renal failure (Umpierrez et al., 2007, 2011).

We acknowledge the following limitations in this study. We excluded patients undergoing cardiac surgery or in need of ICU care and with clinically relevant hepatic disease or with serum creatinine ≥ 3.0 mg/dL, and history of hyperglycemic crises. In addition, we limited the recruitment to patients treated with diet, oral antidiabetic agents and low-dose insulin therapy and excluded patients receiving a total insulin dose > 0.4 U/kg per day prior to admission. Patients receiving higher insulin doses on admission are likely to benefit from the standard basal bolus approach in order to achieve glycemic control during the hospital stay. In addition, our study was not powered to determine differences in hospital complications between treatment groups.

In summary, our results indicate that most general medicine and surgery patients with T2D treated with diet, oral antidiabetic agents or low-dose insulin (≤ 0.4 U/day) can be managed with a single daily dose of basal insulin with supplemental (correction) doses of rapid-acting insulin analogs before meals. We also found that medicine and surgery patients experienced similar improvement of glycemic control with either treatment group during the hospital stay. These results suggest that basal insulin is necessary for stable glucose control in the hospital in medicine and surgery patients and that the basal plus approach is an effective alternative for the initial management of hyperglycemia for non-ICU patients with T2D.

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Fig. 1.

Differences in glycemic control in medicine and surgery patients with type 2 diabetes treated with basal bolus and basal plus insulin regimens. Treatment groups: basal bolus (close circles) and basal plus regimen (open circles). Treatment groups: basal bolus (close circles) and basal plus regimen (open circles). A: Mean daily glucose levels in medicine patients. * $p = 0.04$, all other p values < 0.05 . B: Mean daily glucose levels in surgery patients. All p values < 0.05 . C: Mean glucose levels before meals and bedtime in medicine patients. * $p = 0.03$, all other p values < 0.05 . D: Mean glucose levels before meals and bedtime in surgery patients. All p values < 0.05 .

Table 1

Overall clinical characteristics of patients treated with basal bolus and basal plus insulin regimens.

Variable	Basal Bolus	Basal Plus	P-Value
Number of patients	144	133	
Gender			0.78
Male, n (%)	86 (60)	78 (59)	
Female, n (%)	58 (40)	55 (41)	
Age, years	58.7 ± 11	58.6 ± 13	0.90
BMI, kg/m ²	32.6 ± 8	33.0 ± 9	0.77
Body weight, kg	96 ± 24	98 ± 28	0.68
Duration diabetes, years	9.9 ± 8	7.5 ± 7	0.006
Admission service			0.87
Medicine, n (%)	82 (56)	76 (57)	
Surgery, n (%)	64 (44)	57 (43)	
Hospital LOS, days	6.0 ± 5	6.2 ± 6	0.91

Data are mean ± standard deviation.

Table 2

Clinical characteristics of medicine and surgery patients with type 2 diabetes.

Variable	Medicine	Surgery	P-Value
Number of patients	158	121	
Gender, M/F	98/60	68/53	0.33
Age, years	57.5 ± 12.1	60.1 ± 11.0	0.053
BMI, kg/m ²	33.6 ± 9.5	31.7 ± 7.0	0.17
Body weight, kg	100.3 ± 28.2	92.8 ± 22.2	0.050
Duration diabetes, years	9.0 ± 7.6	8.5 ± 6.9	0.76
Hospital LOS, days	5.4 ± 5.0	7.1 ± 6.3	0.003
Insulin Regimen, n (%)			
Basal Bolus, n (%)	82 (52)	64 (53)	
Basal Plus, n (%)	76 (48)	57 (47)	
Admission DM therapy			0.17
No therapy, n (%)	19 (12)	13(11)	
Oral agents, n (%)	110 (70)	87 (72)	
Insulin alone, n (%)	22 (14)	9(7)	
Insulin + oral agents, n (%)	7(4)	12 (10)	
Primary Admission Diagnosis			
Cardiovascular, n (%)	74 (47)		
Pulmonary, n (%)	25 (16)		
Infection, n (%)	29 (18)		
Cancer, n (%)	14(9)		
Renal, n (%)	33 (21)		
Type of surgery			
Abdominal, n (%)		27 (24)	
Vascular, n (%)		8 (7)	
Orthopedics, n (%)		39 (35)	
Thoracic, n (%)		10 (9)	
Urologic, n (%)		14 (13)	
Other, n (%)		9 (8)	
Glycemic Control			
HbA1C, %	9.1 ± 2.5	7.7 ± 2.1	<0.001
Admit BG, mg/dl	220.0 ± 89	193.9 ± 78	0.012
Randomization BG, mg/dl	196.7 ± 45	197.3 ± 49	0.92
Average BG Hospital stay	169.4 ± 36	164.1 ± 35	0.13
Mean BG, after 1st day of therapy	161.4 ± 37	156.7 ± 37	0.18
% BG readings 70-140 mg/dl	37.1 ± 289	42.1 ± 31	0.24
% BG readings > 140 mg/dl	60.9 ± 30	56.5 ± 32	0.29
% BG readings > 180 mg/dl	32.6 ± 29	26.3 ± 30	0.041
Treatment failures			
Treatment failures, n (%)	1(1)	2(2)	0.58

Variable	Medicine	Surgery	P-Value
Day of treatment failure	3.0 ± 0.7	3.5 ± 0.7	
Insulin Treatment			
Total insulin, U/day	31.0 ± 15.2	28.3 ± 11.4	0.36
Total insulin, U/kg/day	0.3 ± 0.1	0.3 ± 0.1	0.85
Total glargine insulin, U/day	17.7 ± 9.2	16.9 ± 7.4	0.78
Total glulisine insulin, U/day	12.7 ± 9.6	10.8 ± 8.6	0.10
Hypoglycemic Events			
Number of BG tests	13.7 ± 9.6	15.8 ± 11.2	0.15
# Patients < 70 mg/dl, n (%)	23 (15)	17 (14)	0.95
% BG readings < 70 mg/dl	1.7 ± 5.3	1.1 ± 3.4	0.79
# Patients < 60 mg/dl, n (%)	10 (6)	9(8)	0.81
% BG readings < 60 mg/dl	0.6 ± 3.2	0.5 ± 1.8	0.74
# Patients < 40 mg/dl, n (%)	1 (1)	1 (1)	>0.99
% BG readings < 40 mg/dl	0.1 ± 0.8	0.1 ± 0.6	0.84

Data are mean ± standard deviation.