



Hospital Discharge Algorithm Based on Admission HbA_{1c} for the Management of Patients With Type 2 Diabetes

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Guillermo E. Umpierrez,¹ David Reyes,¹
Dawn Smiley,¹ Kathie Hermayer,²
Amna Khan,³ Darin E. Olson,^{1,4}
Francisco Pasquel,¹ Sol Jacobs,¹
Christopher Newton,¹ Limin Peng,⁵
and Vivian Fonseca³

OBJECTIVE

Effective treatment algorithms are needed to guide diabetes care at hospital discharge in general medicine and surgery patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS

This was a prospective, multicenter open-label study aimed to determine the safety and efficacy of a hospital discharge algorithm based on admission HbA_{1c}. Patients with HbA_{1c} <7% (53.0 mmol/mol) were discharged on their preadmission diabetes therapy, HbA_{1c} between 7 and 9% (53.0–74.9 mmol/mol) were discharged on a preadmission regimen plus glargine at 50% of hospital daily dose, and HbA_{1c} >9% were discharged on oral antidiabetes agents (OADs) plus glargine or basal bolus regimen at 80% of inpatient dose. The primary outcome was HbA_{1c} concentration at 12 weeks after hospital discharge.

RESULTS

A total of 224 patients were discharged on OAD (36%), combination of OAD and glargine (27%), basal bolus (24%), glargine alone (9%), and diet (4%). The admission HbA_{1c} was $8.7 \pm 2.5\%$ (71.6 mmol/mol) and decreased to $7.3 \pm 1.5\%$ (56 mmol/mol) at 12 weeks of follow-up ($P < 0.001$). The change of HbA_{1c} from baseline at 12 weeks after discharge was -0.1 ± 0.6 , -0.8 ± 1.0 , and -3.2 ± 2.4 in patients with HbA_{1c} <7%, 7–9%, and >9%, respectively ($P < 0.001$). Hypoglycemia (<70 mg/dL) was reported in 22% of patients discharged on OAD only, 30% on OAD plus glargine, 44% on basal bolus, and 25% on glargine alone and was similar in patients with admission HbA_{1c} ≤7% (26%) compared with those with HbA_{1c} >7% (31%, $P = 0.54$).

CONCLUSIONS

Measurement of HbA_{1c} on admission is beneficial in tailoring treatment regimens at discharge in general medicine and surgery patients with type 2 diabetes.

Diabetes is the fourth leading comorbid condition associated with any hospital discharge in the U.S., and individuals with diabetes have higher rates of hospitalization compared with people without diabetes for all age-groups than the general population (1). Data from the Healthcare Cost and Utilization Project (HCUP) on hospital use by patients with diabetes reported that in 2008, there were over 7.7 million hospital stays for patients with diabetes in the U.S. (2). Mounting observational and interventional data indicate that hyperglycemia in hospitalized patients

¹Division of Endocrinology, Department of Medicine, Emory University, Atlanta, GA

²Division of Endocrinology, Department of Medicine, Medical University of South Carolina, Charleston, SC

³Division of Endocrinology, Department of Medicine, Tulane Medical Center, New Orleans, LA

⁴Atlanta Veterans Affairs Medical Center, Decatur, GA

⁵Rollins School of Public Health, Emory University, Atlanta, GA

Corresponding author: Guillermo E. Umpierrez, geumpie@emory.edu.

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with and without diabetes is associated with increased morbidity and mortality (3–12) and that improvement in glyce-mic control reduces hospital complica-tions and hospitalization costs (13). Several weight-based subcutaneous in-sulin regimens have been proven effec-tive in improving glycemic control and in reducing hospital complications in gen-eral medicine and surgery patients with type 2 diabetes (14–16).

Few studies have focused on the op-timal management of hyperglycemia and diabetes after hospital discharge. The recent Endocrine Society inpatient guidelines for the management of non-intensive care unit patients with diabe-tes (17) reported that patients with diabetes and hyperglycemia should have an HbA_{1c} measured to assess pre-admission glycemic control and to tailor treatment regimen at discharge. These guidelines recommended that patients with acceptable diabetes control (HbA_{1c} <7% or 53 mmol/mol) could be dis-charged on their prehospitalization treat-ment regimen (oral agents and/or insulin therapy). Patients with suboptimal glu-cose control and HbA_{1c} between 7 and 9% (53.0–74.9 mmol/mol) should have intensification of therapy either by adding or increasing the dose of oral agents or by adjusting the dose of basal insulin. Those with HbA_{1c} >9% (74.9 mmol/mol) should be considered candidates for a basal bolus insulin regimen. These recommenda-tions were based on an expert consensus, as no previous randomized clinical trials have determined best treatment regi-mens at discharge in patients with diabe-tes. Accordingly, we conducted an exploratory study to test the safety and efficacy of a discharge algorithm based on admission HbA_{1c} in general medicine and surgical patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS

Patients enrolled in the Basal Plus trial (16) were invited to participate in this postdischarge study. The Basal Plus trial was a multicenter randomized inpatient trial that recruited 375 adult patients with a known history of type 2 diabetes and a blood glucose between 140 mg/dL and 400 mg/dL who were receiving treatment prior to admission with diet, any combination of oral antidiabetes agents (OADs), or low-dose insulin ther-apy at a daily dose \leq 0.4 units/kg prior to admission. The use of OADs was

stopped on admission, and patients were randomly assigned to receive a basal bolus regimen with insulin glar-gine once daily and glulisine before meals, a basal plus regimen with a daily dose of glargine and correction doses of glulisine by sliding scale before meals for glucose >140 mg/dL, or regular insulin per sliding scale for glucose >140 mg/dL.

A total of 224 patients in the Basal Plus trial agreed to participate in this 12-week postdischarge, open-label ex-ploratory study. The majority of patients who declined participation opted to be followed by their primary care physician or lived too far away from the hospital to participate in the outpatient arm of the study. In addition, we excluded patients who were expected to undergo read-mission for additional medical or surgi-cal treatment within the following 3 months and patients with clinically rel-evant hepatic disease (diagnosed liver cir-rhosis and portal hypertension); corticosteroid therapy; impaired renal function (serum creatinine \geq 3.0 mg/dL); a mental condition rendering the subject unable to understand the na-ture, scope, and possible consequences of the study; recognized or suspected endocrine disorders associated with increased insulin resistance, as well as patients who were pregnant or breast-feeding, at time of enrollment into the study.

In this study, patients were grouped according to the admission HbA_{1c} con-centration. In this discharge protocol, most patients with HbA_{1c} <7% (53.0 mmol/mol) were discharged on their preadmission oral agents or insulin ther-apy. Patients with an HbA_{1c} between 7 and 9% (53.0–74.9 mmol/mol) treated with OAD or with OAD and insulin prior to admission were discharged on their preadmission OAD and 50% of glargine total daily dose. Patients with admission HbA_{1c} >9% (74.9 mmol/mol) treated with OAD or with OAD and insulin prior to admission were discharged on their OAD and 80% of glargine total daily dose or with basal bolus regimen with glar-gine and glulisine at 80% of hospital dose. The inpatient nurses and diabetes educators provided education on insulin administration. Patients treated with in-sulin prior to admission were discharged on basal bolus insulin therapy at 80% of total hospital daily dose. Patients were asked to measure capillary blood

glucose before meals after discharge and to bring their glucose meter and glucose diary log to each clinic visit. Hypoglycemia data were collected from their self-monitoring of blood glucose records. Treatment was adjusted to achieve a fasting and premeal glucose between 80 and 130 mg/dL. During follow-up, the research team contacted patients via telephone every 2 weeks to determine the presence of complica-tions and to encourage compliance with therapy and clinic visits. Patients were asked to attend the diabetes research center at 1 and 3 months after dis-charge. During follow-up, the diabetes research team adjusted insulin doses following a modification of the glargine treat-to-target study (Tables 1 and 2 and Supplementary Data).

The primary outcome was a change in HbA_{1c} concentration from baseline (hos-pital admission) at 12 weeks after dis-charge. Secondary outcomes included change in HbA_{1c} concentration from baseline at 4 weeks after discharge, fast-ing and mean daily glucose concentra-tion, number of hypoglycemic events (<70 mg/dL) and severe hypoglycemia (<40 mg/dL), daily insulin require-ments, use of oral agents, number of emergency room visits and hospital re-admissions, and number of complica-tions during the study period.

This study was conducted at Grady Memorial Hospital, Emory University Hospital, and the Veterans Administra-tion Medical Center in Atlanta, Georgia; at the Medical University of South Car-olina in Charleston, South Carolina; and at Tulane Medical Center in New Or-leans, Louisiana. The study protocol and consent form were approved by the institutional review board at each of the participating institutions.

Statistical Analysis

The primary goal of this study was to assess differences in HbA_{1c} from base-line at 12 weeks after discharge. The comparisons were made with the use of Wilcoxon tests (or Kruskal-Wallis tests) for continuous variables and χ^2 tests (or Fisher exact test) for discrete variables. Multivariate analysis was con-ducted based on a repeated-measures linear model, which accounted for within-subject blood glucose correlation through an autoregressive model of or-der 1 correlation structure. A *P* value of

Table 1—Clinical characteristics of study patients

Variable	HbA _{1c} <7%	HbA _{1c} 7–9%	HbA _{1c} >9%	P
Number of patients	71	71	81	
Sex, n (%)				0.33
Male	42 (59)	38 (54)	53 (65)	
Female	29 (41)	33 (46)	28 (35)	
Age, years	61.4 ± 11	58.4 ± 11	53.9 ± 12	<0.001
BMI, kg/m ²	31.5 ± 7	33.3 ± 9	34.1 ± 10	0.47
Body weight, kg	94.1 ± 22	97.1 ± 28	101.5 ± 33	0.63
Duration of diabetes, years	8.6 ± 8	9.2 ± 8	10.0 ± 7	0.24
Admission service				0.019
Medicine, n (%)	36 (51)	45 (63)	59 (73)	
Surgery, n (%)	35 (49)	26 (37)	22 (27)	
Hospital LOS, days	5.8 ± 5	6.4 ± 5	5.7 ± 7	0.14
Admission diabetes therapy, n (%)				0.05
Diet alone	9 (13)	5 (7)	14 (17)	
Oral agents	57 (80)	52 (73)	50 (62)	
Insulin alone	4 (6)	7 (10)	11 (14)	
Insulin and oral agents	1 (1)	7 (10)	6 (7)	
Discharge diabetes therapy, n (%)				<0.001
Diet alone	5 (7)	3 (4)	0 (0)	
Oral agents	53 (75)	23 (32)	4 (5)	
Insulin alone	9 (12)	14 (20)	51 (63)	
Insulin and oral agents	4 (6)	31 (44)	26 (32)	
Glycemic control				
HbA _{1c} on admission, % (mmol/mol)	6.2 ± 0.5 (44 ± 6)	7.9 ± 0.6 (63 ± 6)	11.5 ± 1.7 (102 ± 19)	<0.001
HbA _{1c} 4 weeks after discharge, % (mmol/mol)	6.6 ± 1.0 (49 ± 11)	7.2 ± 0.9 (55 ± 9.8)	9.1 ± 1.6 (76 ± 18)	<0.001
HbA _{1c} 12 weeks after discharge, % (mmol/mol)	6.3 ± 0.9 (45 ± 10)	7.1 ± 1.0 (54 ± 11)	8.1 ± 1.7 (186 ± 19)	<0.001
FBG 4 weeks after discharge, mg/dL	133.7 ± 24	142.6 ± 37	148.4 ± 40	0.26
FBG 12 weeks after discharge, mg/dL	125.9 ± 21	129.5 ± 20	151.1 ± 34	0.002

Data are means ± SD unless otherwise indicated. For conversion of HbA_{1c} value in % to mmol/mol: 10.93 × %HbA_{1c} value – 23.5. FBG, fasting blood glucose; LOS, length of hospital stay.

<0.05 is considered significant. Statistical analyses were performed using SAS (version 9.2). The data were generally presented as means ± SD for continuous variables and count (percentage) for discrete variables.

RESULTS

Among the 224 patients (140 medicine and 84 surgery), a total of 71, 71, and 81 patients had an admission HbA_{1c} <7%, 7–9%, and >9% (<53.0, 53.0–74.9, and >74.9 mmol/mol), respectively. Their

clinical characteristics are shown in Table 1. Patients with HbA_{1c} <7% were older than those with levels 7–9% and >9%. There were no significant differences in BMI, duration of diabetes, type of treatment prior to admission,

Table 2—Change in HbA_{1c}, daily blood glucose, and frequency of hypoglycemia after hospital discharge

	All patients	OAD	OAD + basal	Basal bolus	Basal alone	P
Patients, n (%)	224	81 (36)	61 (27)	54 (24)	20 (9)	
HbA _{1c} on admission, % (mmol/mol)	8.7 ± 2.5 (72 ± 27)	6.9 ± 1.5 (52 ± 16)	9.2 ± 1.9 (77 ± 21)	11.1 ± 2.3 (98 ± 25)	8.2 ± 2.2 (66 ± 24)	<0.001
HbA _{1c} at 4 weeks, % (mmol/mol)	7.9 ± 1.7 (63 ± 24)*	7.0 ± 1.4 (53 ± 15)	8.0 ± 1.4 (64 ± 15)*	8.8 ± 1.8 (73 ± 20)*	7.7 ± 1.7 (61 ± 24)	<0.001
HbA _{1c} at 12 weeks, % (mmol/mol)	7.3 ± 1.5 (56 ± 16)*	6.6 ± 1.1 (49 ± 12)	7.5 ± 1.6 (73 ± 18)*	8.0 ± 1.6 (64 ± 18)*	6.7 ± 0.8 (50 ± 9)	0.003
Fasting BG at 4 weeks, mg/dL	142 ± 35	136 ± 23	138 ± 36	154 ± 39	142 ± 50	0.28
Fasting BG at 12 weeks, mg/dL	137 ± 29	134 ± 26.9	135 ± 28	145 ± 34	129 ± 22	0.71
Patients with BG <70 mg/dL, n (%)	62 (29)	17 (22)	17 (30)	23 (44)	5 (25)	0.039
Patients with BG <40 mg/dL, n (%)	7 (3)	3 (4)	0 (0)	3 (6)	0 (0)	0.69

Data are means ± SD unless otherwise indicated. Basal insulin = glargine. Bolus = glulisine insulin. BG, blood glucose. *P < 0.01 vs. baseline value.

or mean hospital length of stay among the admission HbA_{1c} groups.

At discharge, a total of 81 patients (36%) were treated with OAD, 61 patients (27%) received OAD and glargine, 54 patients (24%) were on basal bolus, 20 patients (9%) were on glargine alone, and 8 patients (4%) received diet treatment alone. Most patients with HbA_{1c} <7% were discharged on OAD (75%), while those with HbA_{1c} >9% were discharged on OAD plus insulin (32%) or on a basal bolus regimen (57%). Those with HbA_{1c} between 7 and 9% were treated with OADs (32%), OAD and insulin (44%), basal alone (11%), or basal bolus (8%).

The HbA_{1c} on admission in the entire cohort was 8.7 ± 2.5% and decreased to 7.9 ± 1.7% at 4 weeks and to 7.3 ± 1.5% (56.3 mmol/mol) at 12 weeks of follow-up (both, *P* < 0.001) (Fig. 1) (Table 2). The mean fasting blood glucose was 158 ± 39 mg/dL at discharge and decreased to 142 ± 35 mg/dL and 137 ± 29 mg/dL at 4 and 12 weeks, respectively (both *P* < 0.001). The change of HbA_{1c} from baseline to 12 weeks was -0.1 ± 0.6%, -0.8 ± 1.0%, and -3.2 ± 2.4% in patients with HbA_{1c} <7%, 7–9%, and >9%, respectively (*P* < 0.001). There were no significant differences in the change in HbA_{1c} from baseline among each group of patients treated

with different treatment agents (*P* = 0.35).

A total of 62 patients (29%) experienced one or more episodes of mild hypoglycemia (<70 mg/dL), and 7 patients (3%) had glucose <40 mg/dL during follow-up. Hypoglycemia was reported in 26, 25, and 36% of patients with HbA_{1c} <7, 7–9, and >9% (<53.0, 53.0–74.9, and >74.9 mmol/mol) (*P* = 0.27) and was present in 22% patients discharged on OAD, 30% on OAD and glargine, 44% on basal bolus, and 25% on glargine alone (Supplementary Table 3). A glucose <40 mg/dL was reported in 4% of patients on OAD and in 6% on basal bolus therapy (*P* = 0.69). None of these episodes resulted in hospital admission or in serious neurological or cardiovascular complications.

Table 3 shows differences in clinical characteristics, glycemic control, use of insulin, and frequency of hypoglycemic events after discharge between medicine and surgery patients. Surgery patients had a lower HbA_{1c} on admission compared with medicine patients (*P* = 0.005). Difference in HbA_{1c} persisted at 4 weeks, but there were no differences in HbA_{1c} between medicine and surgery patients at 12 weeks after discharge. In addition, we observed no differences in insulin use or in the frequency of hypoglycemia events between medicine and

surgery patients after discharge. Similarly, we observed no differences in the rate of emergency room visits, hospital readmissions, or infection complications among treatment groups after discharge.

CONCLUSIONS

This prospective, multicenter clinical trial aimed to determine the safety and efficacy of an HbA_{1c}-based algorithm to guide outpatient therapy in general medicine and surgery patients with type 2 diabetes. Our study indicates that measurement of HbA_{1c} is helpful in assessing glycemic control prior to admission and in tailoring the treatment regimen at the time of hospital discharge. The proposed algorithm was successful in improving HbA_{1c} by ~1.5% with an acceptable rate of hypoglycemia during the 12 weeks of the study period. Our results indicate that patients admitted with an HbA_{1c} <7% (53.0 mmol/mol) can be discharged on the same preadmission diabetes therapy (oral agents or insulin). Those with HbA_{1c} between 7 and 9% (53.0–74.9 mmol/mol) can be discharged on the combination of oral agents plus half of the inpatient basal insulin dose, and patients with HbA_{1c} >9% (74.9 mmol/mol) can be discharged on oral agents and 80% of the inpatient basal insulin dose or on a basal bolus insulin regimen.

There is extensive evidence of clinical inertia, defined as failure to initiate or intensify therapy when it is clinically indicated, in the inpatient management and at the time of hospital discharge (18,19). In a multicenter, retrospective study of patients with poorly controlled diabetes and at least one hospitalization within the Veterans Affairs health system, less than a quarter received any change in outpatient diabetes therapy upon discharge (19). In a different study among 2,025 admissions in adult patients with diabetes and a median postdischarge HbA_{1c} of 8.7% (71.6 mmol/mol), only 22.4% of patients had some change in diabetes medications at discharge. Lipska et al. (20) and Lovig et al. (21) reported that one out of eight older diabetic patients were discharged on no antihyperglycemic therapy after acute myocardial infarction, a practice that is associated with increased 1-year mortality, more frequent hospitalizations, and greater health care expenditure (22).

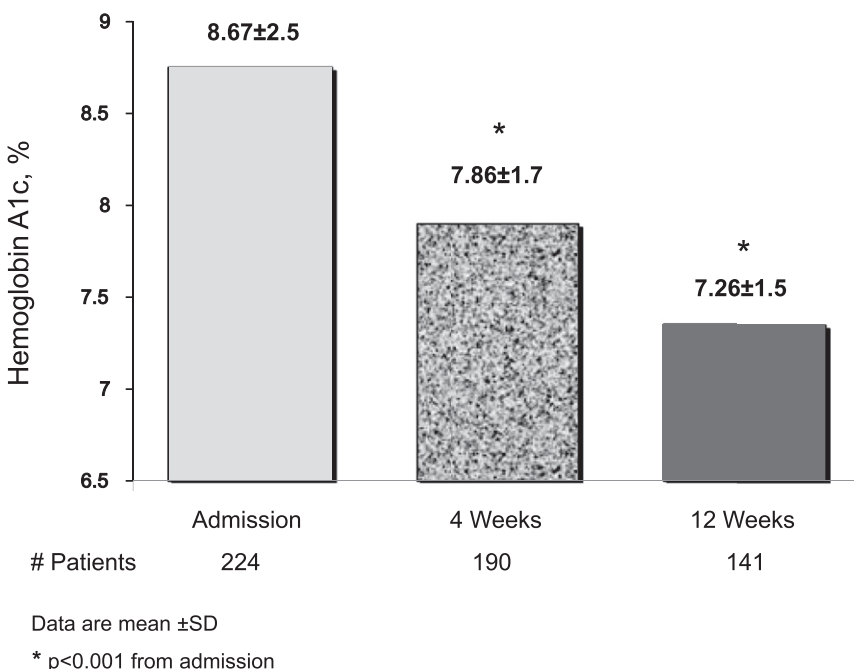


Figure 1—Change in HbA_{1c} concentration at 4 weeks and 12 weeks after hospital discharge.

Table 3—Summary of follow-up data by hospital service

Variable	Medicine	Surgery	P
N	140	89	
Age, years	57.0 ± 12.3	59 ± 11.0	0.26
Sex, n (%)			0.28
Female	53 (38)	38 (45)	
Male	87 (62)	46 (55)	
BMI, kg/m ²	33.6 ± 9.9	31.9 ± 7.9	0.34
Duration of diabetes, years	9.7 ± 8.2	8.6 ± 6.8	0.54
Admission HbA _{1c} , % (mmol/mol)	9.0 ± 2.5 (75 ± 27)	8.1 ± 2.3 (65 ± 25)	0.005
HbA _{1c} 4 weeks after discharge, % (mmol/mol)	8.1 ± 1.7 (65 ± 19)	7.4 ± 1.5 (57 ± 19)	0.010
HbA _{1c} 12 weeks after discharge, % (mmol/mol)	7.3 ± 1.4 (56 ± 15)	7.2 ± 1.6 (55 ± 18)	0.41
FBG 4 weeks after discharge, mg/dL	145.4 ± 39	135.6 ± 26	0.25
FBG 12 weeks after discharge, mg/dL	136.9 ± 27	136.4 ± 33	0.60

FBG, fasting blood glucose.

Several barriers may prevent the intensification of a patient's regimen at discharge, including the fear of hypoglycemia, lack of confidence to effectively address these therapies at discharge, lack of effective transition of care processes, and patient-specific factors such as fear or refusal to initiate insulin injections, mental or physical disabilities, or financial and social barriers.

Recent inpatient guidelines for the management of non-intensive care unit patients with diabetes recommend the use of insulin for most patients with diabetes during the hospital stay but recognize that many patients will not need insulin at discharge. Our study supports this recommendation. For patients with a history of diabetes with acceptable control and with HbA_{1c} within goal range, oral antihyperglycemic drugs can be restarted at discharge in the absence of contraindications. Patients with suboptimal control should have intensification of therapy, by either the addition or increase in oral agents, through addition of basal insulin, or on a basal bolus insulin regimen. In this study, we showed that effective glycemic control after discharge was achieved with restarting oral agents in combination with 80% of hospital daily dose of basal insulin in patients with HbA_{1c} >9% (74.9 mmol/mol) or restarting oral agents in combination with 50% of hospital daily dose of basal insulin in patients with HbA_{1c} between 7 and 9% (53.0–74.9 mmol/mol).

Discharge planning recommendations in the 2014 American Diabetes Association standards of care include

having a follow-up within 1 month with a primary or diabetes care provider for all patients who are hyperglycemic in the hospital (23). Early postdischarge telephone follow-up with diabetes nurse specialists was shown to improve HbA_{1c} and result in better adherence to self-monitoring of blood glucose at 24 weeks after discharge in patients with suboptimal glycemic control (24). Mons et al. (25) reported that a patient-centered supportive counseling intervention comprised of monthly telephone-based counseling sessions by nurses over 12 months improved diabetes-related medical and psychosocial outcomes compared with usual care in type 2 diabetic patients with HbA_{1c} >7.5% (58.5 mmol/mol). In our study, patients had telephone contacts every 2 weeks during the first 2 months and follow-up visits at 1 and 3 months, which may have in part explained the observed improvement in glycemic control after hospital discharge.

The transition of care from the inpatient to the outpatient setting is an important national priority. The 2013 National Patient Safety Goals include goals and requirements for hospital discharge planning and transitional care (26). These requirements emphasize the development of a diabetes discharge planning that should include appropriate communication among caregivers, reconciling medication across the continuum of care, and encouraging patients' involvement in their own care. Unfortunately, transition from hospital to home does not always

go smoothly, resulting in an adverse event, poor glycemic control, and increased rate of emergency room visits (27,28) and higher hospital readmission rates and costs (28). One study estimated that 80% of serious medical errors involve miscommunication during the hand off between medical providers (29). To reduce both readmission rates and adverse events, hospitals must improve the effectiveness of transitions of care in which they play a role. Hospitals with unacceptably high readmission rates for Medicare and Medicaid patients may face financial penalties under the Patient Protection and Affordable Care Act (30).

There are several limitations including a relatively short duration of follow-up after discharge in a small number of patients in the study. The use of an HbA_{1c} value is a widely accepted tool to assess the response to antidiabetes therapy in ambulatory patients; however, HbA_{1c} values in the inpatient setting could have been altered in the presence of blood transfusions, iron deficiency anemia, hemoglobinopathies, high-dose salicylates, acute blood loss, and high-turnover anemia states (e.g., hemolysis) (31). Large randomized controlled studies with duration of follow-up of 6–12 months are needed to determine the impact of improved glycemic control after discharge on clinical outcome and resource utilization.

In summary, hospital discharge represents a critical time for ensuring a safe transition to the outpatient setting and to reduce the need for emergency department visits and repeated hospitalizations in patients with diabetes. Our study indicates that measurement of HbA_{1c} on admission is helpful in assessing glycemic control and in tailoring the treatment regimen at the time of hospital discharge in patients with type 2 diabetes.

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Author Contributions. G.E.U. wrote the initial research proposal and manuscript. D.R. collected and researched data. D.S., K.H., A.K., S.J., C.N., and V.F. reviewed and edited the research proposal and manuscript and contributed to discussion. D.E.O. and F.P. reviewed and edited the research proposal and manuscript, contributed to discussion, and collected and researched data. L.P. reviewed and edited the research proposal and manuscript, contributed to discussion, and conducted the statistical analyses. 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.

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