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 HbA1c. Patients with HbA1c <7% (53.0 mmol/mol) were discharged on their preadmission diabetes therapy, HbA1c 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 HbA1c >9% were discharged on oral antidiabetes agents (OADs) plus glargine or basal bolus regimen at 80% of inpatient dose. The primary outcome was HbA1c 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 HbA1c was 8.7 ± 2.5% (71.6 mmol/mol) and decreased to 7.3 ± 1.5% (56 mmol/mol) at 12 weeks of follow-up (P < 0.001). The change of HbA1c from baseline at 12 weeks after discharge was −0.1 ± 0.6, −0.8 ± 1.0, and −3.2 ± 2.4 in patients with HbA1c <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 HbA1c ≤7% (26%) compared with those with HbA1c >7% (31%, P = 0.54).

CONCLUSIONS
Measurement of HbA1c 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...
with and without diabetes is associated with increased morbidity and mortality (3–12) and that improvement in glycemic control reduces hospital complications and hospitalization costs (13). Several weight-based subcutaneous insulin regimens have been proven effective in improving glycemic control and in reducing hospital complications in general medicine and surgery patients with type 2 diabetes (14–16).

Few studies have focused on the optimal management of hyperglycemia and diabetes after hospital discharge. The recent Endocrine Society inpatient guidelines for the management of non-intensive care unit patients with diabetes (17) reported that patients with diabetes and hyperglycemia should have an HbA1c measured to assess pre-admission glycemic control and to tailor treatment regimens at discharge. These guidelines recommended that patients with acceptable diabetes control (HbA1c <7% or 53 mmol/mol) could be discharged on their prehospitalization treatment regimen (oral agents and/or insulin therapy). Patients with suboptimal glucose control and HbA1c 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 HbA1c >9% (74.9 mmol/mol) should be considered candidates for a basal bolus insulin regimen. These recommendations were based on an expert consensus, as no previous randomized clinical trials have determined best treatment regimens at discharge in patients with diabetes. Accordingly, we conducted an exploratory study to test the safety and efficacy of a discharge algorithm based on admission HbA1c 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 therapy at a daily dose ≤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 glargine 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 exploratory 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 readmission for additional medical or surgical treatment within the following 3 months and patients with clinically relevant hepatic disease (diagnosed liver cirrhosis and portal hypertension), corticosteroid therapy; impaired renal function (serum creatinine ≥3.0 mg/dL); a mental condition rendering the subject unable to understand the nature, 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 breastfeeding, at time of enrollment into the study.

In this study, patients were grouped according to the admission HbA1c concentration. In this discharge protocol, most patients with HbA1c <7% (53.0 mmol/mol) were discharged on their preadmission oral agents or insulin therapy. Patients with an HbA1c 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 HbA1c >9% (74.9 mmol/mol) treated with OAD or with OAD and insulin prior to admission were discharged on their preadmission OAD and 80% of glargine total daily dose or with basal bolus regimen with glargine and glulisine at 80% of hospital dose. The inpatient nurses and diabetes educators provided education on insulin administration. Patients treated with insulin 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 complications and to encourage compliance with therapy and clinic visits. Patients were asked to attend the diabetes research center at 1 and 3 months after discharge. 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 HbA1c concentration from baseline (hospital admission) at 12 weeks after discharge. Secondary outcomes included change in HbA1c concentration from baseline at 4 weeks after discharge, fasting and mean daily glucose concentration, number of hypoglycemic events (<70 mg/dL) and severe hypoglycemia (<40 mg/dL), daily insulin requirements, use of oral agents, number of emergency room visits and hospital readmissions, and number of complications during the study period.

This study was conducted at Grady Memorial Hospital, Emory University Hospital, and the Veterans Administration Medical Center in Atlanta, Georgia; at the Medical University of South Carolina in Charleston, South Carolina; and at Tulane Medical Center in New Orleans, 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 HbA1c from baseline at 12 weeks after discharge. The comparisons were made with the use of Wilcoxon tests (or Kruskal-Wallis tests) for continuous variables and χ² tests (or Fisher exact test) for discrete variables. Multivariate analysis was conducted based on a repeated-measures linear model, which accounted for within-subject blood glucose correlation through an autoregressive model of order 1 correlation structure. A P value of
Table 1—Clinical characteristics of study patients

| Variable                                | HbA1c <7% | HbA1c 7–9% | HbA1c >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/m²                               | 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                        |           |            |           |     |
| HbA1c on admission, % (mmol/mol)        | 6.2 ± 0.5 (44 ± 6) | 7.9 ± 0.6 (63 ± 6) | 11.5 ± 1.7 (102 ± 19) | <0.001|
| HbA1c 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|
| HbA1c 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 HbA1c value in % to mmol/mol: 10.93407 * HbA1c 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 HbA1c <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 HbA1c <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, and

Table 2—Change in HbA1c, 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) |     |
| HbA1c 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|
| HbA1c, 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|
| HbA1c, 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 = glusiline insulin. BG, blood glucose. *P < 0.01 vs. baseline value.
or mean hospital length of stay among the admission HbA1c 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 HbA1c <7% were discharged on OAD (75%), while those with HbA1c >9% were discharged on OAD plus insulin (32%) or on a basal bolus regimen (57%). Those with HbA1c between 7 and 9% were treated with OADs (32%), OAD and insulin (44%), basal alone (11%), or basal bolus (8%).

The HbA1c 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) (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 HbA1c from baseline to 12 weeks was −0.1 ± 0.6%, −0.8 ± 1.0%, and −3.2 ± 2.4% in patients with HbA1c <7%, 7–9%, and >9%, respectively (P < 0.001). There were no significant differences in the change in HbA1c 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 HbA1c <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 HbA1c on admission compared with medicine patients (P = 0.005). Difference in HbA1c persisted at 4 weeks, but there were no differences in HbA1c 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 HbA1c-based algorithm to guide outpatient therapy in general medicine and surgery patients with type 2 diabetes. Our study indicates that measurement of HbA1c 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 HbA1c 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 HbA1c <7% (53.0 mmol/mol) can be discharged on the same preadmission diabetes therapy (oral agents or insulin). Those with HbA1c 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 HbA1c >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 HbA1c 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).
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 HbA1c 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 HbA1c >9% (74.9 mmol/mol) or re-starting oral agents in combination with 50% of hospital daily dose of basal insulin in patients with HbA1c 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 HbA1c 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 HbA1c >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 HbA1c value is a widely accepted tool to assess the response to antidiabetes therapy in ambulatory patients; however, HbA1c 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 HbA1c 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.

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 (%) | 53 (38) | 38 (45) | 0.28 |
| Male    | 87 (62) | 46 (55) |   |
| BMI, kg/m² | 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 HbA1c, % (mmol/mol) | 9.0 ± 2.5 (75 ± 27) | 8.1 ± 2.3 (65 ± 25) | 0.005 |
| HbA1c, 4 weeks after discharge, % (mmol/mol) | 8.1 ± 1.7 (65 ± 19) | 7.4 ± 1.5 (57 ± 19) | 0.010 |
| HbA1c, 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. | | | |

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