Improving Efficacy of Diabetes Management Using Treatment Algorithms in a Mainly Hispanic Population

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OBJECTIVE — To compare clinical outcomes obtained using treatment algorithms versus standard "usual care" to treat patients with type 2 diabetes in a community setting.

RESEARCH DESIGN AND METHODS — An observational group comparison was implemented in three community-based clinics in San Antonio, Texas: *1*) a community clinic following treatment algorithms (CC-TA), *2*) university clinic following treatment algorithms (UC-TA), and *3*) a community clinic following standard "usual care" practices (CC-SC). Three hundred fifty-eight recently diagnosed type 2 diabetic patients (90% Mexican American, from low-income neighborhoods) who were consecutively identified at the three clinics were recruited. Following medical and laboratory evaluation, participants were started on treatment for hyperglycemia, hypertension, and dyslipidemia and followed for 12 months.

RESULTS — Decrements in HbA_{1c} at 12 months in the CC-TA and UC-TA were 3.1 and 3.3%, respectively, compared to 1.3% in the CC-SC ($P < 0.0001$). Corresponding decrements in fasting plasma glucose at 12 months were 94 and 99 mg/dl, respectively, versus 38 mg/dl in CC-SC ($P < 0.0001$). Reductions in total cholesterol, LDL cholesterol, and triglycerides at 12 months were greater in both algorithm-managed clinics compared to standard care–managed clinics ($P < 0.0001$). In algorithm-managed clinics, there were 30% more documented eye exams and 24% more documented foot exams than in standard care–managed patients.

CONCLUSIONS — Adherence to the treatment algorithms improved metabolic outcomes in type 2 diabetic patients to a greater extent than standard care practices. These results have important clinical implications for the treatment of type 2 diabetic patients.

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The prevalence of type 2 diabetes has increased exponentially over the last decade, and it represents a major economical stress on the health care system (1). Type 2 diabetes is especially common in minority populations (2) in whom microvascular complications occur more frequently (3–6). Mexican Americans have increased prevalence of type 2 diabetes relative to non-Hispanic whites (7–9) and, at the time of diagnosis, are more hyperglycemic (10,11) and have more hypertension (12), more retinopathy (13), and a higher incidence of end-stage renal disease (14–16).

Previous studies (17–21) have shown that a nurse specialist using treatment algorithms can improve glycemic control in type 2 diabetic patients in managed care practice. However, the effectiveness of nurse case management with treatment algorithms for hyperglycemia, hypertension, and dyslipidemia has not been evaluated at the community level in a minority population at high risk for diabetes.

RESEARCH DESIGN AND METHODS

— A treatment intervention for type 2 diabetes was implemented in San Antonio, Texas (1994–1996), to evaluate the effectiveness of treatment algorithms versus standard care in improving glycemic control and cardiovascular risk factors in low-income, type 2 diabetic Mexican Americans in Bexar County, Texas (22).

Setting

Programs were established in three community-based outpatient health care facilities: *1*) a community clinic following treatment algorithms (CC-TA), *2*) a university clinic following treatment algorithms (UC-TA), and *3*) a community clinic following standard "usual care" practices (CC-SC). Clinics were in close proximity, served mainly low-income, Spanish-speaking populations, and were well-established community health care centers with similar numbers of physicians (5–7), nurses (5–7), dietitians (1), and staff. CC-TA and UC-TA patients were the primary intervention groups, and nurse case managers followed specific treatment algorithms to treat these patients. CC-SC patients served as the control group, receiving usual diabetes

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Abbreviations: ADA, American Diabetes Association; CC-SC, community clinic following standard "usual care" practices; CC-TA, community clinic following treatment algorithms; CME, continuing medical education; FPG, fasting plasma glucose; UC-TA, university clinic following treatment algorithms; TZD, thiazolidinedione; UTHSCSA, University of Texas Health Science Center at San Antonio.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

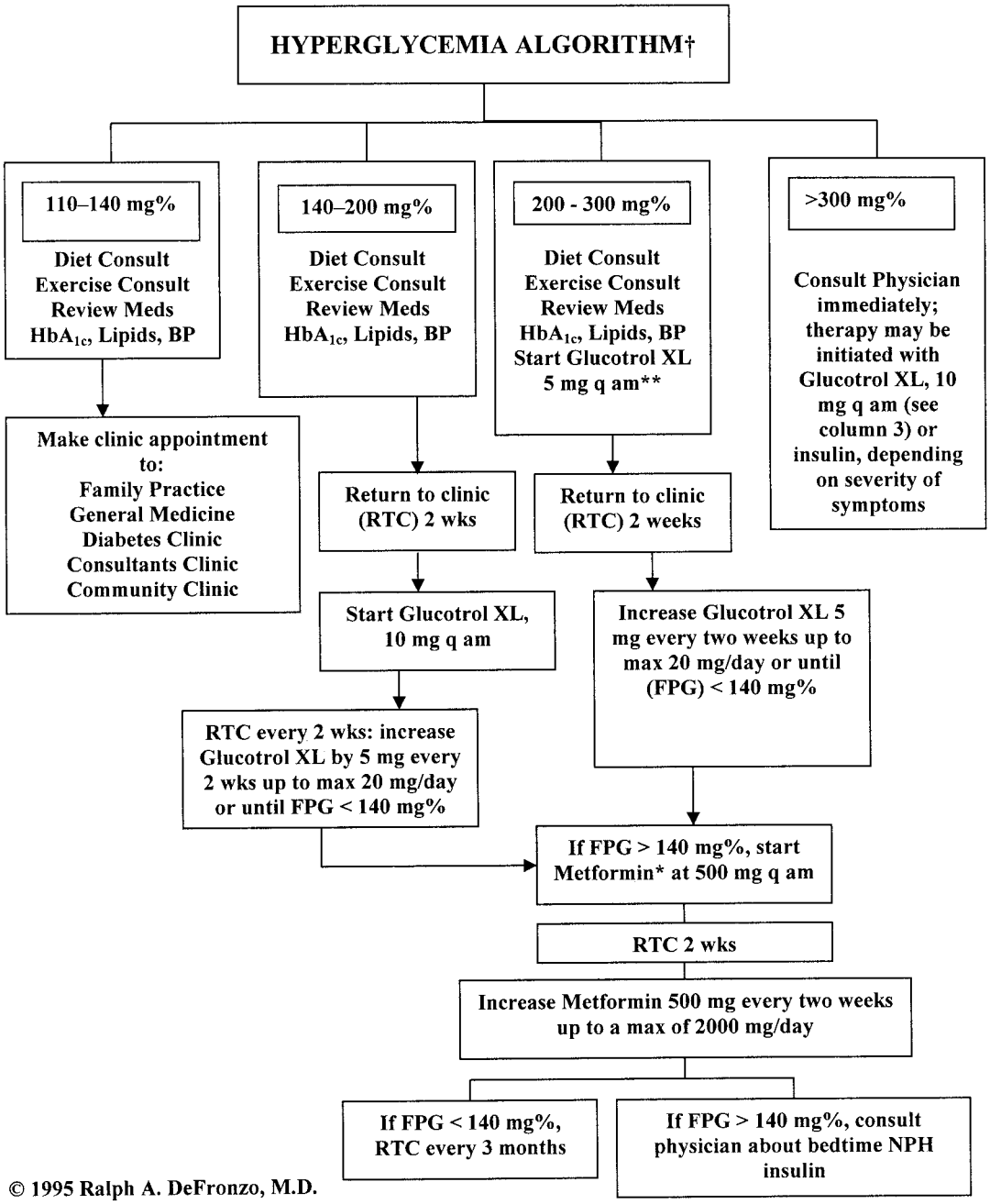

Figure 1—*Treatment algorithm for hyperglycemia. *Diabetic patients with renal disease (serum creatinine >1.4 in women or >1.5 mg/dl in men or creatinine clearance <70 ml/min) should not receive metformin; †HbA_{1c}, **blood pressure (BP), FPG, neutral protamine hagendorn (NPH) insulin. © 1995 Ralph A. DeFronzo, MD.*

care. The study was approved by the institutional review board of the University of Texas Health Science Center at San Antonio (UTHSCSA), and all participants gave written consent before participation.

Study participants and selection criteria

All patients attending the three clinics between June 1994 and December 1995 were eligible if they met the following criteria: *1*) type 2 diabetes diagnosed according to 1994 American Diabetes Association (ADA) criteria (23) within 1 year before entry, *2*) must not have taken an oral agent within 6 months or ever have received insulin, *3*) must not have taken a lipid-lowering or antihypertensive medication within 6 months, *4*) normal serum creatinine, and *5*) no proliferative diabetic retinopathy. At the CC-TA and UC-TA, patients were initially seen by a primary care physician who performed a brief medical history/physical examination (t = 18 min). Diabetic patients meeting entry criteria were referred to a nurse case manager for their initial encounter (t = 60 min). Nurses subsequently managed hyperglycemia (Fig. 1), hypertension, and dyslipidemia according to specific algo-

rithms (online appendix [available at http://care.diabetesjournals.org]). Eligible CC-SC patients were seen by a primary care physician (initial visit = 45 min) and scheduled to see a medical nurse liaison (30-min encounters), who explained the study and obtained written consent. After enrollment, patients had blood drawn for initial laboratory evaluation, were scheduled for foot and eye appointments (by nurse case manager or nurse liaison), and were given the option of attending a diabetes education course at no charge.

Intervention and follow-up

In the CC-TA and UC-TA groups, the primary intervention was adherence to treatment algorithms for management of hyperglycemia, dyslipidemia, and hypertension (Fig. 1 and online appendix). At the initial assessment, patients at the CC-TA and UC-TA met with a physician (~18 min) who, after a brief medical evaluation to determine eligibility, referred the patient to the nurse (~60 min), who assumed responsibility of subsequent medical care according to the treatment algorithms. Blood was drawn for a chemistry profile and complete blood cell count analysis, fasting plasma glucose (FPG), HbA_{1c}, and lipid profile (total, LDL, and HDL cholesterol and triglyceride levels). FPG, HbA_{1c}, and lipid concentrations were determined in the Diabetes Division laboratory at UTHSCSA. Blood pressure was measured after 5 min in the supine position. Eye and foot clinic appointments and diabetes education classes were scheduled. If patients missed a clinic appointment, they were notified by telephone or postcard until returning to the clinic or lost to follow-up for 6 months. After instruction on home blood glucose monitoring, patients received, free-of-charge, the AccuChek Advantage System (glucose meter, lancet, and strips; Roche Diagnostics, Indianapolis, IN). Patients were asked to perform home blood glucose monitoring before breakfast, lunch, and dinner and at bedtime and to return within 2 weeks, at which time CC-TA and UC-TA nurses reviewed the blood glucose log, explained the algorithm steps, and initiated therapy. Weight management, self-monitoring of blood glucose, exercise, and education class attendance were emphasized during this and all subsequent visits (visit time ~25 min). All medications were provided free to eliminate cost as a determinant of measured outcomes. At the CC-TA and UC-TA, medication adjustments were communicated to the patients' physician, who cosigned the medical chart within 24 h. UC-TA nurses had daily access to endocrinologists if diabetes management problems developed. At the CC-TA, treatment interventions were reviewed weekly by one author (R.A.D.). In no case was the therapy prescribed by the nurse using the treatment algorithms in UC-TA or CC-TA altered. At follow-up visits, blood was drawn by a nurse case manager, as indicated by treatment algorithms. During the 12-month follow-up period, the CC-TA had an average of 11 follow-up visits and three HbA_{1c} determinations and the UC-TA had 10 visits and five HbA_{1c} determinations. The CC-SC had nine follow-up visits and two HbA_{1c} determinations.

CC-SC patients served as the usual care group. CC-SC patients were seen by a primary care physician (~45 min), who assumed responsibility for all subsequent medical management. After meeting with the physician, a nurse liaison explained the study, drew blood for baseline laboratory tests, and scheduled appointments for education and podiatry and eye clinics (~30 min). Each appointment was confirmed with the patient, and the physician was notified. CC-SC patients were given return clinic appointments and medications according to practices used by the physician. CC-SC follow-up visits took ~15 min and were followed by a 10-min encounter with the nurse liaison. The nurse liaison did not participate in any management discussions. All medications were provided free to CC-SC patients. If patients missed a clinic appointment, they were notified by telephone or postcard until they returned or were lost to follow-up for 6 months.

Before initiating the study, physicians, nurse case managers, and nurse liaisons attended a continuing medical education (CME) course, taught by one author (R.A.D.). This 2-h CME-approved course was based on the ADA's Standards of Medical Care for Type 2 Diabetes and was repeated twice to enhance comprehension. The importance of treating to goal for hyperglycemia, hypertension, and dyslipidemia for prevention of microvascular/macrovascular complications was emphasized, and treatment algorithms were reviewed in detail. The CME course also emphasized the need for annual eye and foot examinations by trained specialists. Nurse case managers were provided additional training (~5 h) on using the treatment algorithms, which were developed by one author (R.A.D.) and based on the ADA's 1994 Standards of Care (23) and were approved by the Departments of Medicine and Family Practice at UTHSCSA. The intent of the algorithms was to progressively move patients toward ideal goals through medication adjustments, self-monitoring of blood glucose, meal planning, and exercise. Algorithms were modified as new diabetes medications were released or as new guidelines were adopted. Strict adherence to the treatment algorithms was mandatory in the CC-TA and UC-TA groups.

Follow-up visits

Treatment algorithms dictated the frequency of follow-up visits and laboratory tests in the CC-TA and UC-TA (~25 min). All CC-SC patients were seen by a physician (~15 min) who made treatment decisions and determined the frequency of follow-up visits and laboratory tests according to their usual practice. A nurse liaison (~10 min) obtained vital signs, drew blood for laboratory tests, and scheduled follow-up appointments for CC-SC patients. Although CC-SC physicians were encouraged to use the algorithms and medications were provided without charge, the ultimate decision concerning frequency of follow-up visits and laboratory tests was determined by each physician. Blood for end point determinations (HbA_{1c}, FPG, and plasma lipids) was drawn by nurse case managers (CC-TA and UC-TA) and a medical nurse liaison (CC-SC) before the algorithm intervention and at 6 and 12 months after the start of therapy.

Compliance

Four hundred forty-three consecutive patients at the three clinics met enrollment criteria (145 at the CC-TA, 204 at the UC-TA, and 94 at the CC-SC). To be considered compliant, a patient had to keep at least two routinely scheduled appointments during the year, have at least two HbA_{1c} determinations, and have complied with medication changes according to nurse or physician notes. Noncompliant patients were those who kept 0–1 appointment, did not have two HbA_{1c} measurements, had been called for

Table 1—*Characteristics of the participants at baseline*

	CC-TA	UC-TA	CC-SC
Patient characteristics			
n	106	170	82
Women/men (%)	65/35	60/40	72/28
Age (years)	43.0 ± 1.0*	48 ± 0.8*	48 ± 1.0*
Weight (kg)	94 ± 5.3	87 ± 4.0	90 ± 5.1
Education (highest grade)	8 ± 0.4*	9 ± 0.2*	10 ± 1.3*
Employed (%)	60†	41†	49
Mexican American (%)	97†	89†	83*
Financial status (%)			
Cost share program‡	66†	70†	69†
Self-pay	20	16	7
Commercial insurance	8	2	12
Medicare B/Medicaid	4	7	5
Unknown	2	5	7
Metabolic characteristics			
HbA_{1c} (%)	10.4 ± 0.2	10.5 ± 0.2	10.0 ± 0.3
Fasting glucose (mg/dl)	249 ± 6.0	255 ± 5.0	237 ± 8.0
Fasting lipids (mg/dl)			
Total cholesterol	189 ± 5.0§	218 ± 3.0	211 ± 5.0
LDL cholesterol	113 ± 4.0	128 ± 2.0§	117 ± 4.4
HDL cholesterol	39 ± 1.0	41 ± 1.0	41 ± 1.2
Triglycerides	188 ± 15.0§	272 ± 12	256 ± 20.0
Systolic blood pressure (mmHg)	135 ± 2.0	142 ± 2.0‖	130 ± 2.2
Diastolic blood pressure (mmHg)	81 ± 1.0	80 ± 0.9	81 ± 1.4
Patients with abnormal values [*n* (%)]			
Total cholesterol >200 mg/dl	246 ± 8 [34 (32)]	235 ± 3 [119 (70)]	245 ± 6 [45 (55)]
LDL cholesterol >130 mg/dl	166 ± 6 [34 (32)]	154 ± 3 [70 (41)]	161 ± 8 [22 (27)]
Triglycerides >150 mg/dl	275 ± 24 [35 (33)]	306 ± 13 [104 (61)]	323 ± 25 [40 (48)]
Systolic blood pressure >130 mmHg	146 ± 2 [69 (65)]	150 ± 1 [129 (76)]	147 ± 2 [40 (49)]
Diastolic blood pressure >80 mmHg	86 ± 1 [50 (58)]	88 ± 1 [92 (54)]	90 ± 9 [48 (59)]

Data are means ± SE, unless otherwise indicated. *$P < 0.0001$; †$P < 0.1$, for employment (CC-TA versus UC-TA), Mexican-American ethnicity (CC-TA versus UC-TA and CC-TA versus CC-SC), and financial status (CC-TA versus CC-SC and UC-TA versus CC-SC); ‡cost share program is a financial assistance program based on need and eligibility (U.S. Department of Health and Human Services); §$P < 0.01$, for LDL cholesterol (CC-SC versus UC-TA), total cholesterol (CC-SC versus CC-TA), and triglycerides (CC-SC versus CC-TA); ‖$P < 0.0001$, for systolic blood pressure (CC-SC versus UC-TA and CC-TA versus UC-TA).

missed appointments, and did not take the prescribed medications. There were 358 (81%) compliant patients (106 in CC-TA, 170 in UC-TA, and 82 in CC-SC) who completed the study, and 85 (19%) noncompliant patients who dropped out before 6 months. There were no differences in compliant versus noncompliant patient characteristics at baseline among the three groups. Noncompliant patients were excluded from the final analysis of 358 patients. All patients were required to have entry ophthalmologic and podiatric examinations, which were free of charge. At study end, each patient's chart was reviewed to document that eye and foot examinations had been performed.

Analytical determinations

HbA_{1c} was determined by the Cobas Integra Glucose HK Liquid Diagnostic Reagent System (Roche Diagnostics, Basel, Switzerland) and plasma glucose with the Glucose Oxidase Analyzer (Beckman Instruments, Fullerton, CA). Plasma total cholesterol, HDL cholesterol, and triglycerides were determined by the Cobas Integra Direct Reagent System (Roche Diagnostics). LDL cholesterol was calculated from Friedewald's equation.

Statistical analysis

The primary outcome was improvement in plasma HbA_{1c}. Secondary outcomes were decline in FPG, improved lipid profile, reduction in blood pressure, weight loss, and foot/eye examinations kept. Differences between and within groups over 1 year to evaluate the effectiveness of treatment algorithms versus standard care by primary care physicians were analyzed by ANOVA. The ANOVA design was based on between-group effects of the nominal independent variable (intervention) with three levels, *1*) CC-TA following treatment algorithms, *2*) UC-TA following treatment algorithms, and *3*) CC-SC providing standard care, and on the continuous response variable within successive measurements (within-group effects) for HbA_{1c} and FPG at baseline and 6 and 12 months and for blood pressures, weight, and lipid levels at baseline and 12 months. For significant ANOVA results, post hoc correction for multiple comparisons was performed using the Bonferroni test. $P < 0.05$ was considered significant. Results are given as the means ± SE.

The study design allowed us to compare the effectiveness of adherence to specific treatment algorithms versus standard or "usual" therapy in community health care clinics serving mainly His-

panic type 2 diabetic patients. We also evaluated whether the nurse case manager (UC-TA) with daily access to endocrinologists could achieve better metabolic and blood pressure control than a nurse case manager (CC-TA) working without contact with either primary care physicians or endocrinologists.

RESULTS — Baseline patient characteristics and laboratory data are presented in Table 1. CC-TA patients were slightly younger than UC-TA and CC-SC patients, whereas the percentage of Mexican Americans in the CC-SC group was slightly lower. The numbers of patients treated at baseline with Glucotrol XL monotherapy in CC-TA, UC-TA, and CC-SC were 96 (91%), 167 (98%), and 48 (59%), respectively. CC-SC patients also were treated at baseline with chlorpropamide, glyburide, and metformin (9 [11%], 15 [18%], and 8 [10%], respectively). The treatment regimens at the end of the 12-month follow-up period are shown in Table 2.

Baseline HbA_{1c} and FPG were similar in all groups (Figs. 1 and 2). After 6 months, decrements in HbA_{1c} in CC-TA ($\Delta = 3.3\%$) and UC-TA ($\Delta = 3.4\%$) were greater ($P < 0.0001$) than in CC-SC ($\Delta = 1.5\%$). After 12 months, decrements in HbA_{1c} persisted in CC-TA ($\Delta = 3.1\%$) and UC-TA ($\Delta = 3.3\%$) and remained greater ($P < 0.0001$) than those in CC-SC ($\Delta = 1.3\%$). The decrements in FPG in CC-TA ($\Delta = 94$ mg/dl) and UC-TA ($\Delta = 99$ mg/dl) closely paralleled the decline in HbA_{1c} and were greater ($P < 0.0001$) than those in CC-SC (38 mg/dl). There were no reports of hypoglycemia in any group.

According to standards of care (24), the percentage of diabetic subjects achieving $HbA_{1c} \leq 7.0\%$ was 49% for CC-TA, 51% for UC-TA, and 26% for CC-SC ($P < 0.001$, CC-SC versus CC-TA and UC-TA). The percentage with $HbA_{1c} \geq 9.5\%$ was 12% for CC-TA, 10% for UC-TA, and 34% for CC-SC ($P < 0.001$, CC-SC versus both CC-TA and UC-TA).

Of the 358 diabetic subjects, 345 (96%) were considered to have dyslipidemia, as defined by plasma LDL cholesterol ≥130 mg/dl, total cholesterol ≥200 mg/dl, HDL cholesterol <40 mg/dl in men and <50 mg/dl in women, or triglycerides ≥150 mg/dl. The percentage of diabetic patients with elevated LDL cholesterol, total cholesterol, triglycerides, and reduced HDL cholesterol were 35% (126 patients), 55% (198 patients), 69% (248 patients), and 73% (261 patients), respectively. If one examines only those dyslipidemic patients requiring therapy according to preceding definitions, CC-TA and UC-TA were more effective than CC-SC in reducing plasma LDL cholesterol, total cholesterol, and triglyceride concentrations (Fig. 3). After 12 months, LDL cholesterol declined by 46 and 35 mg/dl ($P < 0.0001$) in CC-TA and UC-TA, respectively, compared with 19 mg/dl in CC-SC ($P = 0.01$). The decrements in plasma triglycerides in CC-TA ($\Delta = 60$ mg/dl, $P = 0.01$) and UC-TA ($\Delta = 125$ mg/dl, $P < 0.0001$) were greater than those in CC-SC ($\Delta = 36$ mg/dl). There were small increases in HDL cholesterol

Table 2—*Treatment regimens at the end of 12 months*

Medications	CC-TA	UC-TA	CC-SC
n	106	170	82
Diabetes			
Initial treatment (100%)			
Glucotrol XL	96 (91)	167 (98)	48 (59)
Chlorpropamide	0	0	9 (11)
Glyburide	0	0	15 (18)
Metformin	0	0	8 (10)
Diet and exercise	10 (9)	3 (2)	2 (2)
Final treatment (100%)			
Glucotrol XL	75 (71)	104 (61)	34 (42)
Glucotrol XL/metformin	19 (18)	55 (32)	20 (25)
Glucotrol XL/metformin + insulin	0	3 (2)	1 (1)
Chlorpropamide	0	0	1 (1)
Glyburide	0	0	6 (7)
Metformin	0	0	13 (16)
Insulin	0	0	2 (2)
Diet and exercise	12 (11)	8 (5)	5 (6)
Hypertension			
Initial treatment (100%)			
Monopril	40 (38)	93 (55)	23 (28)
Benazepril	0	0	6 (7)
Captopril	0	0	2 (2)
Diltiazem-SR	0	0	3 (4)
Enalapril	0	0	7 (9)
None	66 (62)	77 (45)	41 (50)
Final treatment (100%)			
Monopril	37 (35)	79 (47)	24 (29)
Monopril/diltiazem-SR	3 (3)	14 (8)	7 (9)
Monopril/diltiazem/hydrochlorothiazide	0	0	4 (5)
Vera pamil	0	0	2 (2)
None	66 (62)	77 (45)	45 (55)
Dyslipidemia			
Initial treatment (100%)			
Pravastatin	31 (29)	29 (17)	2 (2)
Gemfibrozil	7 (7)	16 (9)	9 (11)
Simvastatin	0	0	4 (6)
Lovastatin	0	0	2 (2)
None	68 (64)	125 (74)	65 (79)
Final treatment (100%)			
Pravastatin	31 (29)	29 (17)	2 (2)
Gemfibrozil	8 (8)	16 (9)	7 (9)
Simvastatin	0	0	3 (4)
Lovastatin	0	0	2 (2)
None	67 (63)	125 (74)	68 (83)

Data are *n* (%).

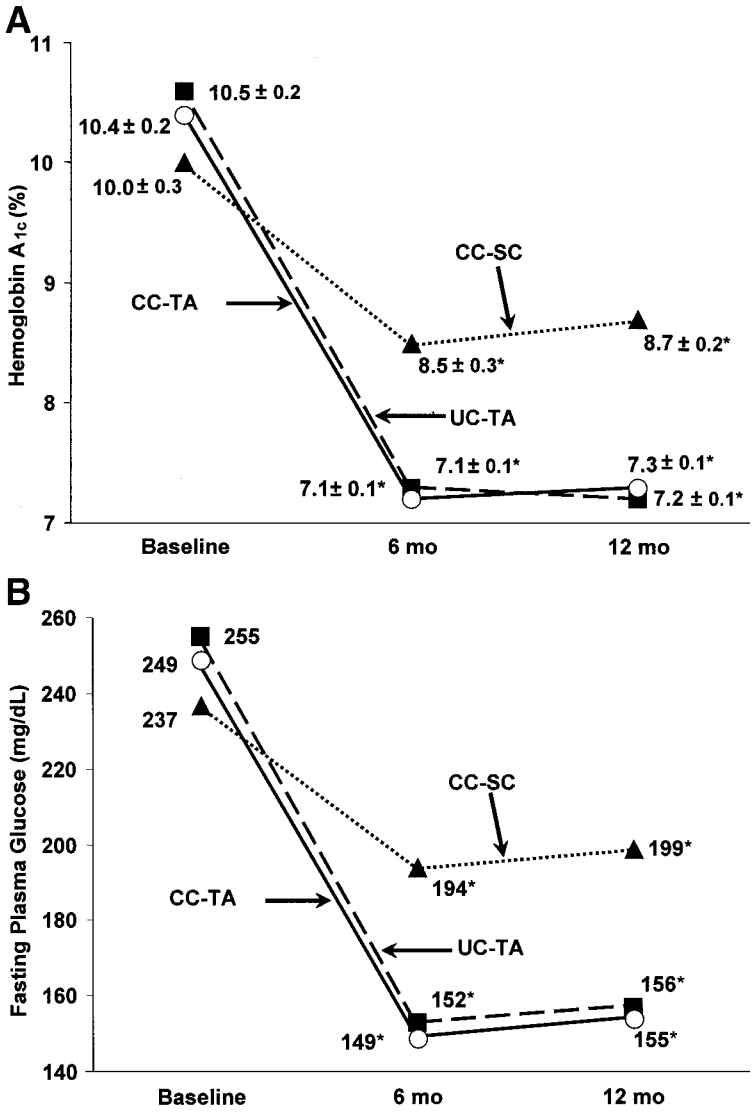

Figure 2—*Effect of treatment on HbA_{1c}* (A) *and FPG concentration* (B). *Decrements in HbA_{1c} and FPG at 6 and 12 months were greater (*P < 0.0001) in the UC-TA and CC-TA groups compared with the CC-SC group.*

in CC-TA (34.0 ± 0.6 to 36.0 ± 0.9 mg/dl, $P = 0.10$) and UC-TA (34.0 ± 0.6 to 39.0 ± 0.9 mg/dl, $P < 0.0001$) compared with slight decline in the CC-SC group (36.0 ± 0.8 to 3.50 ± 0.9 mg/dl).

Blood pressure

Two hundred thirty-nine patients (67%) were hypertensive at baseline, as defined by systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥80 mmHg. In all three clinics, providers were equally effective in reducing systolic (CC-TA, $\Delta = 13$ mmHg, $P < 0.0001$; UC-TA, $\Delta = 15$ mmHg, $P < 0.0001$; and CC-SC, $\Delta = 10$ mmHg, $P = 0.01$) and diastolic (CC-TA, $\Delta = 8$ mmHg, $P < 0.0001$; UC-TA, $\Delta = 14$ mmHg, $P < 0.0001$; and CC-SC, $\Delta = 9$ mmHg, $P < 0.01$) blood pressures (Fig. 3).

Eye and foot exams

Ninety percent of CC-TA, 83% of UC-TA, and 60% of CC-SC patients ($P < 0.0001$, CC-SC versus both CC-TA and UC-TA) had documented eye exams. Eighty-five percent of CC-TA, 81% of UC-TA, and 61% of CC-SC patients ($P < 0.0001$, CC-SC versus both CC-TA and UC-TA) had documented foot exams.

Weight

Despite initial counseling about the importance of weight loss, the follow-up counseling on each return visit, and the opportunity to participate in an ADA-certified Diabetes Education Program, there were no significant changes in body weight in any clinics.

Compliance

Noncompliance was observed in 39 (27%) CC-TA, 34 (17%) UC-TA, and 12 (13%) CC-SC patients ($P < 0.05$, CC-SC versus CC-NTA), who dropped out within 2–4 months after enrollment.

CONCLUSIONS — Prospective epidemiologic studies (25–30) have demonstrated a close association between glycemic control and the development of microvascular complications. Improved glycemic control, whether achieved by oral agents, insulin, or some combination thereof, reduces microvascular complications in type 2 and type 1 diabetic patients (25,26,29–36). A 1% HbA_{1c} reduction produces a 25–35% decrease in eye, kidney, and neurological complications (25,29,37,38). Despite this impressive body of evidence, the level of glycemic control in type 2 diabetic patients remains poor (39,40), with HbA_{1c} levels of ~8.5–9.0% in the U.S. (41).

Many reasons have been proposed to explain the failure to achieve better glycemic control in type 2 diabetic patients: lack of patient and physician education about the importance of glycemic control, poor accessibility to medical care, cost of medications, lower socioeconomic status, lack of office-based monitoring systems, noncompliance, and attitudinal, educational, and systemic factors. We postulated that a lack of well-defined criteria concerning diabetes therapeutic end points (HbA_{1c} and FPG) and failure to use specific antidiabetic medications with well-defined protocols were a major barrier for standard "usual care" providers to achieve more optimal HbA_{1c} levels (<7.0%).

We studied three well-established community hospital clinics that were serving lower socioeconomic, largely Hispanic, type 2 diabetic patients. The support staff (number and type of physicians, nurses, and ancillary staff) was similar in all clinics. Diabetic patients were recently diagnosed, had never received insulin, and had not taken oral antidiabetic medications within 12 months. To negate differences in interventional costs between clinics, participants received the follow-

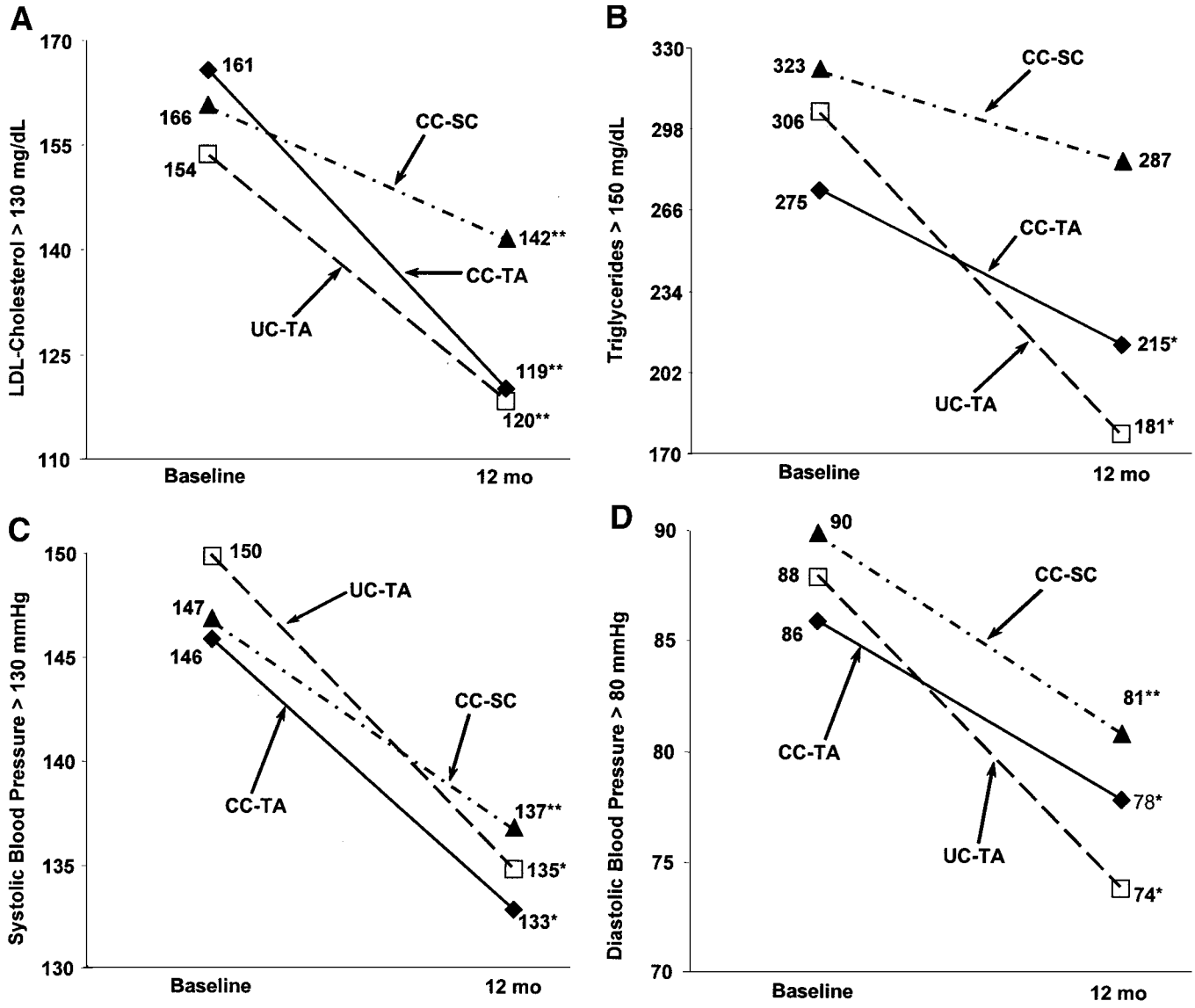

Figure 3—*Effect of lipid-lowering treatment in diabetic patients with fasting plasma LDL cholesterol >130 mg/dl* (A) *and plasma triglyceride >150 mg/dl* (B). *Decrements in LDL cholesterol and triglyceride levels were greater* (**P < *0.0001) in the UC-TA and CC-TA compared with the CC-SC after 12 months. The effects of treatment of hypertension in diabetic patients with systolic blood pressure >130 mmHg* (C) *and diastolic blood pressure >80 mmHg* (D) *are also shown. Decrements in both systolic and diastolic blood pressure were similar in all three groups* (P < *0.01*). *P < *0.0001*; **P = *0.01*.

ing free of charge: oral antidiabetic, antihypertensive, and antilipidemic medications; insulin and syringes; glucose meters and strips; diabetes education classes; eye and foot clinic evaluations; and laboratory tests. There was no clinic or nurse charge. In the CC-SC, a physician fee covered by the patients' insurance was collected. If the patient did not have insurance, no physician fee was assessed. Based on these financial measures, we do not believe that cost issues can explain the outcome differences between nurse- and physician-managed clinics. Importantly, during initial and follow-up visits, the amount of time spent with the patient was similar in all groups. The percentage of patients who participated in the ADA-approved Diabetes Education Program was slightly less in the CC-SC (61%, P = NS) compared with the CC-TA (87%) and UC-TA (76%).

All physicians, nurse case managers, and the nurse liaison received 4 h in the CME-approved Diabetes Education Program, which included the use of hyperglycemic, dyslipidemic, and hypertensive algorithms to improve provider knowledge. The major difference in interventional strategy focused on strict adherence to the treatment algorithms in the CC-TA and UC-TA. Physician providers could use any interventional strategies deemed appropriate to optimize the control of hyperglycemia, hypertension, and dyslipidemia.

Baseline HbA_{1c} (10.0–10.5%) and FPG (237–255 mg/dl) were similar in all clinics (Fig. 1). Within 6 months, CC-TA and UC-TA, using treatment algorithms and a well-defined FPG goal to trigger titration, reduced HbA_{1c} by 3.3–3.4% and

maintained this improvement after 12 months. CC-SC physicians were also successful in reducing HbA_{1c} by 1.3% after 12 months, but the decrement was 60% less than that in both nurse case-managed groups ($P < 0.0001$). At 12 months, the FPG decrement in the physician-managed group was also less (39 mg/dl) than that in nurse case-managed groups (CC-TA, 94 mg/dl, and UC-TA, 99 mg/dl). The nurse case manager working in the community clinic with only end-of-week contact with the responsible physician was as effective in improving glycemic control as the nurse case manager working in the university clinic with daily contact with endocrinologists. These results indicate that adherence to a defined treatment algorithm can achieve very good glycemic control (HbA_{1c} ~7.0%) without consultation with endocrinologists or physicians.

Since the completion of this study, two events have occurred that have led to changes in the hyperglycemic treatment algorithm, *1*) the publication of the U.K. Prospective Diabetes Study (UKPDS) results (26,33) and 2) the introduction of thiazolidinediones (TZDs) (42). Because metformin was as effective as sulfonylureas in preventing microvascular complications and significantly reduced macrovascular complications, we now institute therapy with metformin. If metformin fails to achieve the desired improvement in glycemic control, either a TZD (preference of R.A.D.) or a sulfonylurea can be added. If combination therapy (metformin/TZD or metformin/sulfonylurea) does not achieve the desired goal, triple oral-agent therapy (metformin/TZD/sulfonylurea) is initiated.

CC-TA and UC-TA were equally effective in reducing plasma LDL cholesterol, total cholesterol, and triglycerides and both were more effective than CC-SC ($P < 0.0001$) (Fig. 3). Only for the treatment of hypertension was CC-SC as effective as CC-TA and UC-TA (Fig. 3). We speculate that primary care physicians more readily recognize the importance of hypertension as a risk factor for stroke and coronary artery disease, feel a greater urgency to treat elevated blood pressure, and feel more comfortable treating hypertension (43). Diabetic patients in the CC-TA and UC-TA were more likely to receive chart-documented eye exams (90 and 83%, respectively, vs. 60% in the CC-SC) and foot exams (85 and 70, respectively, vs. 61% in the CC-SC) compared with patients seen by primary care physicians.

Noncompliance was observed in 39 (37%) CC-TA, 32 (19%) UC-TA, and 12 (15%) CC-SC patients, all of whom dropped out within 2–4 months after enrollment. An open-ended telephone interview was conducted at study end, and noncompliant patients were asked questions to determine what factors kept them from participating in a free-of-charge intervention to better control their diabetes. No respondents raised any objections about the medical treatment provided by providers. Inability to take time off from work or be away from their family was the most common explanation for noncompliance in all three clinics. Three CC-TA and two UC-TA patients said they preferred a physician. Thus, societal and financial factors, which are common obstacles in lower socioeconomic minority populations (44), were the main reasons for patients' noncompliance.

In conclusion, the present study demonstrates that adherence to treatment algorithms in newly diagnosed type 2 diabetic patients was more effective in achieving blood glucose and lipid control than usual care.

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