

Changes in Characteristics and Treatment Patterns of Patients with Newly Diagnosed Type 2 Diabetes in a Large United States Integrated Health System between 2008 and 2013

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ABSTRACT: To assess changes in the clinical characteristics and treatment patterns of patients with newly diagnosed type 2 diabetes (T2D), the electronic health record system at Cleveland Clinic was used to create cross-sectional summaries of all patients with new-onset T2D in 2008 and 2013. Differences between the 2008 and 2013 data sets were assessed after adjusting for age, gender, race, and income. Approximately one-third of patients with newly diagnosed T2D in 2008 and 2013 had an A1C $\geq 8\%$, suggesting the continued presence of a delayed recognition of the disease. Patients with newly diagnosed T2D in 2008 were older than those in 2013. Hypertension, cardiovascular disease, and neuropathy were highly prevalent among patients diagnosed with T2D. The prevalence of neuropathy, cerebrovascular disease, and peripheral vascular disease increased from 2008 to 2013. Metformin was the most commonly prescribed antidiabetic medication. Sulfonylurea usage remained unchanged, while use of thiazolidinediones decreased considerably.

KEYWORDS: incidence, diabetes, complications, treatment, antidiabetic therapy, electronic health records

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Introduction

The prevalence of type 2 diabetes (T2D) has steadily risen over the past few decades. In the US alone, approximately 1.7 million adults (>20 years of age) were newly diagnosed with diabetes in 2012.¹ More recently, data suggest that the number (and rate) of newly diagnosed cases has started to decline. In 2014, the number of newly diagnosed diabetes cases was approximately 1.4 million.¹ While it is certainly encouraging that the rate of patients with newly diagnosed T2D appears to be declining, the fact remains that the burden of newly diagnosed diabetes continues to be significant.

Historically, it has been difficult to identify and characterize patients with new-onset T2D, largely because recognition of the disease was often inappropriately delayed. It has been estimated that patients have had T2D for at least four years prior to the formal diagnosis.^{2,3} However, health care in the US is rapidly changing. A large part of that change has been in the manner in which health care is delivered. Integrated health delivery systems have evolved to assist with recognizing

and managing patients with chronic diseases, with a particular focus being placed on population health management. Integrated health delivery systems are organized, coordinated, and collaborative networks that link various health care providers to provide a coordinated, vertical continuum of services to a particular patient population or community.⁴

Characterizing the newly diagnosed T2D population, and assessing the current landscape of treatment, would be important in identifying the ways to manage these patients more effectively, especially given the availability of many new antidiabetic therapies. Currently, there are limited real-world data describing the clinical characteristics, comorbidities, and treatment patterns of patients with newly diagnosed T2D.⁵ These data are important to quantify the overall quality of care provided to newly diagnosed T2D patients in the US. Previous studies have indicated that the US health care system is doing a poor job of effectively managing T2D.^{6–8} In the past 15 years, new knowledge has been generated; patients treated with a sulfonylurea were shown to have worse outcomes



than those treated with metformin,^{9,10} and the results of the ACCORD,¹¹ ADVANCE,¹² and VADT¹³ failed to demonstrate an improvement in cardiovascular disease (CVD) outcomes with intensive glycemic control in high-risk patients. In addition, the available treatment options have increased (first glucagon-like peptide-1 [GLP-1] approved in 2005, first dipeptidyl peptidase-4 [DPP-4] approved in 2006, first sodium glucose transporter-2 [SGLT-2] approved in 2013), and incentives have changed (the HITECH act included in the “stimulus bill” of 2009 created reimbursement incentives for the “meaningful use” of electronic health records [EHRs]). The incentives include electronic prescribing and are tied to quality metrics for the management of chronic diseases that include diabetes, and philosophies for population health management have evolved (The American Association of Family Physicians, The American College of Physicians, and other prominent medical professional organizations published the “Joint Principles of the Patient-Centered Medical Home¹⁴” in 2007 that propose to radically alter the management of chronic disease). Included in these recommendations are expectations that physicians will be actively involved in continuous quality improvement and that coordination of care will be improved through the increased use of technology. The objective of this study was to identify and characterize patients with newly diagnosed T2D within an integrated delivery system and further characterize how the profiles of patients have changed with time.

Methods

Data source and patient identification. The enterprise-wide EHR at the Cleveland Clinic was used to create cross-sectional summaries of all patients with newly diagnosed T2D in 2008 (N = 1650) and 2013 (N = 1869). The team determined that an existing algorithm created for the eMERGE network by Kho et al¹⁵ for identifying prevalent cases of T2D was inadequate for identifying treatment-naïve patients with newly diagnosed T2D in our EHR. The Kho algorithm was designed for a case-control study, where the focus was to have a high specificity for identifying “true” cases of disease (diabetes). The algorithm was not intended to identify incident cases. Therefore, an algorithm for identifying patients with newly diagnosed T2D was created specifically for this project. The algorithm was developed by a multidisciplinary team using an iterative process of development and validation. The final algorithm requires repeated visits to the Cleveland Clinic with no evidence of diabetes prior to the first appearance of a structured International Classification of Diseases, Ninth Revision (ICD-9) code. Specifically, patients were required to have at least two office encounters with either a primary care provider and/or an endocrinologist, and with no prior evidence of diabetes (eg, hyperglycemia, prescription for T2D medication or insulin therapy, ICD-9 code, elevated hemoglobin A1C (glycated hemoglobin [A1C]), or elevated fasting blood sugar), prior to the date of diagnosis (baseline), which was defined as the first encounter diagnosis (ICD-9 code) for T2D. All patients with ICD-9 codes of 250.x0 or 250.x2 were included,

except for codes 250.10 and 250.12, as these are indicative of T2D with ketoacidosis, a condition that more closely resembles that of type 1 diabetes (T1D). The most recent prediagnosis of diabetes encounter with a primary care physician or an endocrinologist must have occurred in the preceding 24 months. Patients with an ICD-9 code specific for T1D were excluded. Patients without a subsequent outpatient visit for T2D after the date of the initial diagnosis were also excluded. Patients not prescribed an antidiabetes medication within one year of the diagnosis date were also excluded. Figure 1 depicts how the final cohort was derived.

Chart review. A chart review of structured and unstructured data of 20 randomly selected patients identified with a first-time diagnosis of T2D via the algorithm in the EHR was conducted by a registered nurse from the study team. The medical record contained no evidence of T2D ever being diagnosed greater than six months prior to the date determined by the algorithm in 85% of patients. A specific breakdown of the chart review results are as follows: 14 patients had corroborating evidence that the first date of diagnosis of T2D was the baseline date determined by the algorithm, 1 patient had unstructured documentation of a first-time diagnosis of diabetes that was <4 months prior to the date determined by the algorithm, the algorithm determined date of first diagnosis could not be corroborated in two patients, and three patients had unstructured documentation of diabetes that preceded the algorithm date by more than six months.

Medications. The following T2D medication classes were included in this analysis: biguanide (metformin), sulfonylureas, thiazolidinediones, α -glucosidase inhibitors, meglitinides, DPP-4 inhibitors, SGLT-2 inhibitors, and GLP-1 receptor agonists and insulin.

Patient characteristics. Patient characteristics were determined at one year after the date of diagnosis of T2D. This time point was chosen to allow stabilization of disease, time for glycemic management, and opportunities to detect/document comorbidities. For example, patients with extremely high glucose levels at the time of diagnosis may initiate therapy with insulin in order to bring glucose levels below an acutely dangerous threshold at which point they are transitioned to oral medications for continued management. Patients with diabetes are recommended to have annual dilated fundoscopic examinations to screen for retinopathy, which may have been silently present before the diagnosis. Newly diagnosed patients with diabetes may also undergo testing for nephropathy, ischemic heart disease, hyperlipidemia, and kidney disease.

Income was defined as the 2008–2012 five-year estimates of median household income at the block group level obtained from the American Community Survey¹⁶ conducted by the US Census Bureau. The census block group was obtained by geocoding the patient’s address that was on file closest to baseline. Body mass index (BMI), weight, and smoking status were defined as the value recorded in the EHR closest to baseline (but without any time restrictions). The included A1C values were those measured within 45 days of the date

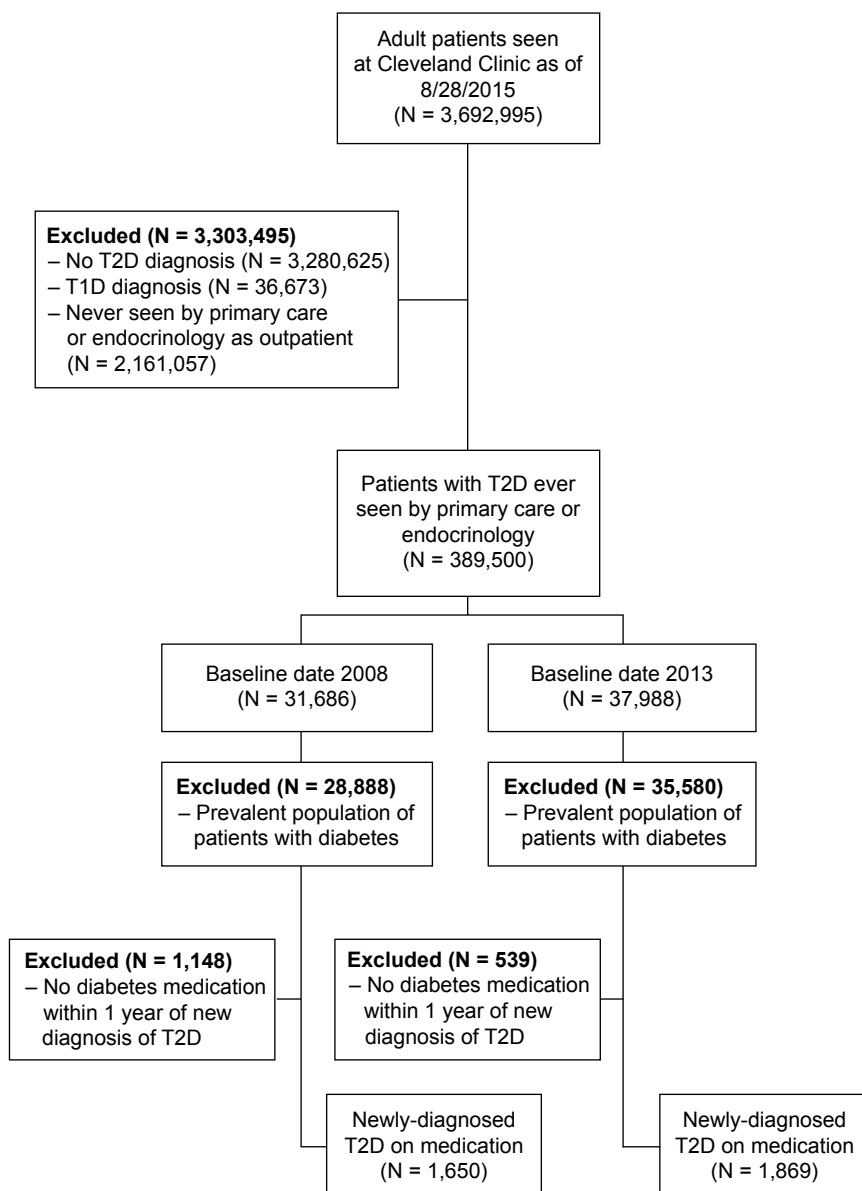


Figure 1. Algorithm used for identifying the cohort.

Abbreviations: T1D, type 1 diabetes; T2D, type 2 diabetes.

of diagnosis (baseline). Patient vitals, the remaining laboratory values, comorbidities, and diabetes-related complications were defined as the last recorded value documented within the EHR during the first year after baseline. Active medications were based on the current medication list at one year after the T2D encounter diagnosis. The Diabetes Complication Severity Index¹⁷ was calculated and reported for the 2008 and 2013 newly diagnosed T2D populations.

Diabetes diagnosis rates were calculated using the number of patients seen in the outpatient facilities of our center by a primary care provider as the denominator (ie, the number of patients at risk of being diagnosed with T2D).

Data analysis. The two cross-sectional data sets (2008 and 2013) were then compared while adjusting for age, gender, race, and income. These four variables were chosen because they

are all nonmodifiable from the perspective of the clinician. The adjusted analysis compares the theoretical characteristics of patients in 2008 vs 2013 if the two populations were composed of similar patients in terms of age, gender, race, and income. The adjusted analyses were performed by fitting individual multiple logistic regression models for each of the variables of interest as the dependent variable and age, gender, race, income, and year as the independent variables. The nonparametric Wilcoxon sign rank test was used to compare age and income, and chi-square test was used to compare gender and race. Complete data were available for all four variables (age, gender, income, and race) used as covariates in >95% of the patients in this study; therefore, a complete case analysis was utilized for the multiple regression. Patients with a missing value for a comparison variable (eg, A1C) were simply excluded from that specific comparison calculation.



Years of study. The years of study, 2008 and 2013, were chosen because it was 2008 when medication reconciliation was mandated to occur at the transitions of care at our institution, and 2013 was the last year/point in time (at the time of data extraction) that would have afforded a full year of follow-up post-T2D diagnosis in order to ascertain the data of interest.

Ethical approval. This study was approved by the Cleveland Clinic's Institutional Review Board. This research complied with the principles of the Declaration of Helsinki.

Results

The 2008 and 2013 data sets included 1650 and 1869 treatment naive patients with newly diagnosed T2D, respectively. Comparisons between age, gender, race, and income were always made in an unadjusted fashion. The remaining variables/results were adjusted by the model.

Characteristics (categorical and continuous variables).

The majority of patients were Caucasian (72.7% and 68.7%, $P < 0.001$) and approximately half were male (51.9% and 50.3%, $P = 0.322$), in the 2008 and 2013 data sets, respectively. The mean age (years) was 58.7 ± 13.7 in 2008, and 55.6 ± 13.0 in 2013, $P < 0.001$. The median household income (in US \$1000) was observed to be higher in 2008 vs 2013 (59.5 vs 55.6, $P < 0.001$). The percentage of active smokers was found to be 49.8% in 2008, and 49.0% in 2013 ($P = 0.627$). Small changes were observed between 2008 and 2013, respectively, for mean BMI (kg/m^2 ; 33.7 and 34.7; $P < 0.001$), systolic blood pressure (BP, mmHg; 127.8 and 129.8; $P = 0.001$), and diastolic BP (76.1 and 77.0; $P = 0.012$). Low-density lipoprotein (LDL, mg/dL) cholesterol levels were similar in 2008 and 2013 (97.0 and 96.9; $P = 0.946$). Tables 1 and 2 provide complete summary of the data.

Comorbidities. The percentages (%) of patients with comorbidities within one year after newly diagnosed T2D in 2008 and 2013, respectively, were glomerular filtration rate $<60 \text{ mL}/\text{min}$, calculated by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula (8.1 and 5.8; $P = 0.004$), hypertension (HTN; 71.5 and 71.0; $P = 0.749$), cerebrovascular disease (3.9 and 5.2; $P = 0.044$), CVD (14.7 and 15.8; $P = 0.394$), and peripheral vascular disease (2.0 and 3.8; $P = 0.001$; Table 1). The Diabetes Complications Severity Index scores (mean) for patients with newly diagnosed T2D in 2008 and 2013 were 0.6 and 0.8; $P < 0.001$, respectively (Table 2).

Microvascular complications. The percentages (%) of patients with microvascular complications within one year of diagnosis in 2008 and 2013, respectively, were retinopathy (1.3 and 3.2; $P = 0.001$), nephropathy (4.4 and 7.2; $P < 0.001$), and neuropathy (9.6 and 16.2; $P < 0.001$; Table 1).

Glycemic control. At the time of diagnosis, the percentages of patients across the A1C categories were similar between those diagnosed in 2008 and patients diagnosed in 2013 at 47.5% and 47.2% for A1C $<7\%$, 21.3% and 21.3% for A1C 7–7.9%, 9.7% and 9.8% for A1C 8–8.9%, and 21.4% and 21.7% for A1C $\geq 9\%$, $P = 0.860$ (Table 1).

Table 1. Clinical characteristics, comorbidities, and complications in patients with new-onset T2D in 2008 and 2013 (N, %).

VARIABLE	2008		2013		P-VALUE
	N = 1650		N = 1869		
	N	%	N	%	
Male	857	51.9	939	50.3	0.322 ^a
Race					
Caucasian	1199	72.7	1284	68.7	$<0.001^a$
Black	225	13.6	452	24.2	
Other	226	13.7	133	7.1	
Smoking	804	49.8	912	49.0	0.627 ^b
A1C					
$<7\%$	503	47.5	691	47.2	0.860 ^b
7–7.9%	226	21.3	312	21.3	
8–8.9%	103	9.7	144	9.8	
$>9\%$	227	21.4	317	21.7	
GFR $< 60 \text{ mL}/\text{min}^c$	133	8.1	108	5.8	0.004 ^b
Hypertension	1181	71.5	1328	71.0	0.749 ^b
Retinopathy	21	1.3	60	3.2	0.001 ^b
Nephropathy	72	4.4	134	7.2	$<0.001^b$
Neuropathy	158	9.6	302	16.2	$<0.001^b$
Cerebrovascular disease	64	3.9	98	5.2	0.044 ^b
Cardiovascular disease	243	14.7	295	15.8	0.394
Peripheral vascular disease	32	2.0	70	3.8	0.001

Notes: ^aCompared using Pearson's chi-squared test. ^bAdjusted for sex, age, race, and income. ^cGFR, glomerular filtration rate, calculated via CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration).

Medications. In the 2008 and 2013 data sets, at one year after diagnosis, the most commonly utilized antidiabetic agent in patients with newly diagnosed T2D was metformin. The percentages of patients receiving metformin therapy overall (either as monotherapy or in combination with other antidiabetic agents), in 2008 and 2013, were 54.3 and 64.8, $P < 0.001$. The percentages of patients receiving metformin monotherapy in 2008 and 2013 were 35.2 and 49.4, $P < 0.001$. Sulfonylureas were the most commonly utilized oral antidiabetic agent as a two-drug combination therapy with metformin in 2008 and 2013 (6.5 and 6.9, $P = 0.650$). The percentages of patients in 2008 and 2013 receiving two-drug combination therapy with metformin and a thiazolidinedione, a DPP-4 inhibitor, a GLP-1 agonist, or insulin were 2.0 and 0.1, $P < 0.001$, 1.5 and 1.6, $P = 0.731$, 0.5 and 0.5, $P = 0.810$, and 2.0 and 2.1, $P = 0.746$, respectively (Table 3).

Sulfonylureas were the second most commonly prescribed antidiabetic therapy for patients with newly diagnosed T2D in both 2008 and 2013, 16.4% and 14.6%; $P = 0.150$. DPP-4 inhibitor utilization in 2008 and 2013 was similar, 4.7% and 5.4%, respectively; $P = 0.370$. Utilization of GLP-1 agonist therapy remained low in both 2008 and 2013 ($\leq 2\%$).

**Table 2.** Clinical characteristics, comorbidities, and complications in patients with new-onset T2D in 2008 and 2013 (mean, SD).

VARIABLE	2008		2013		P-VALUE
	N = 1650		N = 1869		
	MEAN	SD	MEAN	SD	
Age at index dates (years)	58.7	13.7	55.6	13.0	<0.001 ^a
BMI (kg/m ²)	33.7	8.0	34.7	8.5	<0.001 ^b
A1C	7.9	2.4	7.9	2.3	0.870 ^b
Systolic blood pressure (mmHg)	127.8	16.9	129.8	17.9	0.001 ^b
Diastolic blood pressure (mmHg)	76.1	10.6	77.0	11.2	0.012 ^b
LDL cholesterol (mg/dL)	97	35.8	96.9	37.8	0.946 ^b
Diabetes Complications Severity Index (DCSI)	0.6	1.0	0.8	1.0	<0.001 ^b
Median household income (1,000 U.S. Dollars)	59.5	23.3	55.6	23.7	<0.001 ^a

Notes: ^aCompared using Wilcoxon Mann–Whitney test. ^bAdjusted for sex, age, race, and income.

Table 3. Distribution of medications at one year after diagnosis of type 2 diabetes.

	2008		2013		ADJUSTED* P-VALUE
	INDEX YEAR*		INDEX YEAR*		
	N = 1650		N = 1869		
	N	%	N	%	
Biguanides (metformin)	896	54.3	1212	64.8	<0.001
Metformin monotherapy	581	35.2	924	49.4	<0.001
Metformin + sulfonylurea ^a	107	6.5	129	6.9	0.650
Metformin + thiazolidinedione ^a	32	2.0	2.0	0.1	<0.001
Metformin + dipeptidyl peptidase-4 inhibitor ^a	25	1.5	31	1.6	0.731
Metformin + GLP-1 ^a	8	0.5	10	0.5	0.810
Metformin + insulin ^a	33	2.0	40	2.1	0.746
Dipeptidyl peptidase-4 inhibitors	78	4.7	101	5.4	0.370
Sodium glucose transporter-2 inhibitors	0	0	2	0.1	0.774
Glucagon-like peptide-1 agonists	30	1.8	32	1.7	0.793
Sulfonylureas	271	16.4	273	14.6	0.150
Thiazolidinediones	129	7.8	9	0.5	<0.001
Alpha-glucosidase inhibitor	1	–	1	–	0.489
Meglitinides	1	–	0	–	0.767
Anti-diabetic combination therapy ^b	270	16.4	172	9.2	<0.001
Statin	774	44.4	659	35.3	<0.001
Aspirin	185	11.2	97	5.2	<0.001
ACE or ARB	634	38.4	660	35.3	0.070
Insulin Total	153	9.3	112	6.0	<0.001
Human	29	1.7	10	0.5	<0.001
Analogue (basal or bolus)	128	7.8	105	5.6	0.010
Basal	142	8.6	108	5.8	0.001
Bolus	94	5.7	55	3.0	<0.001
Pre-mix	0	–	0	–	–
Insulin + any oral anti-diabetic medication ^c	83	5.0	77	4.1	0.202

Notes: *Adjusted for sex, age, race, and income. ^aRestricted to two-drug combination therapy, metformin + one additional agent. ^bAny two of the nine antidiabetic classes. ^cRestricted to two-drug combination therapy, insulin + one additional oral agent.

Abbreviations: ARB, angiotensin receptor blocker; ACE, angiotensin-converting enzyme inhibitor; aspirin, acetylsalicylic acid.



Insulin usage at one year after newly diagnosed T2D occurred in 9.3% and 6.0% of patients, $P < 0.001$, while combination antidiabetic therapy (any two of the nine medication classes) was used by 16.4% and 9.2% of patients, $P < 0.001$, in 2008 and 2013, respectively.

The most significant difference from 2008 to 2013 in the percentage of patients with newly diagnosed T2D using antidiabetic medications was observed in those who were prescribed thiazolidinedione therapy, 7.8% and 0.5%, respectively, $P < 0.001$. The distribution of the remaining prescribed antidiabetic medications (percentage of patients receiving the therapy) is shown in Table 3.

Aspirin and statin therapy utilization was observed to be higher in 2008 vs 2013, 11.2% and 5.2%; $P < 0.001$ and 44.4% and 35.3%; $P < 0.001$, respectively. Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker utilization was similar in 2008 and 2013 (38.4 and 35.3%; $P = 0.70$).

Discussion

As seen with recent data from the Centers for Disease Control and Prevention,¹ a reduction in the diagnosis rate of T2D was observed in our report. While the rate of T2D diagnosis appears to be on a slight decline, the fact remains that the burden of disease still remains significant.

In our study, the age of diagnosis of the T2D population was very similar in 2008 and 2013; however, on the surface there appeared to be a nearly twofold increase in the percentage of patients with newly diagnosed T2D who were black. However, this finding is largely because of improved documentation of race and ethnicity in the EHR (secondary to the Centers for Medicare & Medicaid Services meaningful use stage 1 requirements). Many patients who were black in 2008 were incorrectly classified as “other”, whereas in 2013, their status was more correctly documented (black). This is supported by the finding that the percentage of patients classified as “other” was found to be nearly 50% less in 2013 vs 2008. The percentage of patients who were active smokers was similar in 2008 and 2013.

Nearly 1/3 of patients diagnosed with T2D in both 2008 and 2013 had an A1C $\geq 8\%$ at the time of diagnosis. This finding, in addition to the finding that many of the patients were found to have T2D-related complications within the first year of T2D diagnosis, suggests that the health care system still has challenges in recognizing these patients early on in the disease course. The continued delay in the recognition of T2D unfortunately postpones the initiation of treatment, thereby allowing the development of complications to continue unabated. Perhaps a better strategy would be identifying and initiating treatment at the earliest sign of a glycemic abnormality (ie, prediabetes). Moreover, the prevalence of HTN was found to be rather high (and similar) in 2008 and 2013, with nearly 3/4 of this population being affected. The high prevalence of HTN magnifies the importance of identifying and managing not only the glycemic control of these patients with new-onset

T2D but also effectively managing their BP, as both of these diseases can influence the development of microvascular complications, specifically retinopathy and nephropathy.

The prevalence of cerebrovascular disease and peripheral vascular disease was higher in the 2013 cohort vs the 2008 cohort, and a nonsignificant increase was also noted with respect to the prevalence of CVD. Likewise, an increase in DM-related microvascular complications was also observed, particularly prominent was the increase in the prevalence of neuropathy (9.6% in 2008 and 16.2% in 2013). It remains unclear if the observed increases in the prevalence of these comorbidities and complications are “real” increases, or perhaps simply a reflection of improved documentation within the EHR, given the ever-increasing focus on documentation and coding in the new health care environment. Further investigation into this finding noted an increase in the coding of microvascular complications with time, across the spectrum of providers, including both primary care providers and specialists (data not shown). Despite the observed increase in prevalence of T2D-related complications, it is very likely that the true prevalence of these complications in the new-onset T2D population is being underestimated, as recognizing T2D-related complications from the EHR is largely dependent on ICD-9 documentation, and historically providers may have simply coded 250.02, T2D, without mention of complication, uncontrolled, even if the patient had recognized complications.

Perhaps the most interesting aspect of this report is the medication utilization profiles. Not surprising, metformin was the most commonly prescribed antidiabetic agent overall, and as monotherapy, in-line with recommendations from the guidelines authored in recent years by the American Diabetes Association (ADA),^{18,19} and the American Association of Clinical Endocrinologists (AACE).^{20,21} Overall, the use of metformin therapy was found to increase from 54.3% in 2008 to 64.8% in 2013. Despite the recommendation by the recent AACE guidelines to try to avoid antidiabetic agents associated with hypoglycemia and weight gain, our report found that sulfonylurea utilization remains high; sulfonylureas were the second most commonly prescribed antidiabetic agent in both 2008 and 2013, and the most common agent used in the two-drug combination therapy with metformin. The utilization of thiazolidinediones was lower in 2013 vs 2008, likely because of the questions/concerns regarding cardiac safety, bladder cancer, osteoporosis, and weight gain that have surrounded thiazolidinediones over the past decade^{22–27} and because of the availability of additional classes of antidiabetic therapies. The availability of these additional classes of medications, and greater utilization of metformin, may also have influenced the decline in insulin utilization observed in 2013 vs 2008. Interesting was the observation of a significant reduction in the utilization of dual antidiabetic therapy in 2013 vs 2008 (16.4 vs 9.2%, $P < 0.001$), despite the recent ADA and AACE guidelines emphasis on more aggressive management/earlier initiation of combination therapy.



Management of the common comorbidities observed in patients with new-onset T2D is also very important. While the prevalence of HTN in this population was found to be rather high, encouraging was the observation that the mean systolic and diastolic BP values in both 2008 and 2013 were below those recommended by the ADA ($<130/80$),²⁸ more recently changed to $<140/80$.²⁹

While the mean LDL cholesterol values were observed to be <100 mg/dL in both 2008 and 2013, surprising was the observed decline in statin utilization. In 2008, the percentage of patients receiving a prescription for statin therapy was 44.4%, whereas it was only 35.3% in 2013 ($P < 0.001$). The reason for the observed drop is unclear, as statin therapy was highly recommended for most patients with T2D during the time interval of this report and remains so to this day.³⁰

Not surprisingly, aspirin use declined as research has questioned the universal use of aspirin in patients with diabetes.^{31–34} In 2008, the percentage of patients receiving aspirin therapy was 11.2%, whereas it was only 5.2% in 2013 ($P < 0.001$).

Despite the effort applied to creating an accurate algorithm for detecting newly diagnosed T2D, our study undoubtedly contains some individuals who were previously diagnosed with T2D at the Cleveland Clinic or elsewhere. We anticipate continued improvements in the structured documentation of diabetes due to existing reimbursement incentives through meaningful use (eg, maintaining an updated problem list) and Medicare reimbursement adjustments using the risk adjustment factor score. Furthermore, the sharing of data between hospital systems is slowly increasing through regional health information exchanges, continuity of care documents, and systems built into proprietary EHR software (ie, Epic's Care Everywhere). The use of the date one year after the diagnoses of T2D as the index date was carefully chosen for the reasons mentioned in the Methods section, but other reasonable baseline dates could be chosen that could significantly alter the results. The requirement that patients receive an antidiabetic agent within one year of diagnosis was found to be necessary during the validation process in order to exclude patients without true, confirmed disease. However, this unfortunately results in the exclusion of some patients under control through lifestyle modifications alone (diet and/or exercise). It is unknown whether the choice of antidiabetic therapies chosen for patients who initially are diet controlled would differ considerably from those who receive a medication within the first year.

We did not have fasting blood sugar or A1C values available on all patients. Thus, we were unable to calculate "true incidence rates" of a new T2D diagnosis from an epidemiology perspective. Accordingly, in an attempt to still portray the rate of new T2D diagnosis observed in our health system, we used the number of patients seen by a primary care provider as the denominator, which represents the number of patients seen at our institution that were at risk of a diagnosis of T2D.

Conclusions

In line with recent reports,^{1,5} a decline in the T2D diagnosis rate was observed. Approximately one-third of patients newly diagnosed with T2D had an A1C $\geq 8\%$ in both 2008 and 2013. In addition, a significant number of T2D patients were found to have diabetes-related complications within the first year of diagnosis. Both of these observations would suggest the continued presence of a delayed recognition of the disease. Patients with newly diagnosed T2D were older in 2008 vs 2013. An increase in the prevalence of neuropathy, cerebrovascular disease, and peripheral vascular disease was observed from 2008 to 2013. HTN, CVD, and neuropathy were highly prevalent among patients diagnosed with T2D. The high incidence of HTN in newly diagnosed T2D patients underscores the importance of BP management, in addition to glycemic control, in these patients.

In both 2008 and 2013, metformin was the most commonly prescribed antidiabetic medication, and in-line with the recommendations by the recent T2D management guidelines, metformin use has increased. Use of thiazolidinedione and insulin has declined in patients with newly diagnosed T2D, likely secondary to the availability of additional/new antidiabetic agents, and the observed greater utilization of metformin. Despite the more recent guidelines encouraging utilization of therapies that are associated with a low-risk of hypoglycemia, sulfonylurea usage, as both monotherapy, and in combination with metformin, remains high.

The results of this report highlight the challenges in identifying patients with newly diagnosed T2D and would appear to support the early/aggressive intensification of therapy, at the time of diagnosis, as recommended by recent diabetes management guidelines, in an attempt to reduce the prevalence of diabetes-related complications, which was observed to be rather high in the newly diagnosed T2D population managed at our institution.

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Author Contributions

Researched the data and wrote the article: KMP. Contributed to the discussion and reviewed/edited the article: TMH and MWK. Researched and analyzed the data, designed the analysis, and contributed to the discussion: BJW. Researched the data and reviewed/edited the article: SXX, JB, and JMB. Researched and analyzed the data: KMC, CY, and BS. Extracted, researched, and analyzed the data: AM. Researched and analyzed data and contributed to the discussion: WW. Researched data, contributed to discussion, and reviewed/edited the article: RSZ. All authors reviewed and approved the final article.



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