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Editor's Choice

Registry of people with diabetes in three Latin American countries: a suitable approach to evaluate the quality of health care provided to people with type 2 diabetes

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SUMMARY

Aims: To implement a patient registry and collect data related to the care provided to people with type 2 diabetes in six specialized centers of three Latin American countries, measure the quality of such care using a standardized form (QUALIDIAB) that collects information on different quality of care indicators, and analyze the potential of collecting this information for improving quality of care and conducting clinical research. **Methods:** We collected data on clinical, metabolic and therapeutic indicators, micro- and macrovascular complications, rate of use of diagnostic and therapeutic elements and hospitalization of patients with type 2 diabetes in six diabetes centers, four in Argentina and one each in Colombia and Peru. **Results:** We analyzed 1157 records from patients with type 2 diabetes (Argentina, 668; Colombia, 220; Peru, 269); 39 records were discarded because of data entry errors or inconsistencies. The data demonstrated frequency performance deficiencies in several procedures, including foot and ocular fundus examination and various cardiovascular screening tests. In contrast, HbA_{1c} and cardiovascular risk factor assessments were performed with a greater frequency than recommended by international guidelines. Management of insulin therapy was sub-optimal, and deficiencies were also noted among diabetes education indicators. **Conclusions:** Patient registry was successfully implemented in these clinics following an interactive educational program. The data obtained provide useful information as to deficiencies in care and may be used to guide quality of care improvement efforts.

What's known

While many reports describe the quality of care provided to people with diabetes in Europe and the USA, scarce information is available on this issue in Latin America.

What's new

The article provides detailed information regarding the quality of care provided to people with type 2 diabetes in diabetes centers of three Latin American countries.

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Disclosures
Nothing to declare

Introduction

Diabetes is steadily increasing all over the world and such expansion will continue, disproportionately affecting developing countries (1,2). Diabetes is associated with the development of micro- and macrovascular complications that lead to high morbidity, mortality and associated costs (3,4). The development and progression of these complications can be reduced by control of hyperglycemia and the associated cardiovascular risk factors (CVRF) in a cost-effective manner (5–10). However, most patients worldwide do not achieve that degree of control (11–14). Additionally, prevention strategies have not yet been incorporated to routine clinical practice (15). Consequently, the care provided to people with diabetes is far from optimal, and unless addressed properly, the socioeconomic burden of the disease will be even worse in the future.

As a first step to address these problems, it is necessary to implement effective and efficient strategies to establish an objective assessment of the weaknesses and strengths of the current overall care provided to people with diabetes. To achieve this goal, a standardized record system that includes the information needed to assess care on a continuous basis should be developed and implemented. Such a system will also help to prioritize human resources and budget allocation based on a real demand. Currently, there is shortage of such information in Latin America, and attempts to obtain it have not been sustained or adequately supported (11,16,17).

In the program described herein, we trained representatives from various Latin American countries with the aim of transforming them into a Quality Control Network that assesses the care provided to people with diabetes and other CVRF. For this purpose, we used the QUALIDIAB registry system (11).

The main objectives of this initiative are to (i) implement a patient registry, QUALIDIAB (a tool used to measure medical quality of care), and collect data on the care of a sample of people with type 2 diabetes in six specialized care centers of three Latin American countries, (ii) measure the quality of care provided by analyzing the recorded information and QUALIDIAB indicators, and (iii) evaluate the potential of collecting such information for improving quality of care and conducting clinical research.

Methods

Representatives of public and private Diabetes Service Centers (4 in Argentina and one each in Colombia and Peru) participated in this study and provided the QUALIDIAB registry information. Participants first attended an intensive and interactive workshop developed by the Indiana University Medical School (USA) under the direction of Prof. Charles Clark Jr. Participants were familiarized with the objectives of the study and presented studies detailing the value of a standardized medical record in assessing and improving quality of care and conducting research.

The patient data analyzed were recorded in the QUALIDIAB annual record form, which includes clinical, metabolic and therapeutic indicators, micro- and macrovascular complications, and rate of use of diagnostic and therapeutic elements and of patient hospitalizations (11). Data were loaded and stored in CENEXA's database in an anonymous format for subsequent analysis. Descriptive statistics were calculated for all variables measured using the Statistical Package for Social Sciences version 15 (SPSS Inc, Chicago, IL, USA). Continuous variable were presented as mean and standard deviation (SD). Categorical variables were reported as proportion and 95% confidence intervals (CIs) when appropriate.

Records from 1157 patients with type 2 diabetes mellitus were analyzed. Their country of origin was Argentina (668), Colombia (220) and Peru (269). Thirty-nine of records were discarded due to data errors or inconsistencies; thus, the final number used for the statistical analysis was 1118 records.

Results

As shown in Table 1, 59% of the patients were women (659), with a disease duration of approximately 10 years.

Dyslipidemia (80%) and overweight or obesity (both together 84%) were the most commonly present CVRFs. Fewer patients had arterial hypertension, and smoking was rare.

Table 1 Characteristics of the study population

Condition	
Women (%)	59 (56–62)
Age (years)	63 ± 12
Age at diagnosis (years)	53 ± 12
BMI (kg/m^2)	30 ± 8
SBP (mm Hg)	129 ± 18
DBP (mm Hg)	76 ± 12
Overweight (BMI > 25 kg/m^2) (%)	40 (36–43)
Obesity (BMI > 30 kg/m^2) (%)	44 (40–47)
Hypertension (> 130/85 mmHg) (%)	57 (54–60)
Dyslipidemia* (%)	80 (77–82)
Smoking (%)	5 (4–7)

*Any serum lipid fraction above target value. Unless otherwise indicated, results are means ± SD; between brackets, CI. BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure.

Average body mass index (BMI) was 30 kg/m^2 and average systolic and diastolic blood pressure was 129 ± 18 and 76 ± 12 mmHg, respectively.

Frequency and results of clinical and laboratory monitoring

Table 2 shows the frequency of laboratory tests, with an average of 3 measurements per year for fasting blood glucose (FBG) and approximately once a year for the rest of the tests (not shown).

None of the recorded determinations was performed at the recommended 100% annual rate, including those with a low cost, such as FBG or creatinine. Additionally, the low density lipoprotein (LDL) cholesterol test, the most validated serum lipid fraction to evaluate dyslipidemia, had the lowest frequency of performance among the lipids measured.

Similarly, performance evaluation of annual vascular complications was far below 100% in many

Table 2 Laboratory tests: frequency of performance and corresponding values

Parameter	n	Patients % (95%CI)	Value
FBG (mg/dl)	1078	96 (95–97)	148 ± 61
HbA_{1c} (%)	1003	90 (88–91)	7.8 ± 2.0
Creatinine (mg/dl)	903	81 (78–83)	1.24 ± 1.4
Cholesterol (mg/dl)	984	88 (86–90)	189 ± 44
HDL cholesterol (mg/dl)	853	76 (74–79)	48 ± 15
LDL cholesterol (mg/dl)	811	73 (70–75)	108 ± 38
Triglycerides (mg/dl)	967	86 (84–88)	167 ± 98

Values are means ± SD. FBG, fasting blood glucose; HDL, high density lipoprotein; LDL, low density lipoprotein.

patients (fundoscopy, 62%; foot examination, 60%; electrocardiogram, 54%).

Laboratory data show that fasting FBG and HbA_{1c} values are above those recommended by the Asociación Latinoamericana de Diabetes (ALAD) and the American Diabetes Association (ADA) guidelines (18,19) (Table 2).

Triglyceride and fraction cholesterol levels were higher than those recommended by these guidelines, even though total cholesterol was within normal range. High density lipoprotein (HDL) cholesterol was within acceptable levels for males, but lower than indicated by guidelines for females.

Chronic complications

Neuropathy was the most common microvascular complication, affecting the somatic as well as the vegetative nervous system (orthostatic hypotension and erectile dysfunction), followed by retinopathy (with a high percentage of its proliferative form) and nephropathy (Table 3). It is important to note that approximately 8% of the patients were blind or needed substitutive treatment for kidney failure (dialysis).

Regarding macrovascular complications, cardiac events were the most frequent ones, followed by peripheral vascular disease (including amputation) and ischemic stroke or transient ischemic attack events.

Table 3 Frequency of each complication

Complications	n	n (yes)	% (95% IC)
Neuropathy	1032	354	34 (31–37)
Retinopathy	967	279	29 (26–32)
Non-proliferative	–	166	59
Proliferative	–	114	41
Nephropathy	987	221	22 (20–25)
Blindness	1020	85	8 (7–10)
Dialysis	997	82	8 (7–10)
Orthostatic arterial hypotension	1026	107	10 (9–12)
Erectile dysfunction	826	172	19 (18–24)
Acute myocardial infarction	1042	115	11 (9–13)
Angina	1038	119	11 (10–14)
Left ventricular hypertrophy	1028	143	14 (12–16)
Heart failure	1036	100	10 (8–12)
Stent	1029	94	9 (7–11)
Ischemic stroke	1042	98	9 (8–11)
Transient ischemic attack	1036	88	9 (7–10)
Acute lower limb ischemia	1029	116	11 (9–13)
Revascularization	1024	90	9 (7–11)
Amputation	1024	86	8 (7–10)
Myocardial revascularization	1032	83	8 (6–10)

The sum of the percentages is not always 100 because one patient may have more than one complication.

Hospitalizations

There was a total of 56 admissions (5% of the cases), with an average stay of 13 ± 16 days. Work absenteeism was 28 ± 27 days within the data collecting period.

Education and treatment

Patient education indicators of diabetes control and treatment showed that 69% of the patients were aware of their treatment goals, 80% were on a prescribed meal plan, 57% practiced physical activity, and 65% knew how to recognize and treat hypoglycemia and take care of their feet. Self-monitoring blood glucose (SMBG) was performed by 57% of the patients (average frequency, 8 ± 6 measurements/week).

Hyperglycemia treatment

Five per cent of the people included in the study controlled their hyperglycemia only with a meal plan and the regular practice of physical activity (Table 4).

Regarding drug treatment (oral antidiabetic drugs [OAD] with/without insulin), 56% used only OAD, 26% the combination of OAD and insulin, and 13% insulin alone. Overall, 39% of the patients received insulin either alone or combined with OADs.

From the group treated with OAD (Table 4), 54% used a single drug, being metformin the most commonly prescribed (76%) followed by sulphonylureas (31%); 32% of the patients on OAD treatment received two drugs, but only 6% of them were treated with ≥ 3 drugs.

Seventy-three per cent of the insulin-treated patients received only intermediate or long-lasting insulin analogs, 0.7% received only rapid-acting analogs, and the remaining 26% received a combination of both. The daily dose of crystalline insulin was

Table 4 Different types of treatment for hyperglycemia

Type of treatment	n	%
Only meal plan + exercise	56	5
OAD (Total)	630	56
1	339	54*
2	202	32*
3	39	6*
OAD + insulin	287	26
Only insulin	145	13

*% from the 630 patients treated only with oral antidiabetic drugs (OAD). Total n = 1118.

Table 5 Patients with $HbA_{1c} \leq 7\%$

Drug	n	n (on target)	% (95% IC)
OADs alone	618	336	54 (50–58)
OAD + insulin	275	73	27 (22–32)
Insulin alone	95	30	32 (23–42)

This table only includes patients that had HbA_{1c} measurement. OAD, oral antidiabetic drug.

12 U/day and the daily dose for insulin analog was 20 U/day.

The percentage of patients with $HbA_{1c} \leq 7\%$ varied according to the treatment received (Table 5). Interestingly, the percentage of patients treated with insulin who achieved such an HbA_{1c} value was significantly lower than that of patients treated only with OADs.

Arterial hypertension treatment

Only 82% (527/640) of the patients with arterial hypertension were being treated with antihypertensive drugs; 66% of them were receiving only one drug, 28% two drugs and 6% received three drugs. The most commonly used drugs were angiotensin-converting enzyme (ACE) inhibitors (75%), angiotensin receptor blockers (ARB) (2%), calcium channel blockers (30%), diuretics (21%) and beta blockers (13%). Most treated patients (76%) reached the target values recommended by the ALAD and ADA guidelines (18,19).

Dyslipidemia treatment

Only 57% of patients with some type of dyslipidemia were treated with lipid lowering agents; 89% of these were using statins, 16% fibrates and 3% were treated with ezetimibe. The sum of the percentages is not always 100 because some patients were receiving a combined treatment. Sixty-four per cent of the treated patients reached the target values recommended by the ALAD and ADA guidelines (18,19); this figure was lower when considering only LDL cholesterol (44% of patients were on target value, $\leq$ 100 mg/dl).

Discussion

The primary aim of this study was to encourage the diabetes centers to settle a systematic registry of patient data (QUALIDIAB) and thereafter analyze the recorded data in order to identify and address quality issues. In this regard, we were successful in having the centers performing the registry and sharing the data. The analysis of these data would enable us to identify weaknesses and strengths of the centers 'performance, improve thereafter the quality of care provided to people with Type 2 diabetes, and optimize the allocation and use of human and economic resources. Given the results obtained, efforts should be made to improve the monitoring of metabolic indicators (laboratory tests); similarly, various clinical procedures were performed with a frequency less than optimal: 38% of the patients did not have a fundoscopic examination, 41% did not have a foot exam, and 46% did not have an electrocardiogram. The last omission would be important more as an indicator of the lack of a complete cardiovascular evaluation rather than as its clinical value performance *per se*.

The data from the laboratory tests showed that values of FBG, HbA_{1c}, triglycerides and cholesterol fractions were all above those recommended by the ALAD and ADA guidelines (18,19). In the case of FBG, it could be assumed than in many cases this control was not prescribed because patients were under frequent SMBG. It should be noted that among insulin-treated patients, the percentage of those who reached $HbA_{1c} \leq 7\%$ values (around 30%) was markedly lower than the one recorded for those treated with OADs. Consequently, the implementation of insulin therapy handling should be improved. Additionally, we need to adequately address overweight/obesity among our population.

Most of the patients analyzed had associated CVRFs, something common in people with Type 2 diabetes. Such combination unfortunately increases the risk of developing cardiovascular complications (20,21). Consequently, it would be important to adequately control such CVRFs in order to prevent the development and progression of chronic complications.

Diabetic retinopathy is the main cause of non-traumatic blindness in adults: 10 years after its diagnosis, around 5% of patients are actually blind and 33% of them suffer a marked reduction of their eyesight (22). In our study, fundoscopy was performed in 62% of patients; thus, this relative low percentage of a periodic retina control in people with 10-year diabetes duration is an issue that needs to be addressed in order to establish an early diagnosis of retina lesions and thereby implement an appropriate treatment to prevent its progression. This concept is reinforced by a recent publication showing that combining the results from 2 consecutive years of photographic screening enables estimation of the risk of future development of serious retinal lesions and vision loss (23). While the blindness rate recorded in our study is below the 9.4% rate reported by Villena et al. in Peru (24), it is still important to strictly apply the above mentioned concepts in order to potentially reduce its current rate. From a preventive perspective,

the strict control of hyperglycemia and other related CVRFs is equally important. Vijan et al. used a simulation model to determine that the decrease of HbA_{1c} from 9% to 7% reduces by 0.5% the risk of blindness in people with diabetes < 65 years (our patient age-range) (25). The potential benefit is even higher when patients move from a poor metabolic control to a moderate one and from a moderate control to a very good one. The authors conclude that the use of an aggressive treatment in 20% of patients within a specific organization may reduce over 80% the possibility of developing blindness and a terminal renal disease. This information acquires further relevance if we consider that diabetic retinopathy and associated eyesight disorders clearly affect the quality of life of those who have the disease (26).

Regarding other microvascular complications, our data show that 22.3% of the patients had micro- or macroalbuminuria, indicating the presence of some impairment in renal function, and that 8.1% was on dialysis. These values are linked to a marked decrease of the glomerular filtration rate; a recent retrospective study in people with Type 2 diabetes showed that progression of nephropathy into end-stage renal disease (ESRD) is 2.5 times more frequent than cardiovascular death and 1.5 times higher than death from any other cause (27). In that study, 19.5% of patients developed ESRD in a 2.8-year period, whereas only 8.1% died from cardiovascular causes before developing ESRD. Patients with low albumin excretion ($\leq$ 1 g/g) and preserved glomerular filtration rate ($\geq$ 45 ml/min/1.73 m^2) did not show such a torpid evolution.

The rate of hospitalizations currently recorded was lower than the one reported in a study performed in Argentina in 2004 (28), but similar to that of the ADVANCE study (8). In these three studies however, the frequency of cardiac events was higher than that of brain-related ones (29). The average duration of hospitalizations was also similar. Since data were taken from diabetes centers, we cannot discard that in many cases hospitalization events were not recorded because patients were regularly treated by other physicians and attended the centers only for periodic controls. Anyhow, the low rate of events leading to hospitalization currently registered is important, because they usually represent 50% of the health care cost of people with Type 2 diabetes (3), and because such cost tends to increase after hospitalization (30).

The patient education indicators recorded improved as compared to data obtained in the region in 2001, especially regarding patient knowledge of his or her own treatment goals, adherence to the meal plan, and SMBG performance. However, such improvement was not observed for foot examination, which is still at 65% (11). This demonstrates that education of people with diabetes is one of our target efforts. Continuous objective monitoring of clinical and metabolic outcomes is a key procedure to assess the impact of education programs after their implementation, either in our Region or globally (31,32). Thus, we should identify apparent barriers for such implementation, such as lack of physician training for data recording, of any type of incentives to perform this task and of evidence on how the recorded data should be used for education and research purposes, and find appropriate strategies to overcome them. Further, these registries could be useful to evaluate the implementation of preventive strategies aimed at reducing chronic complications and the high socioeconomic cost of Type 2 diabetes (33).

When evaluating our results, it must be considered that they belong to some specialized diabetes centers in some countries of the Latin American Region. Therefore, they do not necessarily represent a population sample or what happens at the primary health care level. However, our results demonstrate, as other reports have done (34), the value of establishing a standardized monitoring of the quality of care provided to people with diabetes – in this case, Type 2 diabetes – in order to provide an objective diagnosis and subsequently develop and implement strategies to optimize such quality of care.

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