

CLINICAL INERTIA IN NEWLY DIAGNOSED TYPE 2 DIABETES MELLITUS PATIENTS ATTENDING SELECTED HEALTHCARE INSTITUTIONS IN COLOMBIA

Romero M¹, Gómez L¹, Huérfano L¹, Alvis N², Carrasquilla M², Pinzon A³, Ruiz J⁴, Velásquez A⁴, Beltran C⁴, Urrego JC⁴, Rojas M⁴ .

- ¹ Grupo Proyectame, Bogotá, Colombia;
² ALZAK Group, Cartagena, Colombia;
³ MSD Chile, Santiago de Chile, Chile.
⁴ MSD Colombia, Bogotá, Colombia.

BACKGROUND

Diabetes is one of the fastest growing global health problems. In 2019, 463 million people lived with diabetes and this number will increase to 578 million in 2030¹. Despite the clinical advances in the management of T2DM over the past few decades, it has been reported that nearly 48% of the patients with T2DM do not achieve the recommended glycemic goal of HbA1c < 7%². This could be due to clinical inertia that is a failure to initiate or intensify therapy when glycemic control is not achieved³.

In Colombia, the diabetes treatment guidelines were published in 2016 by the Ministry of Health⁴ to be applied by physicians of the different HMOs. In our country the affiliation to the General System of Social Security in Health (SGSSS), can be done in two ways, through the contributory (working population) or the subsidized (poorest and most vulnerable population) regimen, both with their own HMOs.

Currently, the literature shows that there are only two published studies⁵ ⁶ that have measured clinical inertia in T2DM patients in Colombia. Although these are representative studies, they have limitations; the most relevant is that each one assessed only patients from one of the regimens (contributory or subsidized) but not both at the same time. In addition, one study was developed during 2015 using ADA guidelines as a reference to measure clinical inertia, so no data regarding the adherence to new local guideline established in 2016 is available. Thus, updated information regarding clinical inertia and the associated factors using more recent data may help healthcare policymakers and clinicians streamline strategies for reducing clinical inertia in T2DM and improve patient outcomes.

OBJECTIVE

To estimate the prevalence of clinical inertia in newly diagnosed T2DM patients in selected healthcare institutions in Colombia

METHODS

Study design

This was a retrospective cohort study. The study included data collected from the database of clinical records of two Colombian Health Medical Organizations (HMOs), one from subsidized regimen and one from contributory regimen. They have a broad coverage of health care in the main cities that have reported a representative proportion of T2DM diagnosed cases in Colombia.

Study population

T2DM patients ≥18 years old that were newly diagnosed from April 1, 2016 to March 31, 2017 in diabetes care programs within the participating HMO's with a follow up period per patient of one year.

•Inclusion Criteria: 1) ≥ 18 years old; 2) newly diagnosed Type 2 Diabetes Mellitus (T2DM) (Fasting blood glucose: ≥126 mg/d; or HbA1c ≥ 6.5%; or postprandial glucose ≥200 mg/dl) (International Classification of Diseases 10th Revision, Clinical Modification [ICD-10-CM] codes: E11.0-E11.9); 3) complete information in the databases regarding variables of interest.

•Exclusion Criteria: Diagnosis of type 1 diabetes ([ICD-10-CM] codes: E10.0-E10.9) and gestational diabetes ([ICD-10-CM] codes: O24.0-O24.9).

Variables of interest

Demographic, clinical and medical treatment variables were collected. Clinical inertia was defined as failure to initiate or intensify therapy in a timely manner (at diagnosis and/or 3 to 6 months after diagnosis) according to local evidence-based “Clinical National Guide (CNG) for diagnosis, treatment and follow-up of T2DM in population over 18 years old” of Colombia⁴. Clinical Inertia was also analyzed by Initial Inertia and Follow-up Inertia.

Initial inertia was defined as failure to initiate the recommended pharmacological treatment according to CNG or to a late dispensing (>30days) of it; while follow-up Inertia was defined as a failure to adjust therapy at 3-6 months after diagnosis (considering Hb1Ac level) according to CNG.

The Ethics Committee of the participants HMOs approved this research.

Statistical Analysis

A descriptive statistical analysis was carried out. Categorical variables were described with absolute and relative frequencies, and quantitative data were described as means and standard deviation (SD), and as median and 95% confidence intervals (95% CI). Analyses were performed overall, in two subgroups according to Hb1Ac level (<8 and ≥8) and by affiliation regimen (subsidized and contributory). All analyses were conducted using STATA 14.

RESULTS

Considering the 616 patients that met inclusion criteria and were analyzed, it was found that 68.4% were females with a median age of 61 years (IQR 52-69) and 50% were from each regimen. Regarding clinical variables, it showed that 72% of the population had an altered BMI, 42% with overweight and 30% with obesity; also more than a half (53,7%) had HbA1c <8% at the time of diagnosis. Less than 5% of the patients reported history of acute myocardial infarction or stroke. All general characteristics are presented in table 1.

Table 1. Demographic, clinical and medical history characteristics of newly diagnosed T2DM patients

Variable	Diagnosis HbA1c				Total	
	<8%		≥8%			
	n	%	n	%	n	%
Gender						
Male	117	35.3%	100	35.1%	217	35.2%
Female	214	64.7%	185	64.9%	399	64.8%
Regimen						
Contributory	174	52.6%	134	47.0%	308	50.0%
Subsidized	157	47.4%	151	53.0%	308	50.0%
BMI						
Normal	94	28.4%	76	26.7%	170	28%
Overweight	121	36.6%	137	48.1%	258	42%
Obesity	116	35.0%	72	25.3%	188	31%
Acute Myocardial Infarction history						
Yes	12	3.6%	11	3.9%	23	4%
No	319	96.4%	274	96.1%	593	96%
Stroke history						
Yes	11	3.3%	11	3.9%	22	4%
No	320	96.7%	274	96.1%	594	96%
Smoking history						
Yes	40	12.1%	29	10.2%	69	11%
No	291	87.9%	256	89.8%	547	89%

Figure 1 shows the most prevalent comorbidities among the population. It was found that 72% of patients reported history of arterial hypertension (AHT), 49% had dyslipidemia and 82% had been diagnosed with chronic kidney disease (CKD). Finally, 71% were in stages 1 and 2 (358 of 504) and less than 1% were in stage 5.

Figure 1. Comorbidities among newly diagnosed T2DM patients

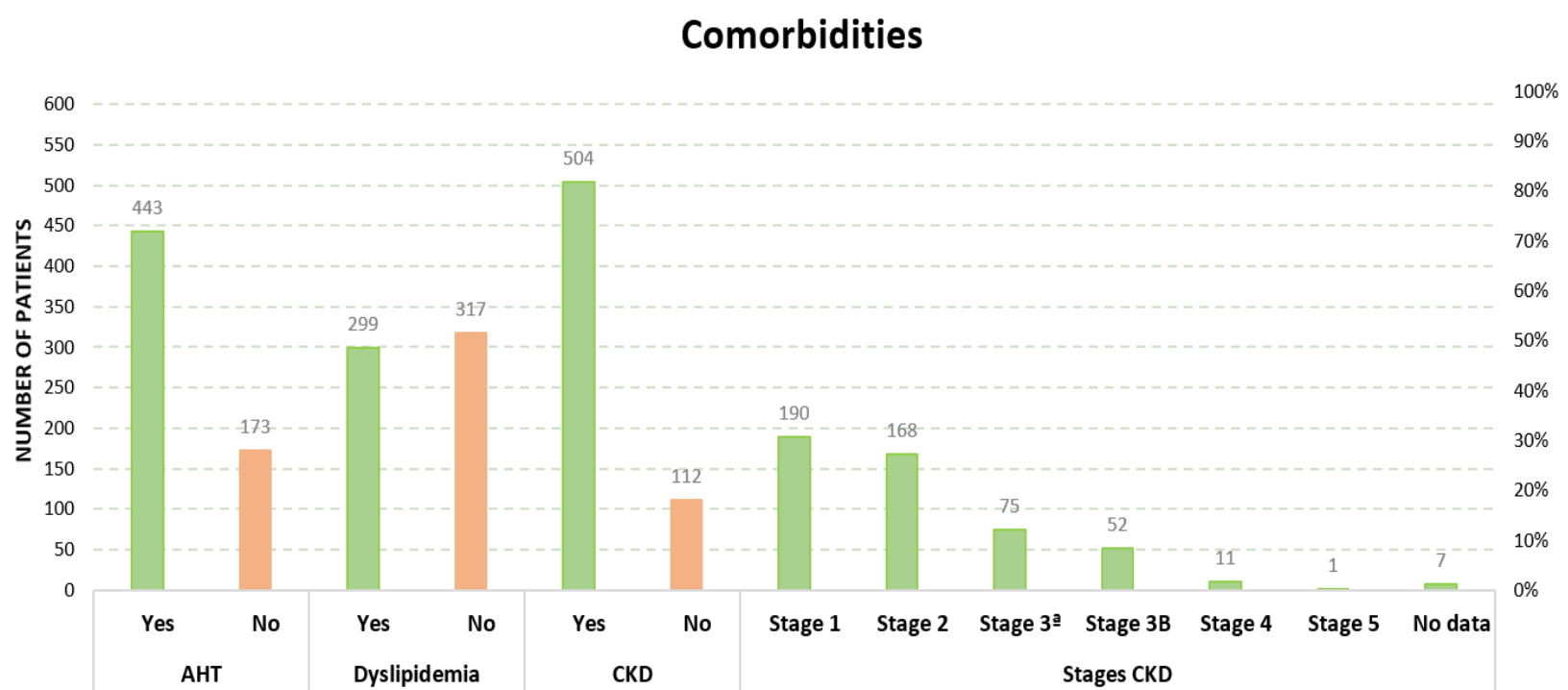


Table 3 summarizes the clinical inertia observed in this study. It was found that, from the 616 patients analyzed, 576 of them (93.5%) presented clinical inertia (CI 95%: 91.4%-95.3%). When discriminated by affiliation regimen it was found, that 87% of patients in the contributory regimen (CI 95%: 82.9%-90.5%) and 100% in the subsidized regimen (IC 95%: 99%-100%) presented clinical inertia.

Regarding initial inertia, it was observed that 361 patients (58.6%) presented initial inertia (CI 95%: 54.7%-62.5%), 61% in the group of patients in the contributory regimen (CI 95%: 55.4%-66.5%) and 56,2% in the group of patients in the subsidized regimen (CI 95%: 50.4%-61.8%). Finally, from the 255 patients with no initial inertia, follow-up inertia was found in 215 (84.3%) patients (CI 95%: 79.4% – 88.4%). When the results were analyzed by regimen, 66.7% of the patients in the contributory regimen (CI 95%: 57.8% – 74.6%) and 100% in the subsidized regimen (CI 95%: 97.8% – 100%) presented follow-up inertia.

Table 3. Type of clinical inertia among newly diagnosed T2DM patients

Type of Inertia	Total (n=616)		Contributory (n=308)		Subsidized (n=308)	
	n	%	n	%	n	%
Total Inertia						
Yes	576	93.5%	268	87%	308	100%
No	40	6.5%	40	13%	0	0%
Initial Inertia						
Yes	361	58.6%	188	61%	173	56.2%
No	255	41.4%	120	39%	135	43.8%
Follow up Inertia (no initial inertia)						
Yes	215	84.3%	80	66.7%	135	100%
No	40	15.7%	40	33.3%	0	0%

Identified factors for initial inertia were: inadequate treatment in 84.5% of the cases (305/361) and a late beginning of treatment (supply of medication > 30 days) in 15.5% of the cases (56/361) (Table 4). When the results were discriminated by affiliation regimen, it was found that all patients in the subsidized regimen received inadequate treatment, while that was the case in 70.2% of patients in the contributory regimen (132/188). Initial inertia in the contributory regimen was also seen by a late beginning of the treatment in 29.8% of the cases (56/188).

Concerning associated factors for follow-up inertia, it was identified that 93% of the cases were due to the lack or delay in follow-up HbA1c testing, within the 3 to 6 months following diagnosis; while 7% were observed due to the lack of proper adjustment or inadequate adjustment of the treatment as per indicated by the follow-up HbA1c level. When these results were discriminated by affiliation regimen, it was found that 100% (135/135) of the cases in the subsidized regimen were due to the lack or delay in follow-up HbA1c testing, while it was the reason in 81.2% (65/80) of the cases in the contributory regimen. The remaining 18.8% (15/80) of the cases in the contributory regimen were observed due to a lack of adjustment in the treatment.

Table 4. Inertia associated factors in newly diagnosed T2DM patients

Inertia identified factors	Total (n=576)		Contributory (n=268)		Subsidized (n=308)	
	n	%	n	%	n	%
Initial Inertia (n=361)						
Inappropriate Treatment	305	84.5%	132	70.2%	173	100%
Late treatment initiation (>30 days)	56	15.5%	56	29.8%	0	0%
Follow up Inertia (n=215)						
Inadequate treatment adjustment	15	7%	15	18.8%	0	0%
No HbA1c during the following 3 to 6 months	42	19.5%	40	50%	2	1.5%
One HbA1c (at diagnosis)	158	73.5%	25	31.3%	133	98.5%

LIMITATIONS

A limitation of the study is its retrospective design. Analyses were developed from the administrative database, which will not determine the current medical behavior or reflect the patient's behavior regarding care of their disease. The lack of patient follow-up data can also represent an issue.

Adherence is not available for this analysis, which could prevent reaching goals. Likewise given the source of the sample (selected health institutions), the results may not be generalizable for the population with T2DM in Colombia.

The analysis only included patients diagnosed between 2016 and 2017, when the formal registry of chronic patients in patient programs was introduced in Colombia, therefore, the registered information was recent and suggests the need of a larger follow-up. Additionally, during this period, there was a drug shortage of DDP-4 and SGLT-2 inhibitors.

CONCLUSIONS

This is the first study that analyzes clinical inertia under the current local clinical guidelines in both regimens of affiliation in Colombia. In this study, clinical inertia constitutes a major issue for diabetic population, not only at the time of diagnosis, but also during the follow up of the patients. The differences observed, according to the HbA1c level among the regimens of affiliation suggest the need to review guidelines knowledge and adherence in both regimens with more emphasis in the subsidized regimen. This information may help payers and clinicians streamline strategies for reducing clinical inertia and improve patient outcomes.

Disclosures

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