

Changes in diabetes care assessed from the number of HbA_{1c} assays performed during COVID pandemic in Slovakia

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Introduction: In Slovakia during the first two years of COVID-19 pandemic a significant increase of mortality in diabetic patients occurred, which returned near to the initial values in its last stage (2022). Patients with diabetes mellitus need regular assessment of HbA_{1c}. The aim of this study was evaluation of the effect of pandemic on the number of HbA_{1c} measurements performed before (2019), during (2020; 2021), and in the last stage (2022) of pandemic.

Methods: 382 803 HbA_{1c} measurements from Medirex Inc. laboratory chain and 23 779 assays from a local laboratory (Cumulus Inc.) were evaluated.

Results: The number of HbA_{1c} measurements in Medirex dropped down in 2020 by 18,7%, returned slightly in 2021 and increased by 4,4% in 2022. In Cumulus the decrease in 2020 was similar to Medirex, but in the next two years no full recovery occurred. Analysis according to type of diabetes (Medirex dataset) revealed that the recovery in 2022 was present only in T2DM patients and not in those with T1DM. Analysis according to age showed a broad distribution, with a 28,3% drop in the oldest T1DM (> 75 years) and an increase by 12,6% in oldest T2DM patients. Despite the changes in assay number the overall level of compensation, assessed by HbA_{1c} levels, remained stable.

Conclusions: The pandemic was a load test for laboratories providing biochemical assays. The increased mortality of diabetic patients during the pandemic was probably not due to deteriorating of basic disease as assessed by HbA_{1c}, but by COVID-19 and its complications.

Key words: COVID-19, diabetes mellitus, HbA_{1c}, glycaemic compensation.

Zmeny v starostlivosti o diabetes hodnotené podľa počtu vyšetrení HbA_{1c} vykonaných počas pandémie COVID-19 na Slovensku

Úvod: Na Slovensku došlo počas prvých dvoch rokov pandémie COVID-19 k výraznému nárastu úmrtnosti u pacientov s diabetes mellitus, ktorá sa v záverečnej fáze (2022) vrátila takmer na pôvodné hodnoty. Pacienti s diabetes mellitus potrebujú pravidelné meranie HbA_{1c}. Cieľom tejto štúdie bolo vyhodnotiť vplyv pandémie na počet meraní HbA_{1c} vykonaných pred (2019), počas (2020; 2021) a v záverečnej fáze (2022) pandémie.

Metódy: Vyhodnotilo sa 382 803 meraní HbA_{1c} z laboratórnej siete spoločnosti Medirex Inc. a 23 779 analýz z malého abo-

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ratória (Cumulus Inc.).

Výsledky: Počet meraní HbA_{1c} v laboratóriách Medirex v roku 2020 klesol o 18,7 % oproti 2019. V roku 2021 sa mierne zvýšil a v roku 2022 vzrástol o 4,4 %. V laboratóriách Cumulus bol pokles v roku 2020 podobný ako v laboratóriách Medirex, avšak v nasledujúcich dvoch rokoch nedošlo k úplnému návratu k prepandemickým hodnotám. Analýza podľa typu cukrovky (súbor údajov spoločnosti Medirex) odhalila, že k obnoveniu počtu meraní v roku 2022 došlo len u pacientov s T2DM, nie však u pacientov s T1DM. Analýza podľa veku ukázala široké rozloženie, pričom u najstarších pacientov s T1DM (> 75 rokov) došlo k poklesu o 28,3 % a u najstarších pacientov s T2DM k nárastu o 12,6 %. Napriek zmenám v počte testov zostala celková úroveň kompenzácie, hodnotená na základe hladín HbA_{1c}, stabilná.

Záver: Pandémia bola záťažovou skúškou pre laboratóriá poskytujúce biochemické testy. Zvýšená úmrtnosť diabetických pacientov počas pandémie pravdepodobne nebola spôsobená zhoršením základného ochorenia, ako to vyplýva z hodnotenia hladín HbA_{1c}, ale ochorením COVID-19 a jeho komplikáciami.

Kľúčové slová: COVID-19, diabetes mellitus, HbA_{1c}, glykemická kompenzácia.

Introduction and aim

After its first outbreak in Wuhan, China, in December 2019, the COVID-19 pandemic caused by the SARS-CoV2 virus has rapidly spread across the globe. In the absence of effective treatments and vaccines (in the first wave of pandemic), drastic measures have been taken to slow the spread of the viral infection by implementing social distancing and lockdowns of large sections of the society. The most severe cases of COVID-19 with high mortality have occurred in the elderly or in patients with chronic pathological conditions, particularly cardiovascular diseases, hypertension, diabetes mellitus, chronic lung and renal disease, and cancer (1, 2).

Patients with diabetes mellitus represent a vulnerable population not only for the underlying disease accommodated frequently with comorbidities and chronic complications, but also due their dependence on regular monitoring of disease compensation based on laboratory measurements. The guidelines for management of diabetes in ambulatory care include blood sampling several times a year glycated hemoglobin (HbA_{1c}) measurement, assessment of renal functions and lipid status (3).

The COVID-19 pandemic has dramatically changed the way of outpatient care delivery in healthcare settings. To minimize the risk of virus transmission to patients and healthcare workers, providers have postponed elective outpatient visits. For patients with diabetes mellitus, missed tests and the lack of personal contact with providers threatened the patients with possible deterioration of disease (4–7).

In Slovakia the first wave of pandemic took place from March to June 2020, the second from August 2020 to May 2021, and the third from September 2021 to May 2022. During the initial wave of COVID-19 Slovakia experienced a relatively low number of cases, due to the swift implementation of containment measures. However, in the second wave, the number of COVID-19 cases in Slovakia significantly surpassed the average reported across the European Union countries. Following a short-term decline in November 2020 the numbers increased again in December, and the situation improved through April and May 2021. During the pandemic the government of Slovak republic announced several lockdowns and or stay-at-home orders (8–10). In 2023 the disease was already not considered as pandemic, and the measures were lifted.

The aim of this work is to evaluate how the COVID-19 pandemic affected outpatient care provided by biochemical laboratories and

long-term compensation of patients with diabetes mellitus in Slovakia assessed from the number of HbA_{1c} measurements performed before, during and at the last stage of pandemic.

Methods

The analysis is based on results of 394 564 HbA_{1c} measurements performed in years 2019–2022 in a provider chain of clinical chemistry, Medirex Group Inc. (40 laboratories in all regions providing services for all regions of the country), and on COVID-19 data from Institute of Health Analyses Health Ministry of Slovakia. Year 2019 was considered as prepandemic and the basis of comparison with pandemic years (2020, 2021) and the last stage of pandemic (2022). In addition, a smaller dataset (23 779 measurements) of a clinical chemistry laboratory in Kosice (Cumulus Inc.) was evaluated, too.

From the original Medirex dataset only data of patients with T1DM and T2DM were analyzed (ICD classification E10, E11). The data of patients classified as „nondiabetics“ (n = 7267) and „other type of diabetes“ (E12 – E14, n = 3789) were omitted due to their low number and lack of diabetes subtype classification. Data on patients with T2DM younger than 25 years (n = 705) were also omitted because there were considered as erroneous data. The total number of omitted data was 11 761, which is less than 3% of the finally analyzed 382 803.

HbA_{1c} measurements in Medirex laboratories were performed with standardized and certified HPLC methods. HbA_{1c} measurements in Cumulus biochemical laboratory were performed by Tina-quant® HbA_{1c} Gen. 3 immunoassay on cobas® Integra (Roche, Switzerland) analyzer. In this smaller dataset the results were not divided according to type of diabetes and age of patients and served only as a comparison and confirmation of Medirex dataset results.

All results are expressed as mmol HbA_{1c}/mol HbA according to IFCC reference method.

The study was approved by the ethical committee of Medical Faculty, Comenius University. Personal data of patients were blinded and replaced by code numbers. Calculations were carried out by MedCalc (Belgium) software. Results of HbA_{1c} are presented as averages and medians because their skewed distribution. Comparison of differences between years and groups divided by age and diabetes type were performed by z-test for independent differences (Poisson test) and by Anova.

Results

The COVID-19 pandemic in Slovakia (population 5,45 million in 2019) has led to 1 885 657 documented cases and 21 270 deaths. In years 2019–2022 the prevalence of patients with diabetes mellitus in Slovakia was between 340–350 thousand (7,5–7,8%) according to national registry and slightly higher according to data of International Diabetes Federation (9,1%).

In the first two years of pandemic, it was a significant increase in mortality of diabetic patients, from 15 200 in 2019 to 18 500 and 24 100 in 2020 and 2021 and returned to 18 700 in 2022 (Fig 1). The cumulative excess mortality during three years of pandemic compared to year 2019 was 15 700. This corresponds approximately to 4,5% increase of mortality (calculate on the basis of 350 000 diabetics in the country).

The final number of evaluated HbA_{1c} measurements from Medirex dataset was 382 803 (28 681 T1DM and 354 122 T2DM). The distribution of measurement numbers and the persons with at least one measurement is in table 1. The number of HbA_{1c} measurements dropped down

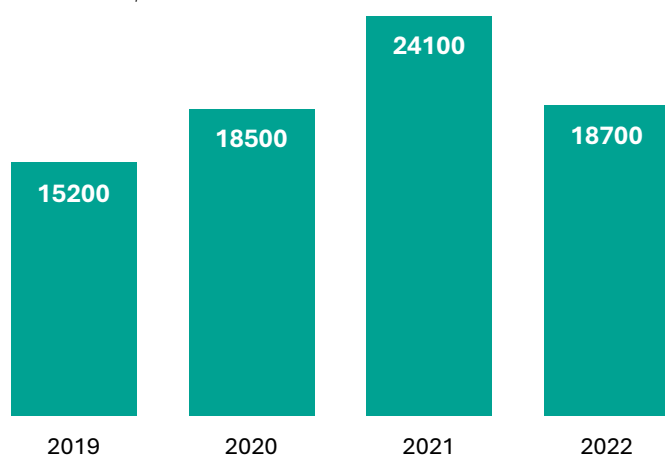
significantly in 2020 by 18,7%, returned near to initial value a year later and increased by 4,4% in 2022. The numbers of persons with at least one measurement in one year showed similar results with exception of number of persons investigated in 2022 remaining slightly below the prepandemic stage.

The data from the smaller Cumulus laboratory were slightly different as compared to those of Medirex chain. In 2020 the decrease of measurement number in Cumulus as compared to 2019 was similar to the big dataset (18,7 vs 21,2%) In the next two years a small improvement occurred in Cumulus but not a full recovery as in Medirex.

In table 2, and in figs 2, 3 measurement numbers from Medirex dataset are presented according to diabetes type and patient age. (There were no differences between men and women in this dataset). The results show that the recovery in measurement numbers occurred only in T2DM patients from the beginning of pandemic to 2022. In 2020 there was a decrease of measurement number in each age and type group (between -11,5 and -21,1%), later a partial improvement occurred except for the oldest T1DM group (decrease by 23,8%) and in the last year the results were diverse (from 12,6% increase in oldest T2DM to 28,3% decrease in the same age group of T1DM patients).

From pseudonymized patient identifiers it was as possible to identify repeated observations across study years. Overall, 64,4% of patients were present in more than one year of the dataset and 29,5% were observed in all four years (2019–2022), allowing longitudinal assessment of glycaemic control in a substantial proportion of the cohort. The number of HbA_{1c} measurements performed in one person was slightly above those advised minimum two measurements yearly by guidelines. It was more in T1DM patients younger than 50 years, and less in all patients with T2DM and the oldest group of T1DM patients (Table 3).

Fig. 1. Mortality of diabetic patients before (2019) and during (2020–2022) the COVID-19 pandemic)



Tab. 1. HbA_{1c} measurement number and number of persons with at least one measurement during the pandemic

YEAR	MEDIRESX				CUMULUS*	
	NUMBER	CHANGE** %	PERSON	CHANGE** %	MEASUREMENT	CHANGE** %
2019	100 198		55 646		6 999	
2020	81 481	-18,7	47 290	-15,0	5 511	-21,2
2021	96 486	-3,7	52 364	-6,0	5 210	-16,6
2022	104 638	+4,4	53 356	-4,1	6 059	-14,4

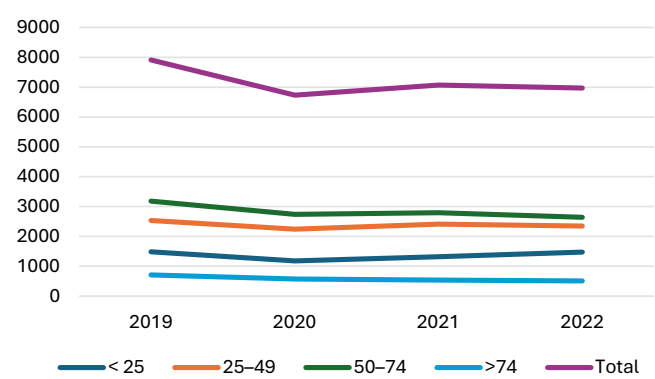
*No further analysis of person numbers, age and disease type distribution Included only as a crude comparison to the big dataset from Medirex.

**2019 = 100%; differences in measurement and person numbers between 2019 and 2020–2022 were statistically highly significant in both laboratories ($p < 0,0001$)

Tab. 2. HbA_{1c} measurement number before and during the pandemic divided according to age of patients and type of diabetes

AGE, YEARS	TYPE	MEASUREMENT NUMBER				CHANGE, %		
		2019	2020	2021	2022	2020	2021	2022
< 25	T1DM	1 485	1 180	1 317	1 476	-20,5	-11,3	-0,5
25–49		2 534	2 243	2 415	2 345	-11,5	-4,7	-7,5
50–74		3 182	2 739	2 794	2 641	-13,9	-12,2	-17,0
>74		710	570	541	509	-19,7	-23,8	-28,3
SUM		7 911	6 732	7 067	6 971	-14,0	-10,7	-11,9
25–49	T2DM	7 231	6 136	7 401	7 974	-15,4	+2,4	+10,3
50–74		64 004	51 997	61 592	65 980	-18,8	-3,7	+3,1
>74		21 052	16 616	20 426	23 713	-21,1	-3,0	+12,6
SUM		92 287	74 749	89 419	97 667	-19,0	-3,1	+5,8

Fig. 2. HbA_{1c} measurement number in before (2019) and during (2020–2022) the COVID-19 pandemic in T1DM patients



Tab. 3. HbA_{1c} measurements in person/year before, and during the pandemic

AGE, YEARS	TYPE	MEASUREMENT/PERSON			
		YEARS			
		2019	2020	2021	2022
< 25	T1DM	2,57	2,14	2,39	2,33
25–49		2,27	2,15	2,27	2,25
50–74		1,95	1,94	2,09	2,03
> 74		1,71	1,72	1,87	1,86
25–49	T2DM	1,68	1,67	1,73	1,83
50–74		1,81	1,74	1,86	1,99
> 74		1,73	1,63	1,76	1,90

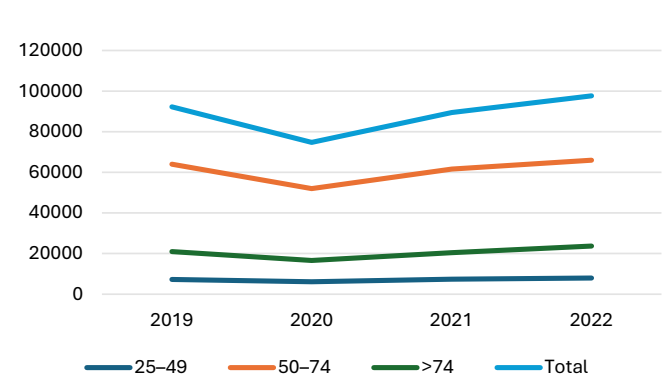
Discussion and conclusions

The health consequences of pandemic caused by coronavirus can be assessed from three different aspects. The basic is the COVID-19 disease itself causing a variety of clinical manifestations from an acute respiratory illness to severe conditions as respiratory insufficiency, (long COVID, etc.) and even death. The second face of the pandemic is associated with the effect of preventive measures implemented from the beginning the pandemic (lockdown, social distancing, etc.) because in its first months the health care systems were not prepared to the situation, and no vaccination was available to slow down the spread of disease. The last, hidden effect („influence“) is the psychologic effect of the unexpected dangerous situation for already stressed population of people with various chronic diseases. The overall effect is a combination of all these conditions and in the case of patients with diabetes mellitus the situation is aggravated with the burden of underlying disease and its comorbidities (11–14).

Our study deals with a specific problem of health care delivery assessed from the number of HbA_{1c} measurements performed before, during and at the last stage of the pandemic. Immediately after the beginning of pandemic the laboratories of clinical chemistry were overwhelmed with requests not only with SARS-CoV2 testing but also with requests of standard measurements associated with the high number of persons with other manifestation of disease (15–16). Later the SARS-CoV2 testing was replaced with mobile testing facilities, and „at home“ diagnostic tests (17) but the burden of laboratories remained high (18–19). The situation was aggravated by high number of laboratory personnel affected by COVID-19.

Diabetes mellitus is a disease highly dependent on regular monitoring by laboratory measurements, selfmonitoring, and continuous glucose monitoring (CGM). Blood glucose measurements are possible in frame of

Fig. 3. HbA_{1c} measurement number in before (2019) and during (2020–2022) the COVID-19 pandemic in T2DM patients



Tab. 4. Average and median HbA_{1c} in T1DM and T2DM patients before and during the pandemic

TYPE	YEAR	HbA _{1c} , mmol/mol HbA	
		Average ± SD	Median & Interquartile range
T1DM	2019	66,2 ± 19,8	63,9 (52, 8–77, 0)
	2020	66,3 ± 21,7	63,9 (52, 1–77, 0)
	2021	66,1 ± 19,3	62,8 (52, 9–77, 0)
	2022	64,4 ± 18,8	61,8 (51, 8–73, 9)
T2DM	2019	54,7 ± 16,3	50,8 (43, 2–62, 6)
	2020	55,7 ± 16,9	51,9 (44, 3–63, 8)
	2021	56,4 ± 16,6	52,9 (44, 9–63, 9)
	2022	55,9 ± 16,2	52,1 (44, 7–63, 0)

self-monitoring at home but HbA_{1c} measurements, the golden standard of glycaemic compensation, are not. From this reason a change of the measurement numbers during the COVID-19 pandemic is a good indicator of problems in outpatient health care system of diabetic patients.

Our results from a big laboratory chain show a significant decrease of HbA_{1c} measurements and person with at least one measurement. The biggest decrease of measurements number was in the first year (-18.7% of measurements from Medirex and -21.2% from Cumulus). In the last stage of pandemic, the numbers from the big provider returned to prepandemic values. A worse picture was evident from the simple analysis from a small local laboratory, where the number of measurements remained low also in the last year of pandemic. Although the differences evaluated by the Poisson's z test were significant across the years and groups divided by type of diabetes and age of patients, from practical point of view we do not consider small differences (e.g. the increase of measurement number by 4.4% between 2019 and 2022 as really „significant“ from the point of view of outpatient care) and we rely on simple comparisons as presented in tables.

Analysis according to type of diabetes and age of investigated persons showed some unexpected results. The improvement of the number of measurements in the big provider was restricted to patients with T2DM and those with T1DM (representing only 7.5% of all measurements) did not show any improvement. The explanation of this unexpected finding needs further analysis in the future.

In the last stage the results in different age groups were variable with a broad distribution from a deep drop by 28.3% in the oldest age group of T1DM and a surprising increase by 12.6% in the same age group of T2DM patients. This age group of diabetics of both types are of special

interest because most of them probably have diabetes for many years often with chronic complications. Moreover, the case fatality rate of COVID-19, in people younger than 65 years of age with the values) below 1% jumps to 2.5%, 8.5 and 28.3% in three subsequent decades of life (20).

In our study, the overall level of compensation, as assessed by the HbA1c measurements, remained unchanged despite a decrease in the number of measurements performed. This contradicts the data on increased mortality of diabetic patients during the pandemic years, raising the possibility that the increase in mortality was not due to deteriorating diabetes, but to COVID-19 disease and its complications.

In our study we did not find any change of average and median values of HbA1c measurements during the pandemic and the same was true of the distribute on of measurement numbers considered as a marker of good (< 53 mmol/mol), satisfactory (54–64 mmol/mol) and bad (> 64 mmol/mol) compensation (data not shown).

In other studies, there were described different results including deterioration, no change or even slight improvement of compensation

level but these were performed in smaller number of patients and mostly in specific groups (21–27. The strength of our study relies on the very high number of analyzed data (around 100 thousand measurements and 50 thousand persons each year) representing a considerable fraction of approximately 350 thousand diabetics in this country. On the other side behind these integrated data important details can remain hidden and there is a need for further analysis.

Before drawing a conclusion of our study, that despite the heavy burden imposed on laboratories and primary diabetes care during COVID-19 pandemic, there was no drastic deterioration of the level of glycemic compensation, one should be aware an insidious side of association between diabetes mellitus and COVID-19. The pandemic lasted three years and it compared with the time of development of diabetic complications and comorbidities it is a relative short period. The accelerated development of consequences in the subsequent years is a lurking menace, and it should be carefully followed in the future.

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