ORIGINAL ARTICLE

CONTENTS

Indicators of biochemical control of diabetes mellitus during limited availability of health service in the context of hypoglycemic therapy

Marcin Kleibert[1], Beata Mrozikiewicz-Rakowska[2], Klaudia Korycka[3], Iga Płachta[3], Patrycja Małgorzata Bąk[3], Daniel Bałut[3], Jakub Zieliński[4], Wojciech Zgliczyński[2]

[1]CHAIR AND DEPARTMENT OF EXPERIMENTAL AND CLINICAL PHYSIOLOGY, LABORATORY OF CENTER FOR PRECLINICAL RESEARCH, MEDICAL UNIVERSITY OF WARSAW, WARSAW, POLAND

[2]DEPARTMENT OF ENDOCRINOLOGY, CENTRE OF POSTGRADUATE MEDICAL EDUCATION, BIELANSKI HOSPITAL, WARSAW, POLAND

[3]FACULTY OF MEDICINE, MEDICAL UNIVERSITY OF WARSAW, WARSAW, POLAND

[4]INTERDISCIPLINARY CENTRE FOR MATHEMATICAL AND COMPUTATIONAL MODELLING, UNIVERSITY OF WARSAW, WARSAW, POLAND

ABSTRACT

Aim: Type 2 diabetes mellitus (T2DM) is a widespread disease that leads to many complications if not adequately controlled. The pandemic and its limitations on healthcare access impaired the management of chronic conditions. The aim of our study was to examine its effects in context of different antidiabetic therapies on key health related factors in patients with T2DM.

Materials and Methods: To the study we enrolled 598 adult patients with diagnosed T2DM treated in diabetology outpatient department of the University Clinical Centre (UCC) of the Medical University of Warsaw. Data on body weight, glycated hemoglobin (HbA1c), and creatinine concentration were collected throughout the first COVID-19 pandemic wave and compared to the results obtained before the 4th of March, 2020 (1st confirmed COVID-19 case in Poland).

Results: The HbA1c mean baseline level was 7.15% (±1.39) and increased significantly (7.34% (±1.37), p=0.02) during observation. Importantly, the attendance of patients for HbA1c testing decreased by 57.82% in comparison to the pre-pandemic period. Similarly, creatinine concentrations increased (from 1.27 mg/dl (±0.76) to 1.34 mg/dl (±1.02), (p=0.004)). The increase in creatinine concentration was significantly lower in the group treated with regimens including metformin compared to other regimens. Somewhat surprisingly, the mean body mass remained unchanged.

Conclusions: The pandemic period had a significant impact on the tested biochemical parameters. The lesser changes of renal parameters in the group of patients treated with metformin confirms its nephroprotective effect and its value as a first-line treatment in T2DM.

KEY WORDS: diabetes mellitus, HbA1c, metformin, creatine, COVID-19 pandemic

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INTRODUCTION

Diabetes mellitus is a widespread disease that also has an impact on the onset of several severe complications, such as cardiovascular or renal issues [1]. Adequate treatment and monitoring of patients with type 2 diabetes mellitus (T2DM) are essential to reduce the risk of developing these complications.

Limited access to healthcare or modern forms of hypoglycemic therapy may have an impact on compliance with medical recommendations, directly affecting treatment outcomes. An example of the aforementioned scenario was encountered during the coronavirus disease 2019 pandemic, which led to a general decrease in the access to medical professionals, medication adherence and the management of chronic conditions [2, 3].

AIM

In our study, we aimed to examine the impact of limited access to healthcare during the COVID-19 pandemic on key health related factors in patients with T2DM - average body weight, creatinine levels, and glycated hemoglobin HbA1c levels in context of used antidiabetic therapies (including insulin, metformin, Sodium/glucose cotransporter-2 inhibitors (SGLT-2 inhibitors), and glucagon-like peptide-1receptor agonists (GLP-1 receptor agonists). Especially, we intended to investi-

Table 1. The baseline study population characteristics

Parameters	Number (percentage %)	Mean(±SD)
Age	598 (100)	68.8±11.87
Females	322 (53.85)	
Males	276 (46.15)	
Weight	559 (93.48)	87.09±19.54
Hypertension	481 (80.43)	
Atrial fibrillation	60 (10.03)	
Chronic coronary syndrome	131 (21.91)	
Dyslipidaemia	231 (38.63)	

Table 2. Treatment regimens

Medicine	Number (percentage %)
Metformine	428 (71.57)
Sulphonylourea	126 (21.07)
SGLT-2i	112 (18.73)
DPP-4i	47 (7.86)
GLP-1A	16 (2.68)
Other antidiabetic agent - acarbose, pioglitazone	11 (1.84)
Insulin	305 (51)

gate the specific impact of metformin on these variables in this setting, given its wider availability to patients compared to newer medications.

MATERIALS AND METHODS

STUDY DESIGN

The analysis involved 598 adult patients (322 females (53.85%) and 276 males (46,15%)) diagnosed with T2DM treated in the diabetology outpatient department at the University Clinical Centre (UCC) of the Medical University of Warsaw. Patients with type 1 diabetes mellitus were not included due to limited availability of clinical data (Table 1).

Clinical data were sourced from the UCC database and encompassed demographic characteristics (age and sex), weight, HbA1c levels, creatinine concentration, and antidiabetic agents. Blood samples were collected from patients using probes with an anticoagulant (EDTA), and all laboratory tests were conducted in the Central Laboratory of the UCC directly after sample collection. Creatinine concentration was measured using the Jaffé method (Roche), while HbA1c levels were assessed through capillary electrophoresis (Sebia). Measurements of weight, HbA1c, and creatinine were tracked throughout the initial pandemic wave until March 2021 and compared to data collected from September 2019 to 4th of March, 2020, the date which marked the first confirmed COVID-19 case in Poland). Antidiabetic treatment adhered to the guidelines of the Polish Diabetes Association [4], with patients receiving insulin, metformin (prescribed only in patients with eGFR>30 ml/min/1.73m2) SGLT-2 inhibitors, or other antidiabetic agents (Table 2).

STATISTICAL ANALYSIS

The data were analysed using Statistica 13 (TIBCO Software Inc., Palo Alto, CA, USA). To confirm the normal distribution of the data, the Lilliefors and Shapiro-Wilk tests were conducted. Analysis included Pearson and R-Spearman correlations, as well as one-way and two-way ANOVA and t-test comparisons. Statistical significance was established at a p-value less than 0.05.

STUDY ETHICS

This retrospective study was conducted in accordance with the Declaration of Helsinki. The Institutional Review Board at the Medical University of Warsaw was informed about the study (Approval ID: AKBE/162/2022) and the requirement for written informed consent from each patient was waived.

RESULTS

BODY WEIGHT

The mean body weight of patients before and during the pandemic did not show a significant change. There was no correlation between patient age and fluctuations of body weight. Moreover, various drug combinations were analysed for their impact on body weight. The sole instance where weight gain was noted was in patients concurrently receiving SGLT-2 inhibitors and insulin (p=0,03). No other notable variations in body weight were observed among patient groups categorized based on their prescribed therapies.

HBA1C CONCENTRATION

The HbA1c mean baseline level was 7.15% (±1.39) and increased significantly (7.34% (±1.37), p=0.02) during observation.

Upon segregating patients into distinct treatment groups, it was observed that none of the examined medications (metformin, insulin, SGLT-2 inhibitors) showed a more significant influence on this change compared to the others. There was no observable impact of patient age on the change in HbA1c concentration. Furthermore, none of the drug combinations showed a significant effect on the change in HbA1c levels.

Importantly, the attendance of patients for HbA1c testing decreased by 57.82% in comparison to the pre-pandemic period.

CREATININE LEVEL

The creatinine mean baseline concentration was 1.27mg/dl (±0.76) and increased significantly (1.34 mg/dl (±1.02); p=0.004) during observation. However, the increase in creatinine concentration was significantly lower in the group treated with regimens including metformin compared to other regimens (concentration change respectively 0.038 mg/dl vs 0.138 mg/dl, p=0.043). No other similar relationships were found, regardless of the treatment.

CORRELATIONS OF COMORBIDITIES

No significant correlations were found between the presence of comorbidities such as hypertension, atrial fibrillation, chronic coronary syndrome, dyslipidemia, and the monitored parameters (changes in creatinine level, body weight, and HbA1c levels), only body weight before the pandemic exhibited a positive correlation with the presence of dyslipidemia (Table 3-4).

DISCUSSION

Recent events, such as the COVID-19 pandemic and the current challenges in the pharmaceutical market have led to restricted access to medical services, affecting individuals with chronic conditions who require regular monitoring. Present situation in the pharmaceutical market is starting to resemble that of the pandemic due to the limited availability of certain medications, notably glucagon-like peptide-1 receptor agonists - globally overused for treatment of obesity. This scarcity may lead to metabolic changes akin to those observed in the population in 2020. Consequently, patients may be compelled to rely on accessible therapeutic agents.

For individuals with T2DM, maintaining consistent normoglycemia is essential in averting complications associated with diabetes. In our study, we focused on assessing basic metabolic parameters such as serum creatinine, HbA1c levels, and body weight due to their widespread availability enhancing the clinical applicability of the results, particularly in settings with limited resources.

Due to a reduction in access to healthcare services, in-person consultations decreased, leading to the adoption of telemedicine consultations during the pandemic. While basic assessments like self-monitored glucose profiles, signs of hyper/hypoglycemia, and body weight checks could be conducted by patients at home, these measures were often insufficient for a comprehensive evaluation of T2DM control and the implementation of essential therapeutic adjustments to mitigate the risk of diabetes-related complications. Certain critical tools required for these modifications, such as HbA1c and creatinine level measurements, necessitated in-person visits to healthcare facilities. Given the simplicity and widespread availability of these parameters, our study focused on monitoring changes in HbA1c, creatinine levels, and body weight.

In our study, somewhat surprisingly, throughout the observation period, the mean body weight remained stable within our group. This result is not consistent with the expectations and results of other researchers - a considerable number of studies have reported a notable weight gain during this timeframe [5]. It is possible that the lack of significance is due to the relatively small study group. Interestingly, we noted that the combined use of SGLT-2 inhibitors and insulin could potentially lead to weight gain, possibly due to the anabolic effects of insulin.

HbA1c serves as a widely accessible marker for assessing long-term glycemic control, reflecting the cumulative blood sugar levels over the previous two to three months. Its measurement is valuable in assessing the risk of diabetic complications, with even a single

Table 3. General results

Mean(±SD)	Starting point	Ending point	p
Body weight	87.09 kg	86.74 kg	0.105
HbA1c concentration	7.15 %	7.34 %	0.02
Creatinine level	1.27 mg/dl	1.34 mg/dl	0.004

Table 4. The change of measured parameters before and during the SARS-CoV-2 pandemic among patients who were not treated with metformin and treated with it

Delta (Δ)	Other agents	Metformin	p
Body weight	-0.393 kg	-0.207 kg	0.713
HbA1c concentration	0.213 %	0.004 %	0.277
Creatinine level	0.038 mg/dl	0.138 mg/dl	0.043

test offering reliable insights into diabetes diagnosis and prognosis [1].

In our study, a noteworthy increase in HbA1c levels was observed and deemed statistically significant, suggesting a dominant presence of factors associated with deteriorated overall glycemic control in our study population. Furthermore, the increase was similar in all treatment regimens. Additionally, no significant statistical correlation was found between the elevation in HbA1c levels and changes in body weight.

Our results are consistent with expectations, but scientific data from other authors on this subject are conflicting. Some studies, similarly to our data indicated that the lifestyle changes and reduced access to healthcare during the COVID-19 lockdown led to elevated HbA1c levels [6]. Conversely, other research has shown that in selected groups increased physical activity and high medication adherence during the pandemic contributed to lower HbA1c levels [7]. However, an American cohort study found no significant difference in HbA1c levels between 2019 and 2020 [8]. Our study supports the conclusion that the time of the pandemic negatively affected the control of type 2 diabetes in the study population.

Hyperglycemia contributes not only to cardiovascular complications but also to the development of structural and functional changes in the kidneys. Diabetic nephropathy is the leading cause of end-stage renal disease, so regular monitoring of creatinine levels for the assessment of kidney function in these patients is essential [9]. In our study, the creatinine mean baseline concentration increased significantly in the entire study group during observation. This finding, to the best of our knowledge, provides initial evidence that limited access to healthcare services during the COVID-19 pandemic contributed to a decline in kidney function among patients with T2DM. While the analysis of creatinine levels was conducted on 304 subjects (50.84%), the potential for bias due to limited data remains a concern. Nevertheless, the study offers insights into the progression of renal function during the SARS-CoV-2 pandemic. Interestingly, the decline in kidney function was less pronounced among patients receiving metformin compared to those not prescribed this medication. This outcome appears unexpected because other medications utilized within our clinical group also exhibit nephroprotective components.

Numerous clinical studies have highlighted the nephroprotective benefits of SGLT2 inhibitors and GLP-1 receptor agonists in individuals with normal or impaired glomerular filtration rate (GFR). Randomized trials involving patients with type 2 diabetes have shown that SGLT2 inhibitors can attenuate the decline in glomerular filtration rate, decrease the incidence of microalbuminuria, and slow or reverse the progression of proteinuria [10].

The CREDENCE study was a pioneering research focused on kidney disease, demonstrating benefits of SGLT2 inhibitors in patients with type 2 diabetes exhibiting substantial albuminuria and/or impaired kidney function. The primary composite endpoint related to kidney disease, encompassing end-stage kidney disease, doubling of serum creatinine, or renal death, was lowered by 34% [11].

Moreover, a new class of antidiabetic medications, such as GLP-1 receptor agonists, not only improve glycemic control and promote weight loss but also enhance cardiovascular and renal outcomes in patients with type 2 diabetes [12]. Studies in individuals with chronic kidney disease have demonstrated the safety of GLP-1 agonists in this population, showing no increased risk of acute kidney injury and effectiveness even at lower eGFR levels [13]. LEADER and SUSTAIN-6 studies identified a predefined renal composite, including crite-

ria such as new-onset or persistent macroalbuminuria, sustained doubling of serum creatinine, eGFR≤45 ml/min/1.73 m^2, the need for renal replacement therapy, and renal mortality. Liraglutide demonstrated a 22% reduction in this renal outcome, while semaglutide exhibited a 36% reduction [14, 15].

Despite the aforementioned results in numerous clinical trials, in our study the lack of discernible effects among other antidiabetic agents like SGLT-2 inhibitors or GLP-1 receptor agonists may be attributed to the limited number of patients using these medications, with financial constraints being a common reason for their reduced utilization. In Poland, reimbursement for SGLT-2 inhibitors or GLP-1 receptor agonist therapy is typically reserved for advanced cases of type 2 diabetes, making costly treatments financially burdensome for most patients.

Metformin remains a widely available option for patients, serving as the first-line oral therapy for individuals with T2DM [4]. This antihyperglycemic agent is extensively utilized in clinical practice. Historically, the use of metformin was discouraged in patients with acute or chronic kidney injury (AKI/CKD) due to concerns regarding the heightened risk of lactic acidosis [16]. Thus, metformin should not be prescribed for patients with advanced CKD, on account of an increased mortality risk related to metformin use in those patients [17]. On the other hand, a systemic review by Inzucchi et al. showed that when metformin was used in patients with mild to moderate CKD (eGFR 30–60 mL/min/1.73 m2), its serum levels usually remained within the therapeutic range [18].

Multiple studies presented the potential beneficial outcomes of metformin use in diabetic nephropathy and moderate CKD [19, 20]. The impact of metformin on the kidney in diabetics is also a consequence of its glucose-lowering-dependent mechanism [20]. Roussel et al. in a study that investigated the relationship between metformin use and mortality among T2DM patients with atherothrombosis found that metformin, prescribed in subjects with moderate renal failure (eGFR 30–60 mL/min/1.73 m^2), caused 36% risk reduction of mortality (HR 0.64; 95% CI, 0.48–0.86) [19]. Charytan et al. found that in patients in CKD, stage ≥4 metformin administration was associated with a decreased risk of kidney disease outcome, defined as an end-stage renal disease (ESRD) or death. The independent reductions of all-cause mortality were also reported [21]. Kwon et al. showed that metformin usage in advanced CKD patients, decreased the risk of all-cause mortality and incident ESRD by 35%[22].

Our results support the conclusions of other researchers about the nephroprotective effect of metformin and show that (perhaps due to high availability and low price) this effect is also visible in the population during a health care crisis. However, another possible explanation is that metformin was prescribed only in patients with eGFR>30 ml/min/1.73m^2. However, another possible explanation is that metformin was prescribed only in patients with normal to moderately decreased renal function. Another study showed that the decline of eGFR is greater in patients with decreased eGFR, thus the initial difference in eGFR level between the metformin group and non-metformin group may impact overall alternations in creatinine level [23].

There were several limitations to our study. Our research has a retrospective character. The number of patients included in our work was relatively small compared to similar studies. The time of observation was too short (less than two years) to analyse mortality and occurrence of cardiovascular events. Moreover, the time of the pandemic and the significant impact of SARS-CoV-2 infection on mortality and thromboembolic complications would make the interpretation of such results significantly more difficult.

Challenges in data collection arose from difficulties in maintaining contact with patients due to restricted personal interactions during the pandemic and obstacles encountered with lowered rate of participation in consultations.

We chose not to include patients with type 1 diabetes mellitus due to the limited availability of clinical data from this patient group for collection and analysis. Additionally, we reported results for each type of antihyperglycemic agent separately, even when patients were prescribed multiple medications from different groups. However, the number of patients receiving multidrug therapy involving the same categories of antihyperglycemic agents was insufficient to permit individual group analyses. Moreover, although other parameters like microalbuminuria might be more pertinent to diabetic nephropathy, we opted to use creatinine levels to assess renal function. This decision was influenced by the more routine nature of creatinine assessments as opposed to limited availability of microalbuminuria assessments in our study population prior to the COVID-19 pandemic.

Due to the retrospective nature our findings require further prospective studies.

CONCLUSIONS

The limited availability of healthcare services during the COVID-19 pandemic adversely affected the metabolic control of T2DM, evident through elevated levels of creatinine and HbA1c. This could potentially increase the long-term cardiovascular and renal risks for individuals. To mitigate these risks, there is a critical need for enhanced support

for patients and the formulation of preventive strategies that consider the most efficacious therapies in anticipation of future pandemic waves or pharmaceutical challenges.

Our study revealed that the rise in creatinine levels was notably lower in patients receiving metformin compared to those on other commonly prescribed antidiabetic medications. This underlines the nephroprotective potential of metformin, particularly during periods of suboptimal glycemic control or limited availability of modern antidiabetic treatments. It reinforces the importance of retaining metformin as a cornerstone in the treatment strategies for T2DM, emphasizing its value as a first-line therapy.

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CONFLICT OF INTEREST

The authors declare no conflict of interest

CORRESPONDING AUTHOR

Patrycja Małgorzata Bąk
Faculty of Medicine, Medical University of Warsaw,
02-091 Warsaw, Poland
e-mail: patrycjambak@gmail.com

ORCID AND CONTRIBUTIONSHIP

Marcin Kleibert: 0000-0003-1562-8450 A C D
Beata Mrozikiewicz-Rakowska: 0000-0002-1160-9204 A C D E F
Klaudia Korycka: 0009-0006-2542-6915 A C D E
Patrycja Małgorzata Bąk: 0000-0001-8259-0718 A B E F
Iga Płachta: 0000-0002-0830-2711 A C D
Daniel Balut: 0009-0003-2994-4400 A B
Wojciech Zgliczyński: 0000-0002-7283-4755 C D
Jakub Zieliński: 0000-0001-8935-8137 C D

A – Work concept and design, B – Data collection and analysis, C – Responsibility for statistical analysis, D – Writing the article, E – Critical review, F – Final approval of the article

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