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Impact of the COVID-19 pandemic on the outcomes of Indonesian chronic disease management program

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ABSTRACT

Background: The Indonesian Government launched chronic disease management program (PROLANIS) with the aim of improving clinical outcomes and preventing disease complications of patients with type 2 diabetes (T2D). During the coronavirus disease 2019 (COVID-19) pandemic, the overwhelmed healthcare system shifted resources away from non-communicable diseases in the attempt to mitigate it. Thus, the implementation of PROLANIS during the COVID-19 pandemic might not be as optimal as before the pandemic era, leading to worse clinical outcomes. This pilot study aims to evaluate the impact of the COVID-19 pandemic on PROLANIS in rural areas by analyzing the changes of metabolic control and renal function parameters.

Methods: This study used data from three PROLANIS groups report in rural areas in East Java Province, Indonesia. Study population was PROLANIS participants who came for six-month-evaluation in December 2019 (T0), June 2020 (T1), and December 2020 (T2). Evaluated metabolic control parameters were body mass index (BMI), blood pressure, hemoglobin A1C (HbA1C), total cholesterol (TC), high-density lipid, low-density lipid, and triglyceride (TG), whereas evaluated renal function parameters were blood urea nitrogen, serum creatinine, and urinary albumin. Independent t-test and Wilcoxon signed-rank test were used for statistical analyses. p-value <0.05 was considered statistically significant.

Results: Among 52 PROLANIS participants included in the analyses, four metabolic control parameters (BMI, blood pressure, TC, and TG) and all renal function parameters significantly worsened right after the pandemic started but improved 6 months afterwards. Meanwhile, HbA1C continuously worsened throughout the study period, albeit statistically insignificant.

Conclusions: The metabolic control and renal function parameters in our study population deteriorates especially in the beginning of the COVID-19 pandemic.

Keywords: COVID-19, Indonesia, government programs, pilot study, type 2 diabetes

INTRODUCTION

Type 2 diabetes (T2D) is one of the major global public health concerns, and the burden of this disease continues to rise over decades. Worldwide, there is an increase of 49% in the prevalence, 10% increase in mortality, and 27.6% increase in disability-adjusted-life-years between 1990 and 2019 [1]. The growing burden of T2D is disproportionately affecting lower-middle-income countries, including Indonesia that has seen a remarkable rise in T2D prevalence in the past two decades [2-4]. Between 2013 and 2018, the national basic health survey reported that the prevalence of T2D in Indonesia increased by 58% [5]. Recent report from the International Diabetes Federation revealed that Indonesia currently ranks fifth among countries with the highest number of adults with diabetes, amounting to 19.5 million adults in 2021, and is projected to rise to 28.6 million by 2045 [6].

The recognition of this increasing burden led to the commencement of a community-based disease-management program for non-communicable diseases called Indonesian chronic disease management program (PROLANIS) in 2010 that later became available for every citizen under the national health insurance scheme [7, 8]. This program is carried out by primary healthcare in collaboration with the local community and national health insurance, with the aims of improving clinical outcomes and preventing disease complications of patients with T2D. Various activities included in this program are free medical consultation and health education, group education and group exercise activities to model healthy lifestyle, healthcare visit reminder to increase engagement, and home visit to increase contact for new participants and those with poor participation and clinical outcome. In addition to that, PROLANIS participants undergo routine laboratory evaluation for metabolic control and renal function parameters every 6 months to foster early detection of disease complications. Other benefit is that while non-PROLANIS participants only received their medications for a maximum of one-two weeks before they have to come to the primary healthcare again, PROLANIS participants will receive their medications for one month so that they do not have to come to the primary healthcare more often, as the requirement to refill prescriptions too frequently has been identified as a barrier to medication adherence [8-11].

Despite comprehensive concept to increase engagement and utilization of health services, the implementation of PROLANIS is still suboptimal due to the barriers from both healthcare providers, such as shortage of healthcare workers and lack of budget and appropriate facilities as well as from the participants such as low awareness regarding the benefit of this program and low adherence to routinely follow the scheduled program [8, 9, 12]. Another barrier is health-seeking behavior of Indonesian people, where some still seek for traditional and/or alternative treatment from informal health providers that they believed can cure any diseases including diabetes [13]. Amidst the need to improve the utilization of PROLANIS, the coronavirus disease 2019 (COVID-19) pandemic occurred. During the pandemic, the healthcare systems around the world were overwhelmed, especially in the developing countries including Indonesia [14, 15]. As more attention is given towards combating the pandemic, management of T2D is overlooked [16]. Previous study in Indonesia reported that more than two-thirds of T2D patients experience difficulties in receiving treatments for their disease during pandemic [17].

Social distancing and mandatory lockdown measures affected PROLANIS as well, leading to conversion of in-person activities to virtual through various platforms [18]. Indeed, it was shown that online coaching program can also improve the metabolic control of patients with T2D, with a few studies showing its cost-effectiveness compared to usual care [19, 20]. Even so, many parts of Indonesia are not ready for this, especially in rural areas, where awareness and knowledge of technology is limited [21]. On top of that, the shortage of healthcare workers in Indonesia was exaggerated during the pandemic, and remainder of the healthcare workers in primary healthcare are overwhelmed by the additional workload of case tracing [15, 22]. Thus, one might hypothesize that the implementation of PROLANIS during the COVID-19 pandemic is even less optimal, leading to worse clinical outcomes for the participants, i.e., deterioration of metabolic control and renal function parameters. But no such evaluation study has been conducted to this date to the best of our knowledge. We therefore conducted a pilot study with the aim of scrutinizing impact of the COVID-19 pandemic by evaluating the changes of metabolic control and renal function parameters of T2D patients who participate in PROLANIS before and during the COVID-19 pandemic in three rural sub district in Indonesia.

MATERIALS AND METHODS

This was a pilot study using secondary data from three PROLANIS groups located at three different rural areas in East Java Province, Indonesia. East Java Province is one of the provinces in Indonesia with the highest prevalence of T2D [5]. The first PROLANIS group included in this study was from Ngajum sub-district, one of the sub-districts in Malang District. The second PROLANIS group was from Balen sub-District, one of the sub-districts in Bojonegoro district. The third PROLANIS group was from Soko sub-District, one of the sub-districts in Tuban district. These three PROLANIS groups were selected because of the ease in obtaining necessary data.

The study population was all T2D patients irrespective of their age who joined one of the above-mentioned PROLANIS groups and attended the six-month-evaluation before the COVID-19 pandemic, i.e., in December 2019 (T0). Participants who left PROLANIS, deceased, or did not attend the 6-month-evaluation during the COVID-19 pandemic in June 2020 (T1) or in December 2020 (T2), were excluded from the analyses. This study was conducted according to the Declaration of Helsinki.

Minimum sample size for the pilot study was 10% of the sample size from the full study. The sample size for the full study was calculated using EpiInfo [23]. According to the latest data, there were 44.999 PROLANIS participants in East Java Province [8]. To obtain sufficient statistical power with 95% confidence levels and acceptable margin of error of 5%, the minimum sample size required for the full study was 381 participants. Therefore, the minimum sample size for this pilot study was 38 participants.

Evaluated parameters were metabolic control and renal function. Evaluated metabolic control parameters were body mass index (BMI), systolic blood pressure (SBP), diastolic blood pressure (DBP), hemoglobin A1C (HbA1C), total cholesterol (TC), high-density lipid (HDL), low-density lipid (LDL), and triglyceride (TG). Evaluated renal function parameters were serum creatinine, blood urea nitrogen (BUN), and urinary albumin. BMI and blood pressure were measured by the healthcare workers, while laboratory evaluation was done by designated third party laboratories. The evaluated parameters were presented using the unit of measurement as follows: BMI in kg/m^2, SBP and DBP in mmHg, HbA1C in %, and TC, HDL, LDL, TG, and BUN in mg/dl. Creatinine serum was converted into estimated glomerular filtration rate (eGFR) using CKD-EPI equation and presented in ml/min/1.73m2. Urinary albumin was re-categorized into normoalbuminuria (urinary albumin concentration <20 mg/L) or albuminuria (urinary albumin concentration ≥20 mg/L) [24]. The targeted cut-off level for good metabolic control was based on the latest Indonesian Society of Endocrinology (PERKENI) T2D guidelines, defined as follows: BMI between 18.5-23 kg/m2; SBP <140 mmHg; DBP <90 mmHg; HbA1C <7%; TC <200 mg/dl; TG <150 mg/dl; LDL <100 mg/dl; HDL >40 mg/dl for male and >50 mg/dl for female [25].

Data analyses were performed using IBM SPSS statistics for Windows version 25.0. (IBM Corp., Armonk, NY, USA). Kolmogorov-Smirnov test was used to evaluate the data distribution. Normally distributed data were presented in mean ± standard deviation (SD), skewed data were presented in median (interquartile range [IQR]), and nominal data were

Table 1. Baseline characteristics of study participants

Baseline characteristics	n=52
Age in years, mean±SD	60±8
Female sex, n (%)	40 (77)
Education level, n (%)	
No formal education	1 (2)
Elementary school	36 (69)
Junior high school	8 (15)
Senior high school	4 (8)
University	3 (6)
Duration of T2D, n (%)	
<5 years	29 (56)
5-10 years	16 (31)
>10 years	7 (13)
Familial history of T2D, n (%)	9 (17)
Hypertension comorbidities, n (%)	40 (77)
Type of medication received, n (%)	
1 OAD	19 (36)
2 OADs	33 (64)
Insulin	0 (0)
BMI in kg/m^2, median [IQR]	23.6 [21.9-26.1]
SBP in mmHg, median [IQR]	130 [120-140]
DBP in mmHg, median [IQR]	80 [70-80]
HbA1C in %, mean±SD	7.96±1.76
TC in mg/dl, mean±SD	215±36
TG in mg/dl, median [IQR]	169 [122-238]
LDL in mg/dl, mean±SD	131±33
HDL in mg/dl, mean±SD	51.6±11.7
BUN in mg/dl, median [IQR]	21.6 [14.4-27.4]
eGFR in ml/min/1.73 m^2, mean±SD	80.2±20.0

presented in frequency (percentage). Paired t-test and non-parametric Wilcoxon signed-rank test were used for statistical analyses, depending on the data distribution. p-value <0.05 was considered statistically significant.

RESULTS

There were 87 PROLANIS participants that presented at T0. However, 32 PROLANIS participants did not attend the 6-month evaluation and three PROLANIS participants died during the study period, leaving only 52 participants to be

Table 2. Six-month routine follow-up evaluation

Parameter	n=52		
	T0 (December 2019)	T1 (June 2020)	T2 (December 2020)
BMI in kg/m^2, median [IQR]	23.6 [21.9- 26.1]	23.8 [22.0-26.4] **p=0.043**	23.7 [22.1-25.9] p=0.230
SBP in mmHg, median [IQR]	130 [120-140]	134 [120-143] **p=0.001**	136 [121-143] p=0.065
DBP in mmHg, median [IQR]	80 [70-80]	80 [73-90] **p=0.017**	80 [70-87] p=0.457
HbA1C in %, mean±SD	7.96±1.76	8.16±1.91 p=0.383	8.35±1.99 p=0.132
TC in mg/dl, mean±SD	215±36	227±39 **p=0.005**	208±41 p=0.326
TG in mg/dl, median [IQR]	169 [122-238]	180 [129-250] **p=0.019**	167 [120-227] p=0.881
LDL in mg/dl, mean±SD	131±33	135±33 p=0.272	124±35 p=0.305
HDL in mg/dl, mean±SD	51.6±11.7	54.7±11.1 **p=0.044**	43.6±9.3 **p<0.001**
BUN, mg/dl, median [IQR]	21.6 [14.4-27.4]	24.7 [12.9-30.6] **p=0.026**	24.5 [14.5-32.0] **p=0.004**
eGFR in ml/min/ 1.73 m^2, mean±SD	80.2±20.0	75.4±19.5 **p=0.008**	75.2±23.3 p=0.073

included in the analyses. The mean age of the participants was 60 ± 8 years old, and 77% of them were female. More than half of the participants had T2D less than five years ago. Detailed baseline characteristics of the study participants and the evaluated parameters at T0 are presented in **Table 1**.

BMI, SBP, DBP, TC, and TG significantly deteriorated at T1. In contrast, HDL showed a significant improvement, whereas HbA1C and LDL did not significantly change at T1. At T2, none of the evaluated metabolic control parameters significantly differs from the value at T0 except for HDL, where it was significantly worsened (p<0.001) (**Table 2**). Looking at the trends, BMI, DBP, and all lipid profiles except for HDL worsened at T1 and improved at T2.

HbA1C, on the other hand, showed a worsening trend from the beginning, albeit statistically insignificant (**Figure 1**).

The number of PROLANIS participants who achieved the target levels for HbA1C and TC increased during the study

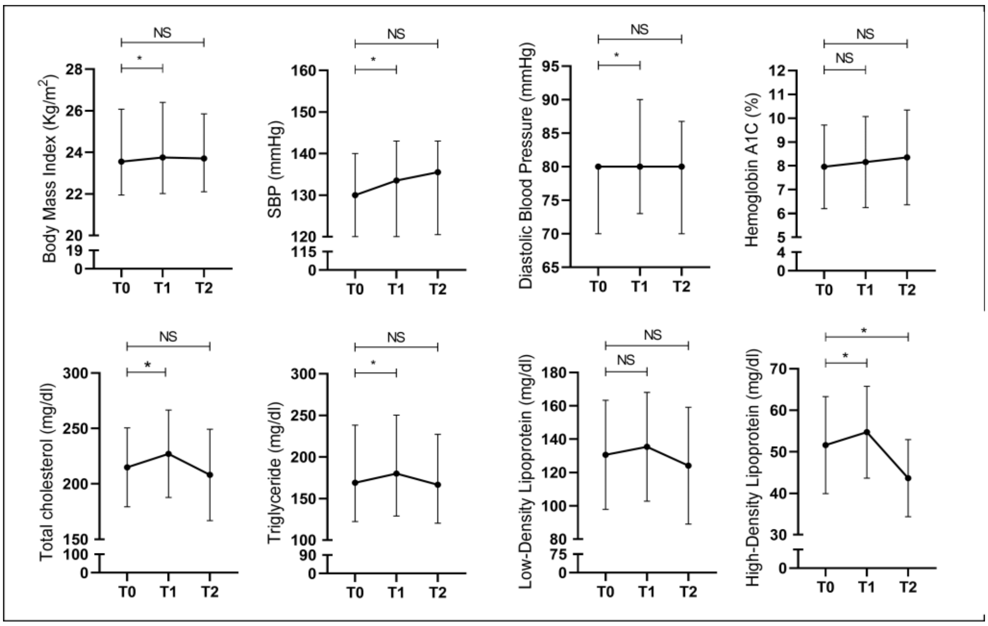

Figure 1. Routine six-month-evaluation of metabolic control parameters (Source: Authors' own elaboration)

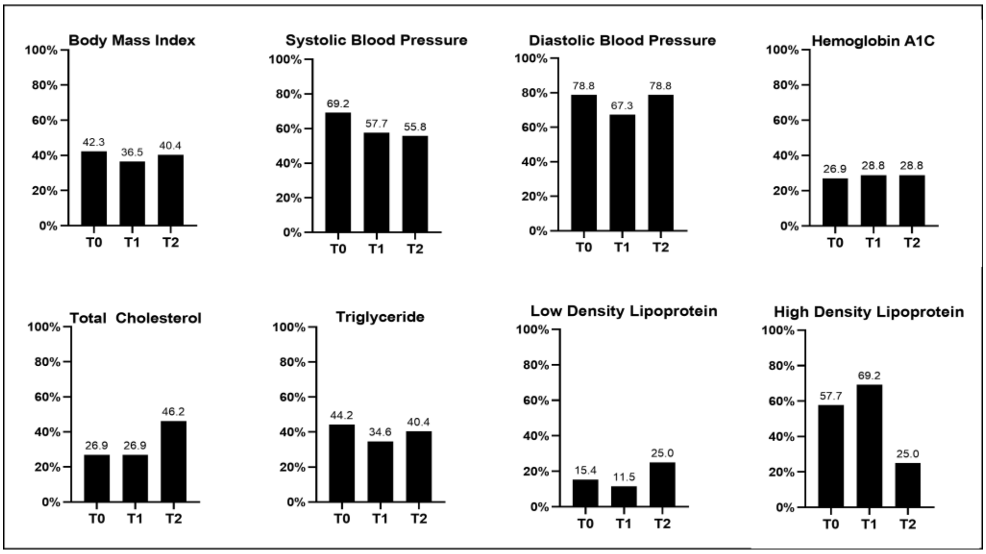

Figure 2. Percentage of study participants that had good metabolic control during routine six-month-evaluation (Source: Authors' own elaboration)

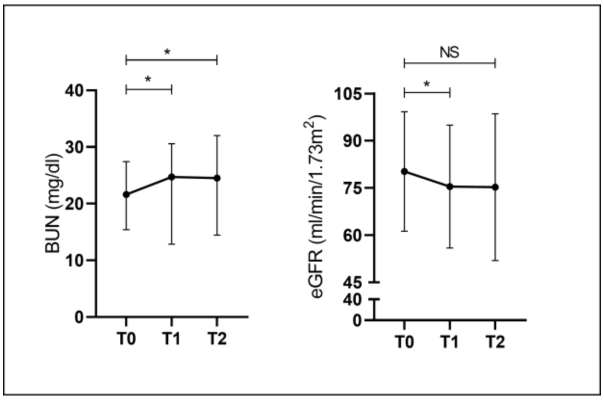

Figure 3. Routine six-month-evaluation of renal function parameters (Source: Authors' own elaboration)

period, and the opposite trend was found in SBP parameters. For BMI, DBP, TG, and LDL, the same trend was observed, i.e., decreased at T1 but increased at T2. Remarkable finding was shown in HDL, where the number of participants who achieved the targeted levels increased at T1 but markedly decreased at T2 (**Figure 2**).

For renal function parameters, both BUN and eGFR levels were significantly deteriorated at T1. At T2, only the BUN parameter still significantly differs from T0 (p=0.004) (**Table 2**).

The changes of BUN and eGFR are presented in **Figure 3**. For urinary albumin, 75% of PROLANIS participants had albuminuria at T0. The percentage increased to 84.6% at T1, and then returned to 75% at T2.

DISCUSSION

In this study, we evaluated the changes in metabolic control and renal function parameters of T2D patients in rural areas who enrolled in PROLANIS before and during the COVID-19 pandemic. We found that from eight evaluated metabolic parameters, five of them (BMI, SBP, DBP, TC, and TG) were significantly worsened in the beginning of the COVID-19 pandemic (T1) and improved in the later period of the COVID-19 pandemic (T2). HbA1C level continuously worsened during the COVID-19 pandemic, albeit the changes were not statistically significant. We also found that the renal function parameters worsened, especially in the beginning of the pandemic.

One of the main principles employed by PROLANIS to improve diabetes control is to increase patient contact that has been identified to make a significant impact in chronic disease management programs [7]. In this study settings, PROLANIS activities were routinely done before the COVID-19 pandemic. However, when the pandemic hit, all routine PROLANIS activities except for medical consultation were temporarily halted due to lockdown and physical distancing as the public health measures implemented by the Indonesian government [26, 27]. In Indonesia, the strict lockdown took place until after T1, and it was eased afterwards. In our study population, PROLANIS activities were halted until after T1 before gradually starting again when it was deemed safe. This can be translated that changes at T1 is a net impact of strict lockdown and suspend of PROLANIS activities, whereas changes at T2 is a net impact of lenient restriction and resume of PROLANIS activities.

There are a number of studies that evaluated the impact of COVID-19 pandemic on the outcomes of patients with T2D [28]; however, the findings were inconsistent. Some of our findings were in line with previous studies, and some were in contrast. It was reported that BMI, HbA1C, and TG level significantly worsened during the COVID-19 pandemic, whereas LDL and HDL were similar compared to before the COVID-19 pandemic [29]. Another study [30] that evaluated the outcomes among T2D patients in Italy reported that BMI and HDL worsened, TC and LDL improved, whereas HbA1C and TG showed no significant changes [30]. A multicenter study from Turkey reported that TG and LDL parameters were worsened during the COVID-19 pandemic, whereas HbA1C and HDL were not affected [31]. The inconsistent findings might be explained by the differences in the country, where the study was performed, and also the time period, where the studies were conducted. During the COVID-19 pandemic, the disruption towards health services in each country varies in magnitude and duration [32]. Furthermore, the duration and the stringency of public health restriction also varies between countries [33].

One possible contributing factor to poor glycemic control and lipid profiles in our study population is the decline in physical activity when the lockdown policy takes places [34-37]. Even before the COVID-19 pandemic, Indonesian people lack physical activities as reflected by the daily steps count, where Indonesian people recorded the least steps compared to people from other countries [38]. COVID-19 pandemic further exacerbated this issue [39]. Compared to healthy individuals, T2D spent less time and effort to exercise during the pandemic [40]. This is especially true in the study region, where group activities that foster a sense of community such as the peer-club exercise has been identified to promote engagement and motivation to pursue healthy behaviors [41]. When this activity is halted, worsening of glycemic control and lipid profiles can be expected.

Dietary habits may also play an important role in glycemic control regardless of the physical activity level [42]. Even before the pandemic, it was noted that Indonesians spent 16.9% of their household spendings on ready-to-eat food [43], and this type of food is known to be positively associated with T2D [44]. During the lockdown period, unfavorable changes of dietary pattern has been reported in various countries [45, 46], including Indonesia [47]. Despite increased awareness about and adherence to good nutrition and health behaviors in Indonesia, the impact is transitory as affordability became a challenge [48]. While specific study on T2D patients is still unavailable in Indonesia, such studies in other countries have shown that those with T2D consumed more snack and sugary food during the lockdown [35, 40, 42, 49]. Thus, it can be argued that unhealthy eating habits contributed to worsening of outcomes in the study participants. Consumption of unhealthy food, in turn, has been identified as one of the coping mechanisms to elevated stress levels. Such phenomenon was found among T2D patients, which was associated with increased worry due to overwhelming information over higher risk of more severe COVID-19 symptoms and mortality [50, 51].

This study also found that renal function parameters significantly deteriorated at T1 and started to improve at T2. Indeed, studies have shown that renal function is tightly associated with glycemic control [52, 53]. On top of that, unfavorable lipid profiles may also contribute to the renal function deterioration [54]. In this study, while the HbA1C level continued to deteriorate throughout the study period, the lipid profiles (TC, TG, and LDL) worsened only at T1 and improved at T2. We hypothesized that the changes of eGFR is due to the net effect from both glycemic control and lipid profiles combined.

One method to maintain contact with healthcare providers that gained popularity during the pandemic was telemedicine. While its use has been shown to aid the management of T2D amidst the COVID-19 pandemic most people in Indonesia are still not familiar with telemedicine . Even during the COVID-19 pandemic, the majority of T2D patients in Indonesia did not use telemedicine, as they still prefer to have a face-to-face interaction with the doctor [17, 55, 56]. For PROLANIS, the use of telemedicine as a replacement for home visit and medical consultation were also deemed inefficient, as the majority of PROLANIS participants were elderly who are not familiar with technology [26, 27, 57]. Thus, utilization of telemedicine has to account for the need to increase accessibility and technology literacy for all populations.

There are several important limitations in the current study. We only included 52 patients from three different PROLANIS groups from three different rural areas in one province. Data from 2016 showed that the registered PROLANIS participants in the province, where this study was conducted was 44.999 participants, and PROLANIS participants nationwide was 260.364 participants [8]. Additionally, the level of COVID-19 exposure differs per region, and each region has its own health policies including the continuation of PROLANIS activities during the COVID-19 pandemic [58]. Therefore, generalization of our study findings regarding the impact of the COVID-19 pandemic on PROLANIS outcomes should be done cautiously. Next to that, although we had sufficient samples for the analyses based on the sample size calculation, this study was prone to selection bias since there were 37% PROLANIS participants in our study population that were excluded because they did not attend the 6-month-evaluation. Furthermore, we also did not evaluate the medication adherence nor the daily food intake of the participants because this was a retrospective study, and such data are not available in PROLANIS report. Lastly, we did not have data on the history of COVID-19 infection of PROLANIS participants. Nevertheless, this pilot study is the first to present preliminary information regarding the impact of the COVID-19 pandemic on PROLANIS outcomes among patients with T2D.

CONCLUSIONS

This pilot evaluation study shows that during the COVID-19 pandemic, especially in the beginning when lockdown policy takes places, the metabolic control and renal function parameters of PROLANIS participants in our study population deteriorated. These findings support the hypothesis that the implementation of PROLANIS during the COVID-19 pandemic is not optimal and lead to worse clinical outcomes. The results of our study indicate the need for a large-scale study to obtain more accurate impression of the impact of the COVID-19 pandemic on the clinical outcomes of T2D who joined PROLANIS.

Author contributions: SS: designed study, analyzed & interpret data, & drafted manuscript; **RR, MRA, & IS:** acquired data; **DN & ANK:** substantially revised manuscript; **FI:** designed study; **AD:** interpreted data & drafted manuscript; **MRR:** interpreted data & substantially revised manuscript; & **FFA:** designed study & substantially revised manuscript. All authors have agreed with the results and conclusions.

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Ethical statement: Authors stated that the study was approved by the Ethics Committee of Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia (approval number: 51/EC/KEPK/FKUA/2022 & approval date: 21 February 2022). The need to obtain the informed consents were waived by the ethics committee because this study used secondary data from PROLANIS group reports.

Declaration of interest: No conflict of interest is declared by authors.

Data sharing statement: Data supporting the findings and conclusions are available upon request from the corresponding author.

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