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Correlation Between Patient's Adherence and Glycemic Control in Children with Type 1 Diabetes During the COVID-19 Pandemic: A Cross-Sectional Study

Tip 1 Diyabetli Çocuklarda COVID-19 Pandemisi Sürecinde Hasta Uyumu ve Glisemik Kontrol Arasındaki Korelasyon: Kesitsel Bir Çalışma

^{ID} Nur ROCHMAH^{a,b}, ^{ID} Muhammad FAIZI^{a,b}, ^{ID} Yuni HISBIYAH^{a,b}, ^{ID} Jeny ROSANINGRUM^d,
^{ID} Bambang Subakti ZULKARNAIN^d, ^{ID} Anang ENDARYANTO^{a,b}, ^{ID} Soetjipto SOETJIPTO^{a,c}

^aPost Graduate Study, Faculty of Medicine, Universitas Airlangga, Surabaya, INDONESIA

^bFaculty of Medicine, Department of Child Health, Dr. Soetomo General Hospital, Universitas Airlangga, Surabaya, INDONESIA

^cDepartment of Medical Biochemistry, Faculty of Medicine, Universitas Airlangga, Surabaya, INDONESIA

^dDepartment of Clinical Pharmacy, Faculty of Pharmacy, Universitas Airlangga, Surabaya, INDONESIA

ABSTRACT Objective: The pandemic condition has hampered the health system because of government efforts to limit the spread of the coronavirus disease-2019 (COVID-19). These restrictions can affect the management of children with Type 1 diabetes mellitus (T1DM). We aimed to assess the correlation between patient adherence and glycemic control during early pandemic. **Material and Methods:** T1DM patients who regularly control to Pediatric Endocrine Outpatient Clinic of Dr. Soetomo Hospital, aged 4-18 years old and whose parents were willing to join this study were included. The sample was randomly collected by phone from July 2nd to 28th, 2020 (during early pandemic). We used the Diabetes Management Questionnaire (DMQ) (parents-reported method for children aged <13 years and self-reported for children aged >13 years). The correlation between variables was analyzed by using Pearson correlation test. **Results:** Thirty patients were included in our study (mean age: 11.70±3.49 years old; the mean DMQ score: 56.33±11.30). The mean (±SD) HbA1c level was 11.35 (1.95) %. The DMQ score consists of 4 sectors, including adherence to insulin use, diet management, physical activity and glycemic monitoring, the means of patient's score vs maximum score as followed (10.00 vs 10.00), (24.83 vs 40.00), (6.87 vs 15), (18.25 vs 35). Unfortunately, the correlation analysis on patient's adherence and HbA1c was not significant (r=-0.231; p=0.164). **Conclusion:** The correlation between patient's adherence and HbA1c was not significant. Meanwhile, adherence to insulin showed maximal score during early COVID-19 pandemic.

ÖZET Amaç: Pandemi koşullar hükümetin koronavirüs hastalığı-2019 (COVID-19)'un yayılımını sınırlamak için girdiği çabalar nedeniyle sağlık sistemini aksatmıştır. Bu kısıtlamalar Tip 1 diabetes mellituslu (T1DM) çocukların yönetimini etkileyebilir. Erken COVID-19 pandemisi sürecinde hasta uyumu ile glisemik kontrol, glikolize hemoglobin (HbA1c) arasındaki korelasyonu değerlendirmeyi amaçladık. **Gereç ve Yöntemler:** Yaşları 4 ile 18 arasında değişen, Dr. Soetomo Hastanesi Pediatrik Endokrin Polikliniğine düzenli olarak kontrole gelen ve ebeveynleri çalışmaya katılmaya istekli olan T1DM tanılı çocuklar çalışmaya alındı. Verileri 2-28 Temmuz 2020 tarihleri arasında (erken pandemi dönemi) telefon görüşmesi yoluyla rastgele örneklem yöntemi ile çevrimiçi olarak topladık. Diyabet Yönetimi Anketini (DYA) (<13 yaş çocuklar için ebeveyn tarafından, >13 yaş çocukların kendilerinin doldurduğu bir anket) kullandık. Değişkenler arasındaki korelasyon Pearson korelasyon testi kullanılarak incelendi. **Bulgular:** Çalışmamıza 30 hasta alındı (ortalama yaş 11,70±3,49 yıl; ortalama DYA skoru 56,33±11,30). DYA insülin kullanımına uyum, diyet yönetimi, fiziksel aktivite ve glisemik takip olmak üzere 4 bölümden oluşmaktadır. Hasta skorlarının ortalaması vs DYA anketinin her bölümünün maksimum skoru şöyleydi: 10,00 vs 10,00), (24,83 vs 40,00), (6,87 vs 15), (18,25 vs 35). Her DYA bölümünün HbA1c ile korelasyonu şöyleydi: sırasıyla (r=0,026; p=0,893), (r=-0,058; p=0,761), (r=-0,004; p=0,982), (r=0,007; p=0,973). Ortalama (±SS) HbA1c düzeyi 11,35 (1,95) % idi. Maalesef, hasta uyumu ile HbA1c'nin korelasyon analizi anlamlı değildi (r=0,231; p=0,164). **Sonuç:** Çalışmamızda hasta uyumu ile HbA1c arasındaki korelasyon anlamlı değildi. Bu arada, insüline uyum erken COVID-19 pandemisi döneminde maksimum skoru aldı.

Keywords: T1DM; COVID-19; children; adherence; glycemic control

Anahtar Kelimeler: T1DM; COVID-19; çocuklar; uyum; glisemik kontrol

Correspondence: Nur ROCHMAH

Post Graduate Study, Faculty of Medicine, Universitas Airlangga, Surabaya, INDONESIA/ENDONEZYA

E-mail: nur-r@fk.unair.ac.id



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The novel coronavirus disease-2019 (COVID-19) outbreak reported from Wuhan, China, was declared a pandemic by the World Health Organization Emergency Committee in March 2020.¹ This viruses spread to Indonesia since March 2nd 2020.² COVID-19 patients with diabetes are at high risk of experiencing adverse outcomes, including the need intensive care for hospitalization within high mortality.^{3,4} Study in children and adolescence showed that most cases were mild to middle clinical manifestation. However, during pandemic era, the risk of ketoacidosis in Type 1 diabetes mellitus (T1DM) children increased frequently due to poor glycemic control and delayed diagnosis.⁵

Optimal glycemic control in patients with T1DM can help avoiding complications and improving the quality of life. Glycated hemoglobin (HbA1c) is the standard parameter to assess glycemic control in patients with DM. Medication adherence is required to achieve adequate glycemic control.^{6,7} The adverse effects of the COVID-19 pandemic on the daily life (reduced physical activity, lack of social interaction, psychological stress, sleep disturbance, and unhealthy eating patterns) can affect the adherence of patients to medications.⁸ A study revealed a trend of poor glycemic control in children with T1DM during the COVID-19 pandemic, which is liable to increase their vulnerability to COVID-19 and its adverse outcomes.^{9,10} This, in turn, can worsen the burden on the healthcare systems, leading to poor outcomes. Patients with diabetes are prone to psychological health issues, and the COVID-19 pandemic can aggravate this phenomenon, hampering treatment adherence.¹⁰

In this study, we aim to assess the correlation of patient's adherence to all aspects of diabetes care (insulin use, diet management, physical activity, and glycemic control monitoring) and glycemic control (HbA1c) during early COVID-19 pandemic.

MATERIAL AND METHODS

ETHICS APPROVAL

This cross-sectional study was approved by the Ethics Committee and Research Development of Dr. Soetomo General Hospital, Surabaya (a tertiary care hospital) (ref. no: 1975/KEPK/IV/2020; dated: April 28,

2020). This research was conducted in accordance with the declaration of Helsinki. Informed consent was obtained for experimentation with human participants before the start of the study.

Study Setting

This study was conducted at the pediatric endocrinology outpatient clinic Dr. Soetomo Hospital, Indonesia, from July 2nd to 28th, 2020. This study involved children and adolescents diagnosed with T1DM (according to the International Society for Pediatric and Adolescent Diabetes guidelines) and their parents. The inclusion criteria were T1DM children aged 4-18 years old who regularly controlled to pediatric endocrine outpatient clinic Dr. Soetomo Hospital and willing to join the study. The exclusion criterion was T1DM patients who suffered from critical illness and needed hospitalization in intensive care unit. A total of 30 random patients joined this study. The research team offered the participant to join the study via social media group. Patients and parents who consented can put the name in the study list participants.

Data Collection

This research was conducted during the COVID-19 outbreak, which made it difficult to meet directly with the respondents. Therefore, all data were collected by phone. Prior to data collection, all respondents were explained regarding the study and the voluntary nature of participation. Researchers obtained the informed consent sheets filled out by the participants via short messages that were then printed out, signed, and sent back to research team. Subsequently, the respondents were contacted telephonically, and the demographic data of the patients and the responses to the Diabetes Management Questionnaire (DMQ) were obtained. For children aged <13 years, the questionnaire was filled out by their parents (parent-reported), and for children aged >13 years, the questionnaire was filled out by the patients themselves (child-reported). The time required for data collection was 20-25 min per participant. Prior to data collection, the validity and reliability of the research instrument were assessed with respondents who qualified the research inclusion criteria and answered all questions in DMQ. Furthermore, the validity and reliability test of the DMQ was assessed by

a statistician from Universitas Airlangga, and it has been reported to be valid.

The Personal Characteristic Form

The personal form consisted of the demographic details of the children and the parents such as age, sex, weight, height, ethnicity, educational level and occupation of parents, and family income. Illness-related data such as age at diagnosis of T1DM, duration of illness, type and dosage of insulin used, and HbA1c levels were also noted.

Diabetes Management Questionnaire

Patient's adherence was assessed using the Indonesian version of the DMQ.¹¹ The items in the DMQ are based on a 5-point Likert scale (1=almost never, 2=sometimes, 3=half of the time, 4=most of the time, and 5=almost often) and then each item scale was scored 0 to 4, with a higher score reflecting greater adherence to diabetes management. Six of the 20 question items were scored inversely. The DMQ is used to assess the adherence of patients with T1DM to the various aspects of diabetes management [adherence to insulin use (2 items), adherence to diet management (8 items), adherence to physical activity (3 items), and adherence to monitoring of glycemic control (7 items)]. The average of all items was multiplied by 25 to convert to a scale of 0-100 for interpretation. A higher total DMQ score indicates greater adherence to diabetes management.

EVALUATION OF DATA

Continuous variables are expressed as mean±standard deviation or as median (range) where appropriate, and categorical variables are expressed as frequency (percentage). Normality of distribution of variables was assessed using the Shapiro-Wilk test. The correlation between patient adherence and glycemic control was assessed using the Pearson correlation test. All statistical analyses were performed using SPSS (IBM) version 17.0. p values <0.05 were considered indicative of statistical significance.

RESULTS

A total of 30 children and adolescents with T1DM were included in this study (18 males and 12 females; mean age: 11.70±3.49 years), and the mean duration

of illness was 4.25±2.57 years. The majority of the children were of Javanese ethnicity and most participants had good nutritional status. The parents of most patients had received 9-12 years of education and were working in the private sector. All participants were prescribed a basal-bolus regime using a combination of short- and long-acting insulin, and most patients regularly performed physical activity (≥3 times a week). Most patients monitored their HbA1c levels 3-4 times/year. However, the last HbA1c monitoring showed poor results, and the HbA1c level of most participants was above the recommended level. The mean of the previous HbA1c before the COVID-19 infection was 9.2%, lower than this study.¹² The baseline clinical characteristics of the patients with T1DM are presented in Table 1.

Figure 1 and Table 2 showed the mean or median score of each aspect of DMQ. Adherence to insulin use showed the best score among all sectors, and adherence to physical activity was the worst among all sectors. The mean total DMQ score was (56.33±11.30). The correlation between each sector of DMQ score and HbA1c were as follows (r=0.026; p=0.893), (r=-0.058; p=0.761), (r=-0.004; p=0.982), (r=0.007; p=0.973), respectively. The adherence of insulin use gain the maximum score in our study.

DISCUSSION

Our study has found that correlation between patient's adherence and glycemic control was not significant. This result is consistent with the study from Cramer that showed adherence of medication have no correlations with glycemic control.¹³ In contrast, some studies revealed a negative correlation between adherence and glycemic control, as adherence increases, HbA1c values decrease.^{14,15}

In this study, adherence of insulin use is excellent (based on DMQ score on the insulin aspect, see Figure 1). However, adherence to diabetes management in other aspects was still lacking. Studies showed poor insulin adherence correlate to poor HbA1c, meanwhile the insulin adherence study in T1DM during COVID-19 pandemic is very limited.¹⁶⁻¹⁸

This study reported that there was poor adherence of dietary management. This result is consistent

TABLE 1: Demographic characteristics of the study population (n=30).

Characteristic	n (%)
Weight*	33.49±12.20
Height*	136.17±17.77
BMI**	16.90 (30.80-13.40)
	38.50 (98-1)***
Age at onset of T1DM (years)*	7.15±3.16
Educational background of parents	
<9 years	4 (13.30)
9-12 years	21 (70)
>12 years	5 (16.60)
Occupational background of parents	
Government employee	2 (6.70)
Private sector employee	13 (43.30)
Self-employed	4 (13.30)
Others	8 (26.70)
Unemployed	3 (10)
Ethnicity	
Chinese	1 (3.30)
Javanese	25 (83.30)
Maduranese	4 (13.40)
Associated illness or complication	
Asthma	1 (3.30)
Cataract	1 (3.30)
Hepatomegaly	1 (3.30)
Physical activity	
Mild activity min 2 hours/week, any time	8 (26.70)
Mild activity 1-2 times/week, regularly	10 (33.30)
Regular activity ≥3 times/week	12 (40)
HbA1c monitoring	
1-2 times/year	2 (6.70)
2-3 times/year	5 (16.70)
3-4 times/year	22 (73.30)
>4 times/year	1 (3.30)
HbA1c*	11.35±1.95
<7.5%****	1 (3.30)
≥7.5%	29 (96.70)

*Mean±SD; **Median (minimum-maximum); ***BMI category (in percentile) based on Centers for Disease Control and Prevention; ****HbA1c target for children with T1DM based on the 2019 recommendations of the American Diabetes Association; SD: Standard deviation; T1DM: Type 1 diabetes mellitus; BMI: Body mass index; HbA1c: Glycated hemoglobin.

with the other researches which reported bad adherence of dietary management correlate to poor HbA1c.^{10,17} Children tend to have poor diet management during lockdown at home.¹⁸ Good dietary management correlates to optimal HbA1c.^{19,20}

The adherence of physical activity in this study was poor. The study reported that children and adolescents have much longer screen time and limits their physical activity during pandemic, which in turn may lead to poor glycemic control.^{10,21} The physical activity improves insulin sensitivity so the HbA1c will be optimal.²² This result is consistent with the study from Beraki et al. who stated that children with more physical activity have better HbA1c.²³ In addition, a recent study of Carral et al. said that patients with intense physical activity (more than 150 min/week) can significantly reduce of HbA1c levels.²⁴

This study used DMQ to measure the level of patient adherence. However, there are limitations to its use for people with low language proficiency, and the results may be affected by memory bias if the measurement period is very long. Distraction and lack of concentration can also result in inaccurate reporting of adherence.²⁵ A key limitation of this study was that the data were collected online by phone because of the COVID-19 outbreak. The effect of connectivity problems and miscommunication due to lack of understand-

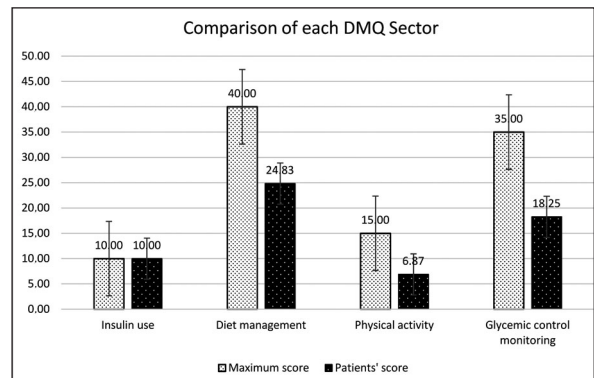


FIGURE 1: Comparison of patient's score with maximum score of each DMQ sector.

TABLE 2: The mean of DMQ sections.

DMQ category	Mean±SD or median (minimum-maximum)
Adherence to insulin use	10.00 (5.00-10.00)
Adherence to diet management	24.83±7.12
Adherence to physical activity	6.87 (0.00-37.5)
Adherence to glycemic monitoring	18.25±5.59
Total DMQ score	56.33±11.30

DMQ: Diabetes Management Questionnaire; SD: Standard deviation; HbA1c: Glycated hemoglobin.

ing or misinterpretation of the questionnaire items cannot be ruled out. Another limitation is that the number of T1DM cases in this study is limited than Caucasians as mentioned by other studies, although the study was conducted at a referral hospital in East Indonesia.^{12,26-32}

CONCLUSION

In this study, the correlation between patient's adherence and glycemic control was not significant. However, the trend of this study showed that the diet management, physical activity and glycemic control monitoring contribute to the result of poor glycemic control.

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connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Nur Rochmah; **Design:** Nur Rochmah, Muhammad Faizi, Yuni Hisbiyah; **Control/Supervision:** Soetjipto Soetjipto, Anang Endaryanto; **Data Collection and/or Processing:** Jeny Rosaningrum; **Analysis and/or Interpretation:** Jeny Rosaningrum, Bambang Subakti Zulkarnain; **Literature Review:** Jeny Rosaningrum, Bambang Subakti Zulkarnain; **Writing the Article:** Yuni Hisbiyah, Jeny Rosaningrum, Nur Rochmah; **Critical Review:** Nur Rochmah, Soetjipto Soetjipto, Muhammad Faizi; **References and Fundings:** Anang Endaryanto, Soetjipto Soetjipto; **Materials:** Yuni Hisbiyah, Nur Rochmah.

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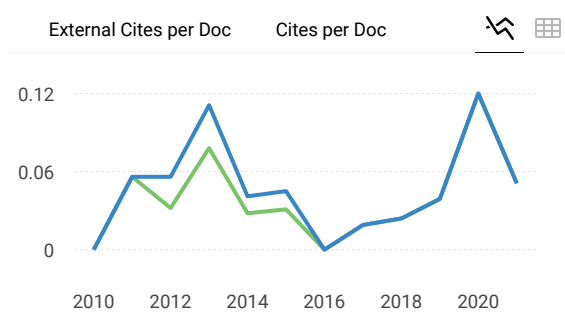
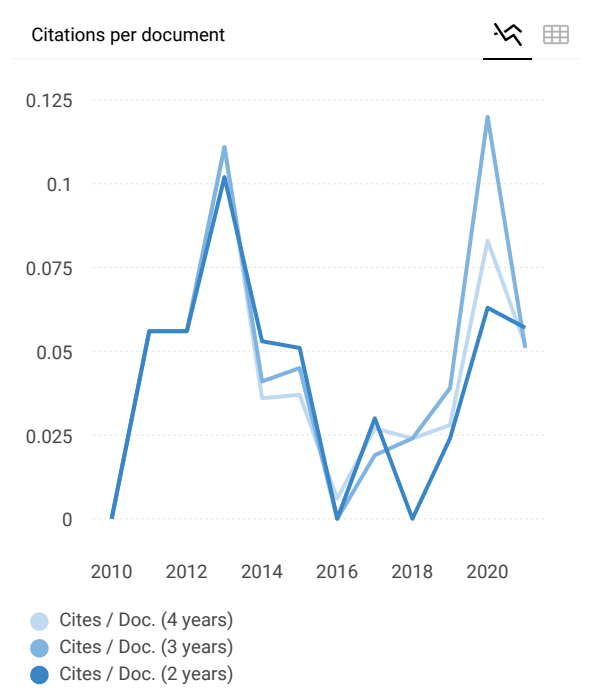
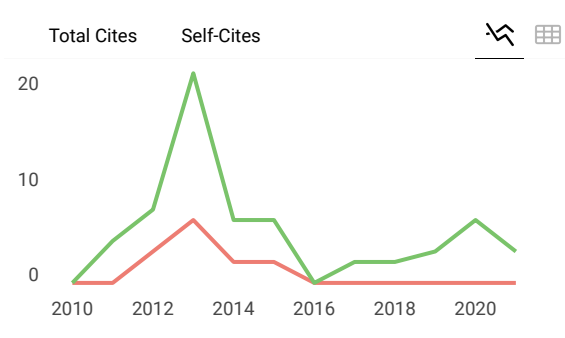
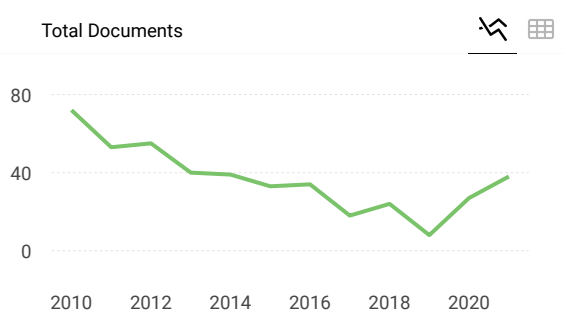
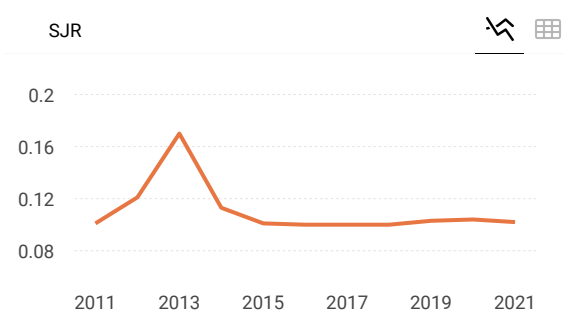
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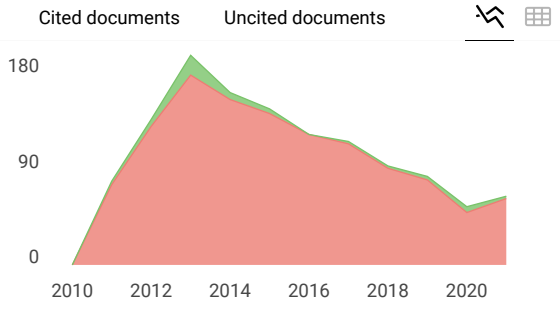
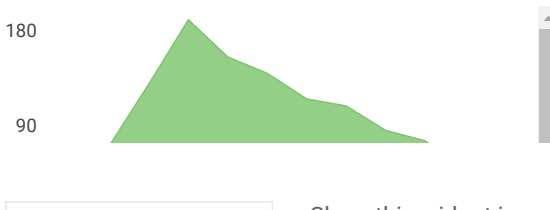
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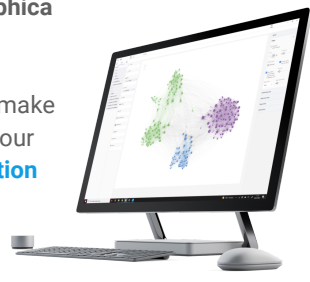
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