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Has COVID-19 lockdown improved glycaemic control in pediatric patients with type 1 diabetes? An analysis of continuous glucose monitoring metrics

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Aims: Our observational study aimed to evaluate the impact of the lockdown period due to 2019 Coronavirus disease pandemic on glycaemic control in a cohort of paediatric patients with type 1 diabetes (T1D).

Methods: Eighty-five patients with T1D aged 5–18 years using continuous glucose monitoring (CGM) systems were enrolled. Demographic and clinical data, including glucose metrics generated by CGM-specific web-based cloud platforms, were collected in three different periods (pre-lockdown phase, lockdown phase, and post-lockdown phase) of 90 days each and were statistically analysed.

Results: During the lockdown period, a clear improvement in almost all CGM metrics (time in range, time above range, coefficient of variation, and glucose management indicator) was observed in our study population, regardless of age and insulin type treatment. In the months following lockdown, maintaining satisfactory diabetes outcomes was confirmed only in younger patients (aged 5–9 years) and in those individuals on hybrid closed loop therapy.

Conclusions: The increasing use of innovative technological devices together with data sharing systems and interaction with multidisciplinary diabetes team through telemedicine allowed paediatric patients with T1D to improve glucose metrics during the lockdown period. However, our findings showed that the achievement of better glycaemic control was transient for most patients.

1. Introduction

Since the beginning of the last year, global health authorities have been facing a deadly foe called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As of 30 March 2021, more than 128,000,000 people have been infected and more than 2,800,000 deaths have been reported.
We performed an observational, retrospective study that involved reviewing the electronic medical records of children and adolescents with T1D followed-up at the Paediatric Diabetes Centre at the University Hospital of Messina. The study was conducted in accordance with the Helsinki Declaration, good clinical practice, and all applicable laws and regulations.

Inclusion criteria were as follows: age between 5 and 18 years, duration of disease ≥ 1 year, current insulin type treatment >3 months, daily sensor use >75%, informed consent from patients and their parents to access the CGM data remotely. Exclusion criteria were changes in insulin type treatment, use of corticosteroids or drugs known to have a relevant impact on glycaemic control, and hospitalizations during the entire study period. We collected clinical data in three different periods of 90 days each: Period 1 (pre-lockdown phase) from December 10, 2019 to March 8, 2020, Period 2 (lockdown phase) from March 9 to June 6, 2020, and Period 3 (post-lockdown phase) from June 7 to September 4, 2020.

Demographic and clinical data (e.g. duration of diabetes, auxological parameters, presence of other autoimmune diseases, type of insulin treatment, brand and model of glucose sensor, last year glycated haemoglobin mean value) were collected from data recorded in the computerized clinical registry. Anthropometric parameters were missing from the lockdown phase (Period 2) due to the closure of hospital outpatient services. Glucose data were extracted from the ambulatory glucose profile generated by CGM-specific web-based cloud platforms. The following CGM metrics were considered: time in range (TIR – time expressed in percentage in the ideal range of glucose between 70 and 180 mg/dl), time above range (TAR - time expressed in percentage above 180 mg/dl), time below range (TBR – time expressed in percentage below 70 mg/dl), coefficient of variation expressed in percentage (%CV), and glucose management indicator (GMI).

To evaluate the role of age on glycaemic control during the study period, we considered three age classes: pre-pubertal age (5–9 years) that is usually characterized by close parental care of diabetes, pubertal age (10–14 years), and adolescence (15–18 years) that is a well-known period of life at high-risk of poor clinical outcomes [12]. To assess the potential relationship between insulin treatment type and glucose levels, we also divided patients into three groups: those who practiced multiple daily injections of insulin (MDI group), those who used insulin pumps with non-automated delivery systems (CSII group), and those who used hybrid closed loop insulin pumps (HCL group).

3. Material and methods

We performed an observational, retrospective study that involved reviewing the electronic medical records of children and adolescents with T1D followed-up at the Paediatric Diabetes Centre at the University Hospital of Messina. The study was conducted in accordance with the Helsinki Declaration, good clinical practice, and all applicable laws and regulations.

The numerical data were expressed as mean ± standard deviations, and median with interquartile ranges. Categorical variables were described as absolute frequencies and percentages. The non-parametric approach was used since most numerical variables were not normally distributed, as verified by the Kolmogorov-Smirnov test.

To evaluate variation of the auxological parameters over time, the Wilcoxon test was applied. The same test was applied to perform all two-by-two comparisons between three time points (pre-lockdown phase, during lockdown and post-lockdown phase) for glycometabolic parameters (TIR, TAR, TBR, %CV, and GMI). For these multiple comparisons, we applied Bonferroni’s correction, for which the significance alpha level 0.050 was divided by the number of possible comparisons (equal to three); thus, the “adjusted” significance level for this analysis is equal to 0.050/3 = 0.017.
This analysis was performed both for all casuistry and stratifying for age classes (5–9 years, 10–14 years and 15–18 years) and for insulin treatment type (MDI, CSII, and HCL therapy).

A chi-square test was applied to evaluate association between categorical variables such as gender, age classes, and insulin treatment type.

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 22 (Armonk, NY, IBM Corp.). A p-value < 0.05 was considered statistically significant.

4. Results

Our study population consisted of a cohort of 85 patients with an equal distribution among males and females. Mean age of the study participants was 11.5 ± 3.7 years. Mean duration of diabetes was 5.2 ± 3.3 years. Of the 85 patients, 22.4% were on MDI therapy, 29.4% used HCL systems, and the remaining 48.2% belonged to the CSII group. Study participants had a mean HbA1c value of 6.9 ± 0.8% (52.4 ± 8.6 mmol/mol) in the year preceding the start of the study. Of the 85 patients, 12 (14.1%) had at least one other autoimmune disease. Details of demographic and clinical data of our study population are described in Table 1.

Fig. 1 and Table 2 summarize the main findings during the three periods analysed. No significant changes were found in anthropometric parameters between Period 1 and Period 3. There was a significant increase of TIR at Period 2 and Period 3 compared to Period 1 (p < 0.001 both). Similarly, across the different time points, there was a significant reduction of TAR (p < 0.001 both) and GMI (p < 0.001 and p = 0.015). %CV was significantly lower in Period 2 than in Period 1 (p = 0.003), whereas %CV in Period 3 significantly increased compared with Period 2 (p < 0.001). TBR remained unchanged between Period 1 and Period 2, whereas TBR in Period 3 was significantly higher than in Period 2 (p = 0.004).

When dividing the study population according to age, we found that TIR in Period 2 was higher than TIR in Period 1 in the three groups (p < 0.001 for 5–9 years, p = 0.004 for 10–14 years, p = 0.001 for 15–18 years), but this improvement was confirmed only in younger patients (aged 5–9 years) in Period 3 (p = 0.005). TAR was significantly lower in Period 2 compared to Period 1 in all the age groups (p < 0.001 for 5–9 years, p = 0.003 for 10–14 years, p = 0.007 for 15–18 years). This finding was also seen both in younger patients and in those aged 10–14 years (p = 0.001 and p = 0.007, respectively) by comparing Period 3 with Period 1, whereas no changes were seen in adolescents. In Period 2, GMI levels significantly decreased in patients aged 5–9 years and in those aged 10–14 years (p = 0.008 and p = 0.016, respectively) in comparison with Period 1. No significant differences in the other metrics of glucose control were observed (Table 9). Interestingly, TBR levels remained stable across the different periods of study in all the age classes.

When considering different insulin treatment types used by the study participants, we found that patients belonging to the HCL group significantly improved glucose metrics, particularly in terms of TIR (p < 0.001), TAR (p = 0.001), and %CV (p = 0.005) in Period 2 compared to Period 1. Better TIR and TAR levels were also observed in Period 3 in comparison with Period 1 (p < 0.001 both). By comparing Period 1 and Period 2, in the CSII group, TIR, TAR, and GMI

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Table 1 – Descriptive statistics for categorical (percentages) and numerical (mean ± SDS and interquartile ranges) variables of 85 patients included in study.

| Variables                      | Percentages and mean ± SDS | Median (IQR) |
|--------------------------------|----------------------------|--------------|
| Age (years)                    | 11.5 ± 3.7                 | 12 (9; 14.5) |
| Age classes                    |                            |              |
| 5–9 years                      | 27 (31.8%)                 |              |
| 10–14 years                    | 37 (43.5%)                 |              |
| 15–18 years                    | 21 (24.7%)                 |              |
| Gender                         |                            |              |
| Male                           | 43 (51.6%)                 |              |
| Female                         | 42 (49.4%)                 |              |
| Age at diagnosis (years)       | 6.4 ± 3.5                  | 6.2 (3.4; 8.9) |
| Duration of diabetes (years)   | 5.2 ± 3.3                  | 4.8 (2.8; 7.6) |
| Weight Z score                 | 0.25 ± 0.79                | 0.20 (-0.10; 0.80) |
| BMI Z score                    | 0.39 ± 0.81                | 0.39 (-0.19; 0.94) |
| Last year mean value HbA1c (%) | 6.9 ± 0.8                  | 6.8 (6.4; 7.3) |
| Last year mean value HbA1c (mmol/mol) | 52.4 ± 8.6                      | 51.2 (47; 56.2) |
| Insulin treatment type         |                            |              |
| Multiple daily injections      | 19 (22.4%)                 |              |
| Sensor augmented pump          | 25 (29.4%)                 |              |
| Hybrid closed loop             | 41 (48.2%)                 |              |
| Autoimmune comorbidities       |                            |              |
| Hashimoto’s thyroiditis        | 6 (7.0%)                   |              |
| Celiac disease                 | 4 (4.7%)                   |              |
| Hashimoto’s thyroiditis + celiac disease | 1 (1.2%)                  |              |
| Celiac disease + autoimmune hepatitis | 1 (1.2%)                |              |
| None                           | 73 (85.5%)                 |              |
significantly improved in Period 2 (p = 0.002 for TIR, p = 0.002 for TAR, p = 0.003 for GMI), and patients on MDI therapy also showed better TIR and TAR levels (p = 0.004 both). Interestingly, in patients on MDI or CSII therapy, none of the metrics of glucose control significantly changed between Period 1 and Period 3 (Table 4).

5. Discussion

The COVID-19 pandemic has dramatically changed the approach to patients with chronic diseases. Telemedicine services have been strengthened to minimize hospitalizations, outpatient visits, and, consequently, SARS-CoV-2 exposure risk...
### Table 3 – Changes in CGM metrics from pre-lockdown phase to the following months according to age of study participants.

| Variables | 5–9 years | 10–14 years | 15–18 years |
|-----------|-----------|-------------|-------------|
|           | Period 1 (Pre-lockdown) | Period 2 (Lockdown period) | p |
|           | Period 1 (Pre-lockdown) | Period 2 (Lockdown period) | p |
|           | Period 1 (Pre-lockdown) | Period 2 (Lockdown period) | p |
| TIR       | 59.7 ± 13.4 | 64.3 ± 13.3 | <0.001 |
| TAR       | 35.9 ± 14.4 | 31.4 ± 14.9 | <0.001 |
| TBR       | 4.2 ± 3.1 | 4.3 ± 3.1 | 0.423 |
| CV        | 38.2 ± 5 | 37.9 ± 5.2 | 0.275 |
| GMI (%)   | 7.2 ± 0.6 | 6.9 ± 0.6 | 0.008 |
| Period 1 (Pre-lockdown) | Period 2 (Lockdown period) | p |
| TIR       | 63.5 ± 11.2 | 66.7 ± 11 | 0.004 |
| TAR       | 33.1 ± 11.8 | 29.6 ± 11 | 0.003 |
| TBR       | 3.4 ± 3.3 | 3.5 ± 3.3 | 0.893 |
| CV        | 36.7 ± 5.4 | 35.8 ± 4.9 | 0.169 |
| GMI (%)   | 7.2 ± 0.6 | 7.1 ± 0.6 | 0.016 |
| Period 1 (Pre-lockdown) | Period 2 (Lockdown period) | p |
| TIR       | 64.9 ± 15.2 | 69.4 ± 15.4 | 0.001 |
| TAR       | 31.1 ± 14.9 | 27.5 ± 15.2 | 0.007 |
| TBR       | 4 ± 3.5 | 3.6 ± 3.9 | 0.264 |
| CV        | 35.5 ± 8.3 | 34.8 ± 7.2 | 0.041 |
| GMI (%)   | 7 ± 0.7 | 7 ± 0.7 | 0.560 |

### Table 4 – Changes in CGM metrics from pre-lockdown phase to the following months according to insulin treatment type used by study participants.

| Variables | MDI group | CSII group | HCL group |
|-----------|-----------|-------------|-----------|
|           | Period 1 (Pre-lockdown) | Period 2 (Lockdown period) | p |
|           | Period 1 (Pre-lockdown) | Period 2 (Lockdown period) | p |
|           | Period 1 (Pre-lockdown) | Period 2 (Lockdown period) | p |
| TIR       | 58 ± 15.6 | 63.7 ± 15.1 | 0.004 |
| TAR       | 39.2 ± 17 | 33 ± 16.8 | 0.004 |
| TBR       | 2.8 ± 3.2 | 3.3 ± 3.6 | 0.122 |
| CV        | 35.4 ± 5.4 | 35.4 ± 5.7 | 0.711 |
| GMI (%)   | 7.3 ± 0.7 | 7 ± 0.7 | 0.024 |
| Period 1 (Pre-lockdown) | Period 3 | p |
| TIR       | 63.2 ± 10.9 | 65.9 ± 10.3 | 0.002 |
| TAR       | 32.5 ± 12.2 | 29.6 ± 11.2 | 0.002 |
| TBR       | 4.3 ± 3.3 | 4.5 ± 3.2 | 0.308 |
| CV        | 38 ± 4 | 37.4 ± 4.4 | 0.139 |
| GMI (%)   | 7 ± 0.7 | 7 ± 0.6 | 0.003 |
| Period 1 (Pre-lockdown) | Period 3 | p |
| TIR       | 64.6 ± 12.6 | 68.5 ± 13.2 | <0.001 |
| TAR       | 31.5 ± 11.8 | 28.1 ± 12.8 | 0.001 |
| TBR       | 4 ± 3.8 | 3.5 ± 3.4 | 0.148 |
| CV        | 36.9 ± 7.5 | 35.4 ± 6.6 | 0.005 |
| GMI (%)   | 7 ± 0.5 | 7 ± 0.6 | 0.065 |
| Period 1 (Pre-lockdown) | Period 3 | p |
| TIR       | 64.6 ± 12.6 | 68.9 ± 12.1 | <0.001 |
| TAR       | 31.5 ± 11.8 | 30 ± 11.7 | <0.001 |
| TBR       | 4 ± 3.8 | 4.3 ± 4 | 0.436 |
| CV        | 36.9 ± 7.5 | 36.5 ± 7.3 | 0.153 |
| GMI (%)   | 7 ± 0.5 | 7 ± 0.6 | 0.107 |
Technology has played a crucial role during this pandemic, particularly for children and adolescents who have been able to continue school lessons and maintain socialization with their peers [14]. The increasing use of innovative technological devices (i.e. CSII and CGM) together with data sharing systems and the interaction with multidisciplinary diabetes team through telemedicine allowed patients not to worsen glycaemic control during the lockdown period. Rachmiel et al. reported their experience on a large cohort of paediatric and young adult patients who greatly benefited from telehealth visits during the COVID-19 lockdown [15]. Our results showed that there was a significant improvement of almost all the glucose control metrics, as suggested by the increase of TIR levels and the reduction of TAR values. Although TBR values remained unchanged, glycaemic variability improved as demonstrated by the reduction of %CV. Finally, GMI levels also decreased. The improvement of glycaemic control during the lock-down period in our study population was absolute, regardless of age and insulin type treatment.

Despite the conclusions of a simulation model that predicted a direct association between duration of lockdown and worsening of glycaemic control and increase in diabetes-related complications [16], our findings, as well as those of other studies, demonstrate the opposite [17-21]. Aragona et al. [22] introduced the term “lockdown effect” to define the surprising, beneficial impact among patients with T1D on glycaemic control. The reasons that could explain this effect are various. The family environment certainly had a relevant impact, especially for younger T1D patients as they spent most of their time at home with their parents. Closer attention to the management of diabetes by children’ parents facilitated the achievement of better glycaemic outcomes. It has been demonstrated that children attending school are often not adequately managed due to several causes such as limited availability of gluconog kits and the shortage of trained personnel able to manage daily diabetes-specific emergencies [23]. In addition, abstention from school and the “stay at home” rule may have contributed to maintaining a healthy diet and more regular distribution of meals. This hypothesis is consistent with the results on the comparison of anthropometric parameters between pre- and post-lockdown in our study population. The lack of difference in weight and BMI are suggestive of a regular dietary regimen in our patients during the lockdown period. These results are contrary with those of an Arabian study that showed an association between the lockdown and a significant increase in paediatric patients’ weight and BMI [24]. We suppose that the online consultant schedule with our diabetes team’s dietician might have significantly helped patients and their parents to avoid overeating and consume the correct amount of carbohydrates. Despite Governmental decrees banning outdoor sports and activities, several reports have shown that more than half children and adolescents with T1D regularly exercise at home (e.g. spin bike, treadmill) several times a week [18,19,25]. Maintaining regular physical activity in a safe home environment has been demonstrated as an essential strategy to allow young individuals with T1D to further improve their glycaemic control during the COVID-19 crisis [26]. Of note, unlike other studies [18,19], adolescent patients also obtained satisfactory diabetes outcomes during the lock-down period. We can speculate that the obligation to stay at home has allowed adolescents to have more time to manage their disease and to make appropriate treatment adjustments. Furthermore, the exclusion of the influence of some school and extra-curricular activities might have reduced stress levels and unpredictability caused by multiple and overlapping commitments [26]. Brener et al. also found an improvement in CGM metrics among adolescent patients, particularly in terms of glycaemic variability [27].

The only CGM metric that remained unchanged during the lockdown period was TBR. This could be influenced by satisfactory values at the start of the study since they were already below the target of 4-5% established by recommendations from the International Consensus on Time in Range [28]. However, clear improvements of TIR and TAR allowed reducing the glycaemic variability assessed by %CV. A %CV ≤ 36% appears to be compatible with the definition of stable glycaemic control in diabetes [29]. The achievement of %CV levels below the established threshold is currently considered a relevant therapeutic target since glycaemic variability is recognized as a possible independent risk factor for the development of diabetic macrovascular and microvascular complications [30].

To the best of our knowledge, there are few published data on the evolution of glycaemic control in T1D patients after the end of lockdown. Some studies described that the first weeks after lockdown had no negative impact on glycaemic control [22,31]. Unlike these studies, we used a longer follow-up observation period to evaluate if these results were confirmed also after three months. In our study population, some glycometabolic parameters such as TIR, TAR, and GMI were better in the post-lockdown if compared to pre-lockdown data. However, when analysing changes in glycaemic control based on the age of our patients, we found that the most relevant results were present in younger patients (pre-pubertal age class). On the contrary, there were no significant changes in glucose metrics in adolescent patients between pre-lockdown and post-lockdown. This interesting finding revealed that adolescents with T1D have been reluctant to persist in the proper approach to their disease. Although the lockdown period and Governmental restrictive laws allowed them indirectly to better manage their diabetes, returning to normal daily activities caused an expected worsening of their glycaemic control. It is well known that adolescence is a tricky transition phase during which individuals often want to feel free from parental control and they probably chose to prioritize something else over proper disease management when the lockdown was lifted [32]. This aspect may further explain the different responses in glycaemic control between younger patients and teenagers.

Finally, our results showed that improvements related to the lockdown phase were confirmed in the following months only in patients using the most innovative technological devices available for disease management (i.e. HCL and advanced HCL). The relationship between the HCL insulin therapy and improvements in CGM metrics during the lockdown had already been described among both paediatric and adult patients with T1D [26,31]. Some studies also reported benefits on glycaemic control in patients who were updating to HCL system through virtual training programs.
during the COVID-19 pandemic [33,34]. Based on our findings, we can suppose that eating every meal at home might allow a more precise carbohydrate count. At the same time, spending more time than usual evaluating their own ambulatory glucose profile might allow to make adjustments in pre-programmed settings such as insulin active time, blood glucose target, and insulin to carbohydrate ratio(s). Therefore, we can hypothesise that the lockdown might have represented an opportunity for patients on HCL therapy and their families to carry out a sort of auto-training, so as to ensure better therapeutic targets also in the following months. Previous studies, including real-life experiences, have already demonstrated that HCL use is associated with improved glycaemic outcomes [35–37]. HCL systems are considered to be related to a new era of diabetes management [38] and it would be fair to suppose that HCL will soon become prevalent in the treatment choice rather than MDI therapy or insulin pumps that are not capable of talking to CGM systems.

6. Conclusions

On the basis of our experience, the improvement in glycaemic control during the lockdown period was transient for most paediatric patients with T1D. In the months following the lockdown, the achievement of satisfactory diabetes outcomes was mainly confirmed in younger patients and in those individuals using HCL systems. These results confirm the crucial aspect of parental control in the management of diabetes during childhood, as well as the increasing benefits from the most innovative technological devices that currently represent the best treatment choice for people with diabetes.

Authors’ contributions

SP drafted and wrote the paper; PB, BB and GL collected data; AA realized statistical analysis; FL and GS contributed to discussion and reviewed the paper. The paper has been read and approved by all the authors and each author considers that the paper represents their honest work.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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