Impact of the Menstrual Cycle on Continuous Glucose Monitoring - Derived Glycemic Parameters in Adolescent Girls With Type 1 Diabetes: A Retrospective Observational Study

Lavinia La Grasta Sabolić *, Ana Kovačević, Marija Požgaj Šepec, Anita Špehar Uroić, Ana Smolić, Bernardica Valent Morić

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Article

Impact of the Menstrual Cycle on Continuous Glucose Monitoring - Derived Glycemic Parameters in Adolescent Girls With Type 1 Diabetes: A Retrospective Observational Study

Lavinia La Grasta Sabolić [1,2,*], Ana Kovačević [1], Marija Požgaj Šepec [1,3], Anita Špehar Uroić [4], Ana Smolić [5] and Bernardica Valent Morić [1,2]

[1] Sestre Milosrdnice University Hospital Center, Vinogradska cesta 29, 10000 Zagreb, Croatia
[2] School of Medicine, Catholic University of Croatia, Ilica 242, 10000 Zagreb, Croatia
[3] School of Dental Medicine, University of Zagreb, Gundulićeva ulica 5, 10000 Zagreb, Croatia
[4] Children's Hospital Zagreb, Vjekoslava Klaića 16, 10000 Zagreb, Croatia
[5] Health Center Zagreb - West, Prilaz baruna Filipovića 11, 10000 Zagreb, Croatia
* Correspondence: lavinia.lagrasta@kbcsm.hr

Abstract

Background and Objectives: Emerging clinical data indicate that glucose levels in women with type 1 diabetes (T1D) fluctuate throughout the menstrual cycle. However, data concerning the adolescent population remain sparse. This study aimed to compare continuous glucose monitoring (CGM)-derived glycemic metrics between the early follicular and late luteal phases in adolescent girls with T1D in order to establish a clinical basis for phase-specific treatment adjustments. **Materials and Methods:** Ninety-nine menstrual cycles from 34 female adolescents with T1D were retrospectively analyzed. Time in range (TIR), time above range (TAR), time below range (TBR), mean glucose, and glucose variability were compared between the early follicular and late luteal phases. Additional analyses were performed to evaluate the impact of different insulin delivery methods and to assess glycemic metrics across subgroups by glycemic control. **Results:** During the late luteal phase, TIR was significantly lower, while TAR and mean glucose were significantly higher compared to the early follicular phase ($p < 0.05$). Although the continuous subcutaneous insulin infusion (CSII) group achieved better overall glycemic metrics then the multiple daily injections (MDI) group, phase-related fluctuations in TIR and TAR reached significance precisely within the CSII group. Furthermore, glycemic shifts in TAR, TBR and mean glucose were especially pronounced in adolescents with tight glycemic control (HbA1c < 7.0%). **Conclusions:** The late luteal phase is associated with significant glycemic deterioration in adolescent girls with T1D, particularly in those with optimal glycemic control. These findings underscore the need for targeted education and menstrual-cycle-tailored insulin dose adjustments.

Keywords: type 1 diabetes; adolescent girls; menstrual cycle; phase-related glycemic fluctuations; continuous glucose monitoring

1. Introduction

Beyond lifestyle factors such as diet and physical activity, blood glucose levels are also influenced by cyclical variations in ovarian hormones throughout the menstrual cycle [1]. This is particularly relevant given that the female reproductive lifespan, extending from menarche to menopause, covers nearly four decades. Menstrual cycle-related glycemic fluctuations have been documented in both healthy women and those with diabetes [1-4]. However, establishing conclusive evidence regarding these menstrual-related glycemic shifts in type 1 diabetes (T1D) remains

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challenging, primarily due to methodological barriers, including the requirement for longitudinal glucose monitoring and the inherent complexity of confounding variables [2].

Emerging clinical data suggest that for a significant subset of women with T1D, the menstrual cycle considerably impacts glycemic management [5,6]. This effect is primarily characterized by a heightened vulnerability to hyperglycemia and reduced insulin sensitivity during the luteal phase compared to the follicular phase [7-9]. Although the exact pathophysiological mechanisms driving these shifts remain incompletely understood, they are intrinsically linked to the cyclical fluctuations of estrogen and progesterone.

To date, available findings have been derived predominantly from adult populations, whereas research concerning adolescent girls remains sparse [10]. Given that adolescence is already characterized by puberty-induced insulin resistance, the superimposition of menstrual hormonal shifts creates a multifaceted challenge for achieving glycemic targets in this vulnerable group.

Therefore, elucidating glucose fluctuations across the menstrual cycle in the adolescent population is essential to facilitate personalized improvements in glycemic management. To address this, the aim of the present study was to compare glycemic metrics between the early follicular phase (eFP) and the late luteal phase (lLP) in adolescent girls with T1D, providing a clinical rationale for phase-specific insulin dose adjustments.

2. Materials and Methods

Subjects and Study Design

This cross-sectional study included 34 Caucasian female adolescents with T1D, aged 11.9 to 19.7 years (mean age 16.4 ± 1.9 years). Inclusion criteria were an age below 20 years, spontaneous menstrual cycles lasting 21–35 days, T1D duration of at least one year, and consistent use of continuous glucose monitoring (CGM) devices, including Dexcom ONE+™ (Dexcom), FreeStyle Libre 2 Plus® (Abbott), and Guardian™ 3 or 4 (Medtronic). Exclusion criteria included acute illness, significant changes in physical activity during data collection, poorly controlled T1D (glycated hemoglobin (HbA1c) > 9.0%), use of oral contraceptives or other non-insulin medications affecting glucose metabolism, and suboptimally managed comorbid autoimmune conditions (e.g., thyroid or celiac disease).

Clinical data were retrieved from medical records and questionnaires, and glycemic data were extracted from CGM cloud-based systems. Age, post-menarcheal interval, T1D duration, HbA1c, and insulin delivery method were recorded; the latter was categorized as multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII), with CSII further subclassified as open loop (OL)/sensor-augmented pump (SAP) or advanced hybrid closed-loop (AHCL).

A questionnaire was used to report the first day of the last three (range two to four) menstrual cycles and age at menarche, as well as to screen for confounding factors (medications, illness, activity changes). Glycemic metrics for 99 menstrual cycles were collected. The early follicular phase (eFP) and late luteal phase (lLP), defined as the first and last 7 days of the menstrual cycle respectively, were compared regarding time in range (TIR, 3.9-10 mmol/L), time above range (TAR, >10 mmol/L), time below range (TBR, <3.9 mmol/L), mean glucose, and glucose variability (expressed as coefficient of variation, CV%).

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the Institutional Ethics Committees of the Sestre milosrdnice University Hospital Center (approval number 003-06/25-03/007) and Children's Hospital Zagreb (approval number 01-23/16-8-25). Informed consent was obtained from the patients' parents or legal guardians, and assent was provided by all participants.

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Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). Results are presented as mean ± standard deviation (SD). The normality of distribution was assessed by the Shapiro–Wilk test. A paired t-test was used for phase comparisons, with the menstrual cycle serving as the unit of analysis. Given that most metrics deviated from a normal distribution, a Wilcoxon signed-rank test was also conducted to verify findings. Comparisons across different insulin delivery methods and HbA1c levels were analyzed using a two-way repeated measures ANOVA with Scheffé's post-hoc test. Greenhouse–Geisser correction was applied where Mauchly's test indicated a violation of sphericity. Statistical significance was set at $p < 0.05$.

3. Results

3.1. Study Population Characteristics

A total of 34 adolescent girls with a mean age of 16.4 ± 2.0 years were included. Participants were characterized by a relatively long duration of T1D (6.9 ± 3.3 years), a mean post-menarcheal interval of 4.0 ± 2.1 years, and optimal to suboptimal glycemic control, with HbA1c levels ranging from 6.0% to 8.5% (mean 7.2 ± 0.7%).

3.2. Comparison of Glycemic Metrics Between eFP and lLP

Analysis of glycemic metrics revealed significant differences between the two phases of the menstrual cycle. During the lLP, TIR was significantly lower, while TAR and mean glucose levels were significantly higher than in the eFP (all $p < 0.05$). In contrast, no significant differences were observed in TBR or glycemic variability between the eFP and lLP. Detailed comparisons and respective p-values are presented in Table 1, with the observed trends illustrated in Figure 1.

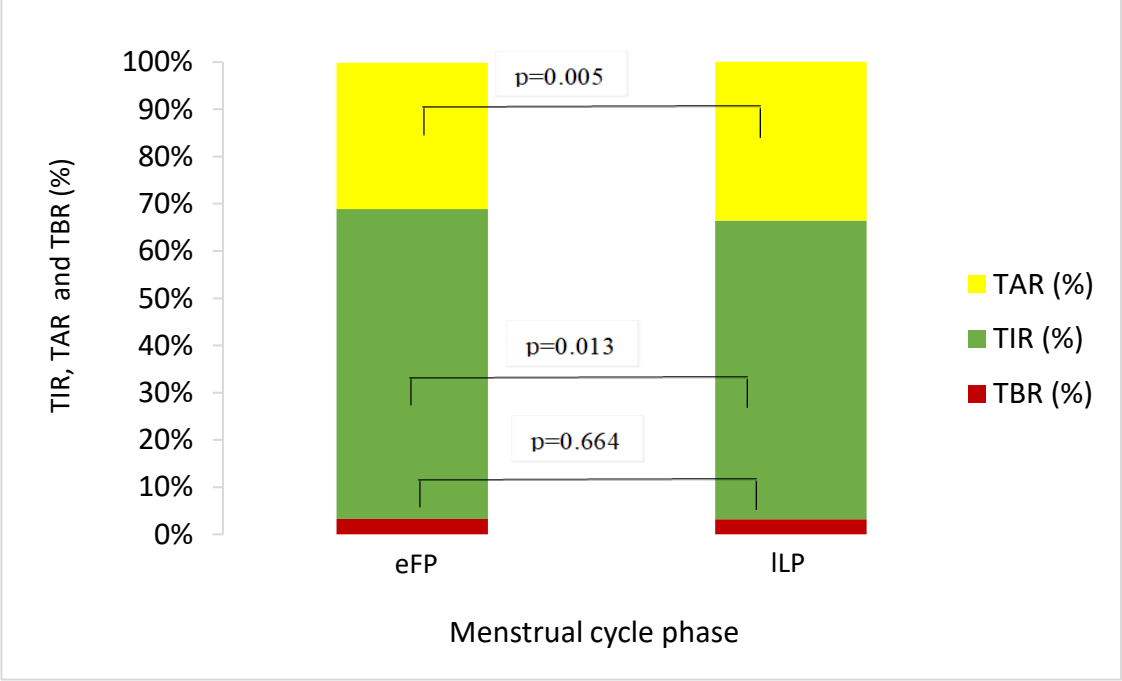

Figure 1. Comparison of glycemic metrics (time in range - TIR, time above range - TAR, and time below range - TBR) between the early follicular phase (eFP) and late luteal phase (lLP) in female adolescents with T1D.

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Table 1. Comparison of glycemic metrics between eFP and lLP.

Glycemic metric	eFP (Mean ± SD)	lLP (Mean ± SD)	p-value
TIR (%)	65.6 ± 14.4	63.3 ± 14.4	0.013
TAR (%)	31.0 ± 15.3	33.6 ± 15.4	0.005
TBR (%)	3.3 ± 3.1	3.2 ± 3.3	0.664
Mean glucose (mmol/L)	8.8 ± 1.4	9.0 ± 1.5	0.023
Glycemic variability (CV%)	36.1 ± 5.3	36.6 ± 7.4	0.527

eFP - early follicular phase; lLP - late luteal phase; TIR - time in range; TAR - time above range; TBR - time below range; CV - coefficient of variation; SD - standard deviation.

3.3. Comparison of Glycemic Metrics Between eFP and lLP According to Insulin Delivery Method

Regarding the insulin delivery method, 17 patients used MDI and 17 CSII (8 OL/SAP, 9 AHCL). Participants on CSII achieved significantly better overall glycemic metrics compared to the MDI group, characterized by higher TIR ($p < 0.001$) and lower TAR ($p = 0.015$), TBR ($p < 0.001$), mean glucose ($p = 0.029$), and glycemic variability ($p = 0.006$).

However, when analysed according to insulin delivery method, statistically significant differences between the menstrual cycle phases were detected only in the CSII group for TIR ($p = 0.024$) and TAR ($p = 0.027$) (Table 2, Figure 2).

Table 2. Comparison of glycemic metrics between eFP and lLP according to insulin delivery method.

Metric	Delivery method	eFP (Mean ± SD)	lLP (Mean ± SD)	p-value *
TIR (%)	MDI	60.4 ± 14.9	59.2 ± 14.9	0.512
	CSII	70.9 ± 11.7	67.5 ± 12.7	0.024
TAR (%)	MDI	34.9 ± 16.8	36.7 ± 16.9	0.212
	CSII	27.0 ± 12.5	30.4 ± 13.3	0.027
TBR (%)	MDI	4.4 ± 3.5	4.0 ± 3.8	0.065
	CSII	2.1 ± 2.2	2.3 ± 2.4	0.603
Mean glucose (mmol/L)	MDI	9.1 ± 1.7	9.3 ± 1.7	0.227
	CSII	8.5 ± 1.1	8.7 ± 1.1	0.112

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Glycemic variability	MDI	37.3 ± 5.8	38.2 ± 8.7	0.947
(CV %)	CSII	34.8 ± 4.4	34.6 ± 4.9	0.971

*p-values derived from Wilcoxon signed-rank test eFP - early follicular phase; lLP - late luteal phase; MDI - multiple daily injections; CSII - continuous subcutaneous insulin infusion; TIR - time in range; TAR - time above range; TBR - time below range; CV - coefficient of variation.

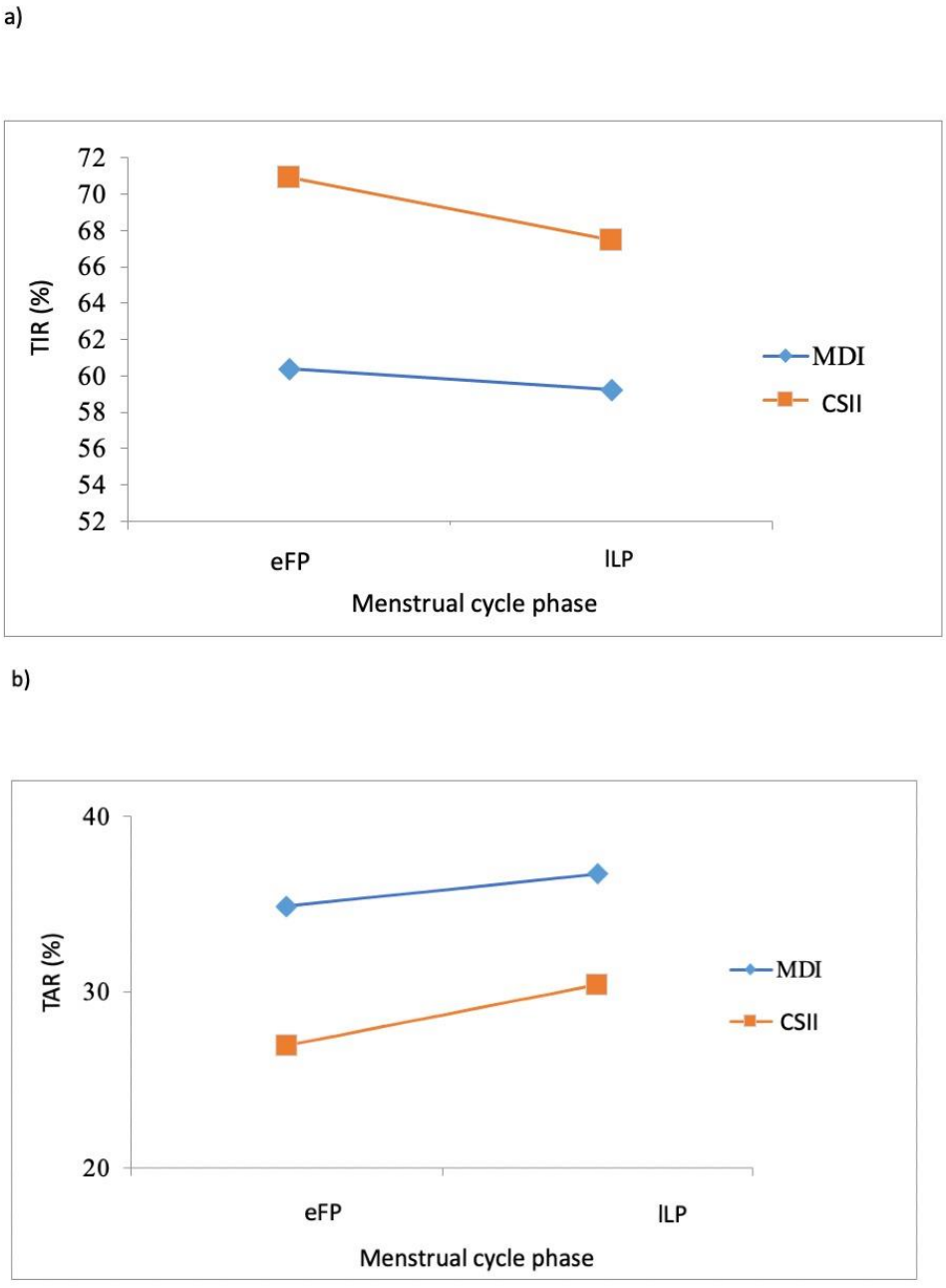

Figure 2. Mean values of (a) TIR, and (b) TAR during the eFP and lLP according to the insulin delivery method (MDI vs. CSII).

3.4. Comparison of Glycemic Metrics Between eFP and lLP According to Baseline Glycemic Control

To further investigate the impact of the menstrual cycle, participants were stratified into three groups based on their HbA1c levels (<7.0%, 7.0 - 8.0%, and 8.0 - 9.0%). In the group with the tightest

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glycemic control (n=13, HbA1c < 7.0%), the transition from the eFP to the lLP was associated with a significant increase in TAR (p = 0.013) and mean glucose levels (p = 0.013), alongside a significant reduction in TBR (p = 0.015) (Table 3). In the intermediate group (n=17, HbA1c 7.0 - 8.0%), a significant decrease in TIR was observed during the lLP (p = 0.032). In contrast, participants with the poorest glycemic control (n=4, HbA1c 8.0 – 9.0%) showed no statistically significant changes in any of the analyzed glycemic metrics across the menstrual cycle (all p > 0.05). Glycemic variability (CV) remained stable across all HbA1c subgroups, with no significant phase-related differences (Table 3).

Table 3. Comparison of glycemic metrics between eFP and lLP stratified by HbA1c levels.

Metric	HbA1c group	eFP (Mean ± SD)	lLP (Mean ± SD)	p-value*
TIR (%)	< 7.0%	74.1 ± 9.5	71.6 ± 13.3	0.306
	7.0 - 8.0%	64.2 ± 10.9	61.4 ± 10.8	0.032
	8.0 - 9.0%	46.9 ± 15.5	46.8 ± 10.1	0.975
TAR (%)	< 7.0%	21.0 ± 10.1	24.9 ± 14.1	0.013
	7.0 - 8.0%	33.2 ± 11.1	35.1 ± 11.7	0.177
	8.0 – 9.0%	51.1 ± 15.4	52.4 ± 9.7	0.649
TBR (%)	< 7.0%	4.9 ± 3.4	3.8 ± 3.1	0.015
	7.0 - 8.0%	2.5 ± 2.5	3.4 ± 3.6	0.111
	8.0 - 9.0%	1.4 ± 1.8	0.8 ± 0.8	0.142
Mean glucose	< 7.0%	7.8 ± 0.8	8.2 ± 1.2	0.013
(mmol/L)	7.0 - 8.0%	9.0 ± 1.0	9.1 ± 1.0	0.363
	8.0 – 9.0%	10.6 ± 1.8	10.9 ± 1.6	0.733
Glycemic variability	< 7.0%	36.1 ± 4.6	36.7 ± 8.8	0.518
(CV %)	7.0 - 8.0%	36.4 ± 5.8	36.8 ± 6.3	0.441
	8.0 - 9.0%	35.1 ± 5.8	35.3 ± 6.8	0.937

*p-values derived from Wilcoxon signed-rank test eFP - early follicular phase; lLP - late luteal phase; TIR - time in range; TAR - time above range; TBR - time below range; CV - coefficient of variation.

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4. Discussion

The impact of different menstrual cycle phases on glycemic control in women with T1D has been the subject of several studies, yielding partially overlapping yet inconsistent results. While some studies confirm significant variations in glucose metrics and insulin sensitivity across the cycle [4, 5, 8, 11, 12], others have failed to detect such differences in the entire study population or in specific subgroups [13,14]. These discrepancies in interpretation and comparison often arise from heterogeneous definitions of menstrual cycle phases, varying observation windows, diverse methodologies for glycemic data collection, and different insulin delivery modalities. Furthermore, glucoregulation is influenced by a multitude of confounding factors, including dietary intake, physical activity, psychological stress, and gut microbiota composition [15-17].

The results of our study highlight notable differences in glucose metrics between the eFP and the lLP. Specifically, among female adolescents with T1D, we observed that TIR was significantly lower, while TAR and mean glucose levels were significantly higher in the lLP compared to the eFP. These findings align with the majority of existing literature. For instance, a pilot study by Goldner et al., evaluating CGM data over three cycles in four women with HbA1c <7.5%, reported an increased frequency of hyperglycemia during the luteal phase in two of them [3]. Similarly, Barata et al. demonstrated a reduction in the percentage of hypoglycemia and an increase in hyperglycemia during the luteal phase compared to the follicular phase in patients using both CSII and MDI [4]. Furthermore, Brown et al. observed an increased risk of hyperglycemia during the periovulatory and early luteal phases in 15 women with well-controlled T1D using CSII and CGM, noting that these changes were consistent across analyzed cycles [5]. The largest study to date, encompassing 179 women on various insulin regimens, also confirmed that glucose levels in the late luteal phase significantly exceeded those in the early follicular phase [7]. This finding was also confirmed by Herranz et al. in their analysis of 168 menstrual cycles [6].

However, it is important to emphasize that cycle-related fluctuations in glucose control are not universal. Previous research indicates that a subset of women with T1D does not exhibit a characteristic cycle-related pattern, with glucose profiles remaining reproducible across cycles [3,6].

In our study, as expected, the method of insulin delivery influenced overall metrics, with MDI users showing lower TIR, higher TAR, TBR, mean glucose and glucose variability compared to CSII users. Interestingly, when data regarding the menstrual cycle phases were analysed according to insulin delivery method, cyclical changes for TIR and TAR remained evident only in the CSII group. Milioto et al. found that while glycemic control worsened during the luteal phase in their cohort of 94 women, phase-related shifts were more pronounced among AHCL users, whereas they were blunted in non-AHCL users with lower baseline TIR [14]. This aligns with our findings, and is further supported by the fact that in our study, patients with tighter glycemic control (HbA1c <7%) exhibited significantly higher TAR, lower TBR, and higher mean glucose in the lLP compared to the eFP, while patients with inadequate control (HbA1c 8.0–9.0%) showed no significant phase-related variations. It can be hypothesized that worse glycemic control overshadows the subtler hormonal influences of the menstrual cycle. We must, however, acknowledge the very small sample size of adolescents with inadequate glycemic control (n=4), which significantly limits the statistical power to detect subtle cycle-related glucose shifts. Nonetheless, the assumption that better regulation reveals phase-related patterns is further supported by Rosado-Fernández et al., who observed higher mean glucose and lower TIR in the luteal phase among women on AHCL systems with a TIR near 70% [17]. Similarly, Monroy et al. reported higher average glucose in the lLP despite an increase in total daily insulin dose in their AHCL cohort [18]. Conversely, Levy et al. found no phase-related differences over three cycles in 16 AHCL users. Although different AHCL algorithms were used across these studies, it is increasingly evident that current insulin delivery technology might benefit from integrating menstrual cycle data into dosing algorithms [19].

Finally, the major strength of our study lies in its exclusive focus on adolescent females under 20 years of age. To our knowledge, this is the first study to examine this specific age group using modern diabetes technology, as previous adolescent-focused research relied on multiple daily

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injections and self-monitoring of blood glucose [10]. Additionally, the analysis of 99 menstrual cycles represents a substantial dataset relative to the existing body of research.

Nevertheless, this study has several limitations. First, it relied on self-reported menstrual cycle data. Second, the use of different CGM systems may have introduced minor variations in data interpretation. Lastly, as this was a dual-center study with an ethnically uniform population, the results, while serving as a robust model for the local population, may not be fully generalizable.

5. Conclusions

Despite a growing body of evidence in adult populations, data regarding the impact of the menstrual cycle on glucose regulation in female adolescents with T1D remain sparse. Specifically, our findings highlight the need for phase-specific insulin therapy adjustments, particularly during the lLP in adolescents with otherwise optimal glycemic control. These results underscore the importance of individualized diabetes management; however, further large-scale studies are warranted to refine clinical guidelines and ensure optimal glycemic control throughout the menstrual cycle in the vulnerable adolescent population.

Author Contributions: Conceptualization: LLS, AK, MPŠ, AŠU, BVM; Data curation: LLS, AK, AS; Formal Analysis: LLS, MPŠ, AS; Methodology: LLS, MPŠ, AŠU, AS, BVM; Validation: LLS, AK, AŠU, AS, BVM; Writing - original draft: LLS, AK; Writing - review & editing: LLS, AK, MPŠ, AŠU, BVM.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board of the Sestre milosrdnice University Hospital Center (approval number 003-06/25-03/007) and Children's Hospital Zagreb (approval number 01-23/16-8-25). Informed consent was obtained from the patients' parents or legal guardians, and assent was provided by all participants.

Data Availability Statement: Raw data that support the findings of this study are available from the corresponding author, upon reasonable request.

Acknowledgments: None.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

T1D – Type 1 diabetes

CGM – Continuous glucose monitoring

TIR – Time in range

TAR – Time above range

TBR – Time below range

CSII – Continuous subcutaneous insulin infusion

MDI – Multiple daily injections

HbA1c – Glycated hemoglobin

eFP – Early follicular phase

lLP – Late luteal phase

CV – Coefficient of variation

SD – Standard deviation

OL – Open loop

SAP – Sensor-augmented pump

AHCL – Advanced hybrid closed-loop

ANOVA – Analysis of variance

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