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Assessment of the Menstrual Cycle and Its Effect on Glycemic Control in a Sample of Egyptian Adolescent Females with Type 1 Diabetes: A Clinical Prospective Study

ABSTRACT

Objective: Assessing the effect of the menstrual cycle on glycemic control and basal insulin requirements in adolescent females with type 1 diabetes (T1D) receiving multiple daily insulin injections. Materials and methods: A clinical prospective study was conducted, involving 78 adolescent females with T1D, who were following at the Diabetes, Endocrine, and Metabolism Pediatric Unit (DEMPU) of Cairo University Children's Hospital. We collected data on their ages at menarche and the regularity and duration of their menstrual cycle, and then followed them for 2 consecutive menstrual cycles during the late luteal, menstrual bleeding, and early follicular phases to observe the effect of hormonal variation on glycemic control and the need for basal insulin dose adjustments. Results: The median age of adolescent females with T1D was 17.3 years. Their median age at menarche was 13 years, and the median duration of T1D was 7 years. Forty-eight (61.5%) patients required modification of their basal insulin dose during the days of menstrual bleeding. Forty-four of them required an increase in their basal insulin by a mean of 10% of their usual dose, while 4 required a decrease in their basal dose by a mean of 9%. The remaining 30 (38.5%) did not require any change in their basal insulin during the days of menstrual bleeding.

Conclusions: In adolescent females, individualized basal insulin dose adjustment, mostly an increase and less frequently a decrease, can prevent worsening of glycemic control and diabetic ketoacidosis during menses. (Clin Diabetol 2024; 13, 4: 208–215)

Keywords: type 1 diabetes, adolescent, menstrual cycle, basal insulin

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Introduction

Adolescence signifies the transition from childhood to adulthood, where adolescents seek privacy,

independence, and are highly influenced by their peers. Many adolescents with type 1 diabetes (T1D) experience deterioration in metabolic control due to various factors such as endocrine changes leading to increased insulin resistance, erratic meal and exercise patterns, poor adherence to treatment regimens, eating disorders, and risky behaviors [1]. Additionally, adolescent girls may experience hormonal variation, mood swings, and changes in insulin resistance, resulting in variations in insulin requirements over the menstrual cycle [2].

Menstrual problems are more common in females with T1D than in the general population. They may also experience delayed menarche, early natural menopause, fewer pregnancies, and more stillbirths than non-diabetics [3]. Oligomenorrhea has been observed in girls with T1D despite optimal metabolic control [4], and some girls with T1D show variable insulin requirements across the menstrual cycle [2].

Insulin resistance tends to increase before ovulation and peak during the luteal phase, with fewer hypoglycemic attacks occurring during this phase [5]. High estradiol and progesterone levels during the luteal phase and menstruation may contribute to increased insulin resistance [5]. Moreover, higher progesterone levels may lead to increased caloric and/or carbohydrate intake, further elevating blood glucose levels [2]. However, the effect of menstrual cycle changes on glycemic control and insulin sensitivity varies among adolescent girls with T1D, highlighting the importance of individualized management [2, 6].

Women with premenstrual syndrome (PMS) often experience greater increases in blood glucose levels or glycosuria during the menstrual cycle, necessitating adjustments to their insulin dosage. This suggests that factors contributing to the somatic and mood symptoms of PMS may also affect preserving euglycemia in women with T1D [7].

Given the numerous factors impacting blood glucose levels and glycemic control in females with T1D, one would expect significant research emphasis on this topic. However, there is a dearth of data available, and even for those on CSII, no pump manufacturer has developed a gender-specific insulin infusion profile [8].

This study aimed at assessing the effect of the menstrual cycle on glycemic control and basal insulin requirements in adolescent females with T1D receiving multiple daily insulin injections.

Materials and methods

Study design and population

This is a clinical prospective study that included 78 adolescent females with T1D following at the Diabetes, Endocrine, and Metabolism Pediatric Unit (DEMPU) of Cairo University Children's Hospital. The study was conducted over a one-year period from May 2021 to May 2022. At recruitment, cases aged from 11 to 19 years were clinically diagnosed as T1D, were on multiple daily insulin injections (basal bolus regimen), and had been menarcheal for at least one year.

Girls with T1D in the honeymoon period, those with documented chronic diabetes complications, uncontrolled hypothyroidism, any other chronic disease, or chromosomal conditions (e.g. Turner and Down syndrome) were not included in the study.

Ethical approval

Informed consent was taken from legal guardians and assent was obtained from the study participants after explaining the aim of the study. All necessary official permissions were obtained from the Ethics Committee of Cairo University (Ethical code MD-184-2020).

Data collection

All enrolled adolescent females were subjected to the following: 1) history-taking, which included name, age (years), menstrual history, including age at menarche, duration since menarche, and regularity and duration of menses. Menses was defined as regular if the duration between the first day of one menstrual bleeding and the first day of the next one equaled 21–35 days [9]. Additionally, information was collected on the onset and duration of T1D, number of diabetic ketoacidosis (DKA) crises since diagnosis, number of perimenstrual DKA crises, and the number of clinically symptomatic severe hypoglycemic attacks confirmed by glucometer (blood glucose < 70 mg) occurring during the perimenstrual period in the last month [10]. HbA1c results from the past year were recorded from their medical records, and the average was calculated based on at least 2 readings. The calculated average HbA1c was categorized as optimal control if < 7%, and suboptimal control if ≥ 7%, following the ISPAD recommendations for glycemic control in adolescents [11]. 2) Clinical examination, which included anthropometric measurements such as weight (in kilograms), height (in centimeters), and body mass index (BMI in kg/m^2). Z-scores were calculated for all measurements. Height was measured using a Harpenden stadiometer and was recorded to the nearest 0.1 cm [12], while weight was measured using digital weighing scales and recorded to the nearest 0.1 kg. Both height and weight were measured by a trained nurse in the DEMPU clinic. BMI was calculated as weight divided by height in meters squared [13]. Girls were also examined for signs of androgen excess (acne and/or hirsutism, consistent with Ferri-

man-Gallwey score ≥ 8) by an endocrinologist at the DEMPU clinic [14]. Additionally, the average systolic and diastolic blood pressure was recorded as part of the clinic's routine follow-up of patients with diabetes using a Dinamap device.

Due to poor adherence among adolescents to the blood glucose monitoring regimen, which required testing 7 times per day (before and after meals and an additional test during sleep), we encountered significant challenges. Consequently, we specifically requested that participants record their blood glucose levels at 3 key times: fasting, pre-lunch, and pre-dinner. This self-monitoring of blood glucose (SMBG) was to be carried out using an Accu-Chek Performa glucometer, compliant with ISO 15197:2013 standards [15], during the perimenstrual period for 2 consecutive menstrual cycles.

The required period included one week before the menses (late luteal phase), the days during the menses, and one week after last day of menses (early follicular phase). After revising the self-recorded fasting and pre-prandial glucose readings during the first studied menstrual cycle, the basal insulin dose was modified for some of them during the second studied menstrual bleeding phase (menses), according to the ISPAD guidelines for basal dose adjustment [11, 16]. Care was taken to improve glycemic control as much as possible without inducing hypoglycemia and excess psychological burden.

Adolescent females with T1D, whose results of self-monitoring of blood glucose (SMBG) during the first studied menstrual cycle did not require insulin dose adjustments during the second menstrual cycle, were placed in group A. Those whose SMBG results during the first menstrual cycle required insulin dose adjustments were categorized into group B, with subgroup B1 indicating an increase in basal dose and subgroup B2 indicating a decrease. Basal dose adjustments were within 5 to 10% of the actual injected basal dose.

Sample size

Based on evidence from a previous, similar study [6] and by considering the mean of self-monitoring blood glucose rather than HbA1c levels in adolescent girls with T1D as the primary outcome, the sample size for this prospective clinical study was calculated using Epi-calc 2000. Assuming 80% power, a 0.05 level of significance, a null hypothesis value of 256.32 g/dL, a standard deviation of 5.94 g/dL, and an estimated mean of 274.27 g/dL, the sample size was determined to be 70 participants. Accounting for a dropout rate of 10%, the final sample size was set at 77 participants.

Statistical methods

Microsoft Excel 2013 was used for data entry, while the Statistical Package for the Social Sciences (SPSS version 24) was employed for data analysis. Median and interquartile ranges were utilized for non-parametric data. Bivariate relationships were depicted in cross-tabulations, and the chi-square and Fisher's exact tests were employed, where appropriate, for comparisons of proportions. Additionally, for independent samples, the Kruskal-Wallis test followed by Bonferroni correction for multiple comparisons was used to compare numerical variables between subgroups of cases.

Results

The median age for adolescent females at time of recruitment was 17.3 years, and the median duration of diabetes was 7 years. Regarding menstrual history, their median age for menarche was 13 years, median days for menstrual bleeding was 5 days, 43.6% of them had irregular menses, 19.2% had hirsutism, and 41% had acne. Regarding their anthropometric measures, the median Z score was +0.32 SD for weight, –0.6 SD for height, and +0.5 SD for BMI (Tab. 1).

Two adolescents were on neutral protamine Hagedorn (NPH) (intermediate acting), 19 on insulin degludec (long acting), 42 on insulin glargine (long acting), and 15 on insulin glargine U300 (long acting). For the NPH we changed the 2 doses.

As mentioned earlier, due to poor adherence to the monitoring regimen, adolescent females with T1D provided fasting and pre-prandial glucose tests through self-monitoring of blood glucose (SMBG) during specific periods. For the first studied cycle, these tests were conducted for one week before the onset of menses, during the days of menstrual bleeding, and for 4 days following the last day of menses. For the second studied cycle, tests were conducted exclusively during the days of menstrual bleeding.

By close observation of blood glucose readings during the 2 studied menstrual cycles, the following was recorded:

Thirty cases (Group A) did not show variations in blood glucose readings during the first menstrual cycle phases and did not need any change in basal insulin dose during the second menses (Tab. 2).

Forty-eight cases (Group B) needed modification in basal insulin dose during the second menses as follows:

Forty-four cases (Group B1) required an increase in basal insulin dose because they exhibited higher readings during the late luteal and the days of menstrual bleeding phases compared to the early follicular phase. Blood glucose readings were highest during the days of menstrual bleeding phase (Tab. 2). The increase in

Table 1. Demographics of Adolescent Females with Type 1 Diabetes (n = 78) on Multiple Daily Dose Injections (Basal Bolus Regimen)

	Median (IQR)	Mean (SD)	Coefficient of variation
Age [years]	17.3 (15–18.5)	16.6 (2)	12
Age of menarche [years]	13 (11–14)	12.6 (1.5)	12.4
Duration of diabetes	7 (4–9)	6.9 (3.6)	–
Duration since menarche [years]	4 (2–5)	3.5 (1.8)	52
Mean days of menstrual bleeding [days]	5 (5–7)	5.6 (1.5)	27.1
Weight [SD]	0.32 (–0.4,1.2)	0.4 (1)	19.9*
Height [SD]	–0.6 (–1.2,0.2)	–0.6 (0.9)	4.3*
BMI [SD]	0.5 (–0.1,1.6)	0.7 (1)	18.5*

Any diabetic female with diabetic complications was excluded from the study; 2 adolescents on NPH, 19 on insulin degludec, 42 on insulin glargine, and 15 on insulin glargine U300
*Coefficient of variation is calculated on the actual values of these measurements.
BMI — body mass index; IQR — interquartile range; NPH — neutral protamine Hagedorn; SD — standard deviation

Table 2. Median (IQR) of Self-Monitored Blood Glucose Readings During the First and Second Studied Menstrual Cycles in the Three Groups

Menstrual cycle		Median (IQR)					
		First studied cycle			Second studied		
		Group A (n = 30)	Group B1 (n = 44)	Group B2 (n = 4)	Group A (n = 30)	Group B1 (n = 44)	Group B2 (n = 4)
Late luteal (The week before menstrual bleeding)	Fasting BG [mg/dL]	160.6 (136.6–172)*	177.8 (139.8–257.2)**	119.3 (105–0)*	NA	NA	NA
	Pre-lunch BG [mg/dL]	164.4 (149.9–193.8)*	196.5 (153.8–234)**	100.5 (79–0)*	NA	NA	NA
	Pre-dinner BG [mg/dL]	156.5 (146.4–188.8)*	186.0 (167.5–234)**	143.3 (130–0)*	NA	NA	NA
Menses (During days of menstrual bleeding)	Fasting BG [mg/dL]	148.2 (129.7–169.4)	214 (188.5–265.5)	95.1 (69.1–120.5)	144.3 (120.8–164.6)	136.1 (119.1–161.5)	106.1 (86.2–116.3)
	Pre-lunch BG [mg/dL]	173.9 (152–194.5)	226.2 (194.3–280.3)	112.2 (104.7–138.5)	152.8 (144.3–172.3)	160.8 (143.5–176.7)	133.3 (111.7–142)
	Pre-dinner BG [mg/dL]	169.3 (156.9–197.1)	222.5 (193.5–247.1)	109.2 (94.4–127.8)	152.5 (133–174.1)	157.7 (141.1–173.9)	120.4 (96.2–143.3)
Early follicular (Four days after end of menstrual bleeding)	Fasting BG [mg/dL]	144.3 (122.2–158.2)	137.2 (116.4–174.3)	112.3 (105.9–120.7)	NA	NA	NA
	Pre-lunch BG [mg/dL]	164.7 (132.8–209.1)	169.3 (148.7–189.1)	112.3 (105.4–118)	NA	NA	NA
	Pre-dinner BG [mg/dL]	163.7 (147.9–181)	159.5 (137.5–178.4)	115.3 (92.6–135.3)	NA	NA	NA

Self monitoring of blood glucose is missing for *2, **9 cases
BG — blood glucose; IQR — interquartile range; NA — not available

basal insulin dose aimed to improve control during the days of menstrual bleeding phase, resulting in median fasting, pre-lunch, and pre-dinner BG reductions of 38.4%, 31.9%, and 28.3%, respectively (Tab. 3). The mean and median percentage increase in basal insulin dose for this group was 10%. However, basal insulin dose adjustments were not implemented during the late luteal phase because most participants had irregular cycles and were reluctant to measure blood glucose during the premenstrual days.

Four cases (Group B2) required a decrease in basal insulin dose due to experiencing repeated hypoglycemic

Table 3. Median (IQR) Percentage Change in Self-Monitored Blood Glucose and Basal Insulin During the Second Studied Menstrual Cycle Across the Three Groups

	Median (IQR) percentage change			P-value
	Group A (n = 30)	Group B1 (n = 44)	Group B2 (n = 4)	
Fasting BG	–6.3% (–17.1, 0.3)	–38.4% (–45.3, –27.5)	6.5% (–12.1, 47.6)	< 0.001
Pre-lunch BG	–9.0% (–20.9, 1.8)	–31.9% (–41.4, –19.7)	9.9% (–1.9, 21.2)	< 0.001
Pre-dinner BG	–7.5% (–18.1, 3.3)	–28.3% (–35.8, –20.6)	22.5% (–18, 29.3)	< 0.001
Basal insulin	0	10 (6–12.8)	–9 (–10, –5)	–

Independent sample Kruskal-Wallis test, the Bonferroni correction for multiple comparison; BG — blood glucose; IQR — interquartile range

attacks during the days of menstrual bleeding phase. Consequently, we reduced the basal insulin dose to prevent hypoglycemia during the second cycle (Tab. 2). These 4 cases reported a decreased appetite during the days of menstrual bleeding. The mean percentage decrease in basal insulin dose for this group was 8% and the median was 9%, accompanied by an increase in the median fasting, pre-lunch, and pre-dinner BG levels by 6.5%, 9.9%, and 22.5%, respectively (Tab. 3).

The occurrence of DKA events was significantly more frequent during the perimenstrual period in Group B compared to Group A because Group B experienced higher glucose levels. However, the 2 groups were comparable regarding symptoms of severe hypoglycemia, type of basal insulin used, and mean HbA1c levels (Tab. 4).

We found that 36.7% of Group A had irregular menses compared to 47.9% of Group B. Additionally, 30% of Group A had hirsutism compared to 12.5% of Group B, and 36.7% of Group A had acne compared to 43.8% of Group B. Further evaluation for the detection of polycystic ovaries is needed, but that was outside the scope of our study.

Discussion

In the present study, 38.5% of adolescent females with T1D showed no fluctuations in blood glucose readings during their first studied menstrual cycle. The remaining 61.5% of adolescent females with T1D exhibited disturbing blood glucose fluctuations during their menstrual cycle. Among these, 56.4% experienced higher fasting and pre-prandial blood glucose levels during the late luteal and days of menstrual bleeding phases compared to the early follicular phase. Additionally, the days of menstrual bleeding phase showed higher blood glucose readings than the late luteal phase. An increase in basal insulin dose was required during the second menstrual cycle, with a mean increase of 10% of the actual dose. Furthermore, 5.1% experienced a decrease in their fasting and pre-prandial blood glucose levels, necessitating a decrease in basal insulin dose during the second menstrual cycle, with a mean decrease of 8% of the actual dose.

According to Milionis et al. (2023) [17], the increase in estrogen levels shortly before ovulation and the increase in serum progesterone during the luteal phase may explain the increased insulin resistance and concomitant hyperglycemia during both the periovulatory period and the luteal phase of the menstrual cycle.

The presence of premenstrual syndrome may also contribute to hyperglycemia in the late luteal phase [18]. The presence of premenstrual symptoms was not included in the current study.

The increase in blood glucose readings was also documented by Shaalan et al. (2022) [6], who studied the effect of puberty on glycemic control in 30 pubertal girls by comparing them to 30 prepubertal girls. Similarly, Barata et al. (2013) [19] achieved similar results in 6 adult females with T1D whose blood glucose control was monitored throughout the menstrual cycle. Conversely, Trout et al. (2007) [7] conducted a study on 5 adult females with T1D and found no statistically significant differences in fasting baseline glucose levels or insulin sensitivity between the luteal and follicular phases. This discrepancy may be attributed to their small sample size.

Our findings align with the study conducted by Brown et al. (2015) [2], which involved 12 women using continuous glucose monitoring over 3 consecutive menstrual cycles. Their study identified 3 patterns of insulin sensitivity (SI) variation during the luteal phase: 42% of cycles showed decreased SI, 36% showed increased SI, and 22% showed unchanged SI compared

Table 4. Comparison between Groups A and B Regarding the Frequency of Acute Diabetes Complications (DKA and Hypoglycemia), Regularity of Menses and the Type of Insulin Used

		Group A (n = 30) [%] (N)	Group B (n = 48) [%]	P-value
DKA on initial diagnosis of diabetes		26.7	41.7	0.179
DKA during perimenstrual period		3.3	20.8	0.043*
Signs of severe hypoglycemia (during last month)**		20	16.7	0.709
Regularity of menses	Regular	63.3	52.1	0.33
	Irregular	36.7	47.9	
Type of insulin	NPH (twice daily)	0 (0)	4.2 (2)	0.146*
	Insulin degludec	16.7 (5)	29.2 (14)	
	Insulin glargine	53.3 (16)	54.2 (26)	
	Insulin glargine U300	30 (9)	12.5 (6)	
HbA1c	< 7%	10.0	8.3	1.000
	≥ 7%	90.0	91.7	
Hirsutism		30	12.5	0.056
Acne		36.7	43.8	0.536

Regular menses — duration between first day of one menstruation and first day of the next is 21-35 days; **Signs of severe hypoglycemia include disturbed conscious level and/or convulsions; chi-squared/*Fisher's exact tests
DKA — diabetic ketoacidosis; HbA1c — glycated hemoglobin; NPH — neutral protamine Hagedorn

to the early follicular phase. Additionally, 3 women experienced low glucose levels during menses, but the study found that blood glucose levels were highest during the early luteal phase rather than the late luteal phase. It is important to note that their study was conducted on premenopausal women with regular cycles, whereas we did not monitor blood glucose during the early luteal phase.

However, our findings contrast with those of Herranz et al. (2016) [20], whose study on 26 adult females with T1D found no significant improvements in blood glucose response to increasing insulin doses among the two-thirds who experienced increases during the luteal phase. It is worth noting that their study had a smaller sample size and included adult diabetic females with regular menstrual cycles and good metabolic control.

Diabetic ketoacidosis during the perimenstrual period occurred significantly more frequently in girls who required basal dose adjustments during their menses compared to those who did not. Therefore, it is important to revise individual basal insulin requirements to prevent worsening of glycemic control and diabetic ketoacidosis in adolescent girls with T1D.

Furthermore, for adolescent females with T1D, achieving the greatest period with near-normal blood glucose between 70 and 180 mg/dl (time in range) even during the menstrual period can potentially prevent or delay the micro- and macrovascular complications of diabetes [21, 22].

Limitations

The lack of continuous glucose monitoring poses a significant challenge in the consistent monitoring of blood glucose levels. Adolescent girls with T1D often exhibit non-adherence and resistance to regular self-monitoring of blood glucose (SMBG), a behavior characteristic of the adolescent period. Additionally, there are intermittent issues with the supply of glucose test strips for SMBG, further complicating the monitoring process as reimbursement is available for 100 to 150 glucose test strips for SMBG per month. These factors collectively contribute to the complexities and challenges faced in this study.

Conclusions

In adolescent females, individualized basal insulin dose adjustment, mostly an increase and less frequently a decrease, can prevent worsening of glycemic control and diabetic ketoacidosis during menses.

Article information

Availability of data

The original contributions presented in the study are included in the article, and any further inquiries can be directed to the corresponding author.

Ethics approval

Informed written consent was taken from legal guardians, and assent from the study participants was obtained after explaining the aim of the study. All necessary official permissions were obtained from the ethical committee of Cairo University (Ethical code MD-184-2020).

Author contributions

The study's conception and design were spearheaded by Dr. Mona Mamdouh Hassan, Dr. Shahenda Shaaban Ismail, and Dr. Nora Elsayed Badawi. Dr. Shahenda Shaaban Ismail, Dr. Nora Elsayed Badawi, and Dr. Samah Ahmed Hassanein were responsible for data acquisition. Analysis and interpretation of the data were conducted by Dr. Mona Mamdouh Hassan, Dr. Shahenda Shaaban Ismail, Dr. Nora Elsayed Badawi, Dr. Samah Ahmed Hassanein, Dr. Eman Hany Elsebaie, and Dr. Marwa Farouk Mira. The manuscript was drafted and revised by Dr. Mona Mamdouh Hassan, Dr. Shahenda Shaaban Ismail, Dr. Nora Elsayed Badawi, Dr. Samah Ahmed Hassanein, Dr. Eman Hany Elsebaie, and Dr. Marwa Farouk Mira.

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Conflict of interest

The authors declare no conflict of interest.

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