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**ORIGINAL ARTICLE** 

# The Effect of Menstrual Cycle on Preprocedural Anxiety in Patients Undergoing Interventional Procedures Under Sedoanalgesia

# Sedoanaljezi Altında Girişimsel İşlem Uygulanacak Hastalarda Menstrüel Siklusun İşlem Öncesi Anksiyete Üzerine Etkisi

1Emine Aslanlar 🔟, 1Mehmet Selçuk Uluer ២, 1Mehmet Sargın ២, 1Faruk Çiçekci ២

<sup>1</sup>Department of Anesthesiology and Reanimation, Faculty of Medicine, Selcuk University, Konya, Türkiye

#### Correspondence

Emine ASLANLAR, MD Selcuk University Medicine Faculty, Department of Anesthesiology and Reanimation, Konva, Türkive

E-Mail: draslanlar@gmail.com,

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### ABSTRACT

Aim: Estradiol and progesterone, the main hormones of the menstrual cycle, have modulating effects on neural mechanisms of anxiety and fear regulation. Anxiety is a common problem in patients undergoing interventional medical procedures. Therefore, interventional procedures are mostly performed under sedation. Studies are reporting that the level of anxiety in daily life varies in women depending on the phases of the menstrual cycle. In this study, we aimed to determine

in women depending on the phases of the menstrual cycle. In this study, we aimed to determine the effect of the menstrual cycle on the level of anxiety related to the interventional procedure in patients to be sedated. **Methods:** ASA I- II female patients between the ages of 18-40, with regular menstrual cycles (one cycle every 23-35 days), planned to undergo interventional procedures under sedation, were included in the study. Patients were asked about their last menstrual period, and those on the 1-10th day of the menstrual cycle were grouped as the follicular phase, and those on the 18-24th day were grouped as the luteal phase. Anxiety levels were assessed with the State-Trait Anxiety Inventory (STAI-X1) and compared between follicular and luteal phase patients. **Results:** The study was completed with 86 patients. Fifty-eight patients were in the follicular phase and 28 were in the luteal phase. The mean cycle frequency of women was 27.93 ± 3.30 days in the follicular phase and 27.29 ± 3.15 days in the luteal phase with no significant difference between the two groups (p= 0.39). While the STAI-X1 score of those in the follicular phase was 44.81, the score of those in the luteal phase was 40.71 and no significant difference was found between the two groups (p= 0.11). Anesthetic drug doses used in sedoanalgesia were similar between the two groups (p= 0.96). **Conclusion:** Patients in the follicular and luteal phases of the menstrual cycle have similar levels of pre-procedural anxiety.

pre-procedural anxiety.

Keywords: Follicular phase, luteal phase, menstrual cycle, preprocedural anxiety, sedoanalgesia

### ÖZ

Amaç: Adet döngüsünün ana hormanları olan östradiol ve progesteron, anksiyete ve korku düzenlemesinin nöral mekanizmaları üzerinde madüle edici etkilere sahiptir. Anksiyete, girişimsel tibbi prosedürler uygulanan hastalarda yaygın bir sorundur. Bu nedenle girişimsel işlemler çoğunlukla sedasyon altında gerçekleştirilmektedir. Kadınlarda günlük yaşamdaki anksiyete düzeyinin menstrüel siklusun evrelerine bağlı olarak değiştiğini bildiren çalışmalar mevcuttur. Bu çalışmada, sedasyon uygulanacak hastalarda menstrüel siklusun girişimsel işlemle ilgili anksiyete düzeyine etkisini belirlemeyi amaçladık.
Gereç ve Yöntemler: Sedasyon altında girişimsel işlem yapılması planlanan 18-40 yaş arası, düzenli menstrüel siklusiarı olan (23-35 günde bir siklus) ASA I-II kadın hastalar çalışmaya dahil edilmiştir. Hastalara son adet dönemleri sorulmuş ve adet döngüsünün 1-10. günlerinde olanlar foliküler faz, 18-24. günlerinde olanlar ise luteal faz olarak gruplandırılmıştır. Anksiyete düzeyleri, State-Trait Anxiety Inventory (STAI-X1) ile değerlendirilmiş ve foliküler ve luteal fazda ve 28 hasta luteal fazdadır. Kadınların ortalama sıkluş sıklığı foliküler fazda 27:93 ± 3.30 gün ve luteal fazda 27:29 ± 3.15 gün olup iki grup arasında anlamlı bir fark yoktu (p= 0.39). Foliküler fazda ve 28 hasta luteal fazdadır. Kadınların ortalama sıkluş sıklığı foliküler fazda 27:93 ± 3.30 gün ve luteal fazda 27:29 ± 3.15 gün olup iki grup arasında anlamlı bir fark yoktu (p= 0.39). Foliküler fazda ve 28 hasta luteal fazdadır. Kadınların ortalama sıkluş sıklığı çolzan iki grup arasında anlamlı bir fark bulunamada anlamlı bir fark bulunamada anlamlı bir fark bulunamada topa danların işlem öncesi anksiyete düzeyleri benzerdir.
Azətbu Kelimeter Gölküler faz işlem öncesi anksiyete düzeyleri benzerdir.

Anahtar Kelimeler: Foliküler faz, islem öncesi anksivete, luteal faz, menstrüel dönaü, sedoanaliezi

# Introduction

menstruation that supports reproduction, covering an (premenstrual) phase (1). average of 28 days. The early follicular phase starts The fluctuating levels of female sex hormones during on the first day of menstruation and estradiol and progesterone hormones are at low levels during this phase. The early follicular phase is followed by the mid-follicular phase when estradiol rises and peaks before ovulation. The luteal phase begins following ovulation, during which estradiol and progesterone gradually increase until the mid-luteal phase, followed

The menstrual cycle is the process of ovulation and by a decrease in both hormones in the late luteal

the menstrual cycle affect the central nervous system (2). Progesterone and its metabolites act on GABA A receptors in the central nervous system, causing sedative, anxiolytic, and analgesic effects, and a benzodiazepinelike sleep profile in electroencephalography (3). Progesterone levels are higher in the luteal phase and



reduce the need for anesthesia in these patients. The minimum alveolar concentration of volatile anesthetics has been reported to decrease during pregnancy when progesterone levels are normally high (2).

Anxiety is an emotional state that can manifest as fear or anticipation of imminent danger and especially it is a common problem in patients undergoing interventional medical procedures (4). Therefore, interventional procedures are mostly performed under sedoanalgesia.

In addition to their role in reproduction, estradiol, and progesterone have modulating effects on neural mechanisms of anxiety and fear regulation. Therefore, anxiety symptoms in women may vary depending on hormonal fluctuation (5). Research shows a complex relationship between progesterone and anxiety. Studies show that rodents given progesterone show less anxiety behavior (6) and vice versa; there are also studies showing that women given progesterone have an increased stress response in stressful situations(7, 8). Anxiety-prone women, for instance, showed a greater cognitive panic reaction during the luteal phase when progesterone levels were higher than during the follicular phase when progesterone levels were lower, according to a study (9).

Mood-regulating centers, such as the amygdala and hippocampus, are the regions in the human brain with the greatest density of estrogen receptors. The activity of these areas can be modulated by estrogen; extensive research indicates that suicidal behavior(10, 11) and negative mood complaints(12, 13) are elevated in women during low estrogen phases of the menstrual cycle, even in healthy women. In a study in which women were shown stressful images and then had their anxiety levels measured, women with higher periovulatory estradiol levels were shown to have lower anxiety scores (14).

In this study, we aimed to determine the effect of follicular and luteal phases of the menstrual cycle on the level of anxiety related to interventional procedures in patients to be sedoanalgesia.

# Materials and Methods

Patients were evaluated after approval was obtained from the Medical Faculty Local Ethics Committee of Selcuk University (Decision No: 2020/528). The study was conducted under the principles of the Declaration of Helsinki.

After ethics committee approval, patients aged 18-

40 years with regular menstrual cycles (23-35 days menstrual cycle) who were to undergo interventional procedures under sedation were included in the study. Patients were informed about the study and their written consent was obtained.

Pregnant women, those receiving hormonal therapy affecting ovulation, those using chronic or acute psychotropic drugs, alcohol, benzodiazepine, anticonvulsant, opioid drugs, those with irregular menstrual cycles, those with a body mass index below 18 and above 33 were excluded from the study.

Demographic information about age, height, weight, educational status, type of procedure, and comorbidity, and regarding the menstrual cycle; the date of the last menstrual period and the number of days of the menstrual cycle were recorded. Patients were asked on which day of the menstrual cycle they were in, and those on days 1-10 of the menstrual cycle were considered as follicular phase and those on days 18-24 as luteal phase.

Patients were asked to evaluate their anxiety levels by filling out the Spielberger State-Trait Anxiety Inventory (STAI) form only before sedoanalgesia in the waiting room (Figure 1). This form measures both state and trait anxiety. STAI is subdivided into two different scales, STAI-X1 and -X2, used to evaluate state anxiety and trait anxiety, respectively. The STAI-X1 Scale consists of 20 questions and the response options collected in four classes are; (1) Not at all, (2) A little, (3) A lot, and (4) Completely. The scale has direct and inverted statements, with direct statements expressing negative emotions and inverted statements expressing positive emotions. The reversed statements in the STAI-X1 are items 1, 2, 5, 8, 10, 11, 15, 16, 19 and 20. After finding the total weights of the direct and inverted statements separately, the total weight score obtained for the direct statements is subtracted from the total weight score obtained for the inverted statements. A predetermined and unchanging value is added to this number. For the State Anxiety Inventory, this constant value is 50. The last value obtained is the individual's anxiety score. A minimum score of 20 and a maximum score of 80 can be obtained from this form and higher scores are associated with more anxiety. According to their scores on this anxiety scale, values 20-29 no state of anxiety, 30–37 slight anxiety, 38–44 moderate anxiety, and 45-80 serious anxiety (15). Anxiety levels of patients in follicular and luteal phase were compared.

		Not at all	Somewhat	Moderately	Very much
1.	l feel calm.	(1)	(2)	(3)	(4)
2.	I feel secure	(1)	(2)	(3)	(4)
3.	I am tense	(1)	(2)	(3)	(4)
4.	I feel strained	(1)	(2)	(3)	(4)
5.	I feel at ease	(1)	(2)	(3)	(4)
6.	I feel upset	(1)	(2)	(3)	(4)
7.	I am presently worrying over possible misfor- tunes	(1)	(2)	(3)	(4)
8.	I feel satisfied	(1)	(2)	(3)	(4)
9.	l feel frighte- ned	(1)	(2)	(3)	(4)
10.	l feel comfor- table	(1)	(2)	(3)	(4)
11.	l feel self-con- fident	(1)	(2)	(3)	(4)
12.	I feel nervous	(1)	(2)	(3)	(4)
13.	I am jittery	(1)	(2)	(3)	(4)
14.	I feel indecisive	(1)	(2)	(3)	(4)
15.	l am relaxed	(1)	(2)	(3)	(4)
16.	I feel content	(1)	(2)	(3)	(4)
17.	l am worried	(1)	(2)	(3)	(4)
18.	l feel confu- sed.	(1)	(2)	(3)	(4)
19.	I feel steady.	(1)	(2)	(3)	(4)
20.	l feel pleasant.	(1)	(2)	(3)	(4)

Figure 1. Spielberger's State-Trait Anxiety Inventory (STAI)

For sedoanalgesia, 1 -2 mg midazolam, 1-2 mg/kg propofol, and 1mcg/kg fentanyl were administered by titrating to maintain spontaneous respiration, and nasal oxygen was administered at 2 l/min. Patients were awakened and taken to the recovery unit after the procedure.

In the power analysis, the required sample size was calculated as 105 people with the G-Power program, taking into account the two-way analysis of variance test for 80% statistical power  $(1-\beta)$  and medium effect size at a significance level of 0.05 (a).

# Statistical analysis

SPSS for Windows 21.0 package program was used for all statistical evaluations in our study. In summarizing the data, nominal data were expressed as numbers and percentages (%), and measured data were expressed as mean and standard deviation. In statistical analysis, the chi-square test was used for nominal data, the t-test or Mann-Whitney U test was used for measured data and p<0.05 was considered statistically significant.

# Results

A total of 105 patients were included in the study, of whom incomplete completion of the STAI form (n=3), patients on days 10-18 (n=10) or 24-28 (n=6) of the menstrual cycle were excluded, and the study was completed with 86

patients.

Upper gastrointestinal endoscopy was performed in 48 patients, colonoscopy in 15 patients, and both upper gastrointestinal endoscopy and colonoscopy in 23 patients. Fifty-eight patients were in the follicular phase and 28 in the luteal phase.

The mean age, height, and body weight of the patients in both groups were similar (Table 1).

The mean cycle frequency of women was  $27.93 \pm 3.30$  days in the follicular phase and  $27.29 \pm 3.15$  days in the luteal phase with no significant difference between the two groups (p= 0.39) (Table 1).

While the STAI-X score of those in the follicular phase was 44.81, the score of those in the luteal phase was 40.71 and no significant difference was found between the two groups (Table 1). In the follicular phase, 4 patients had no anxiety, 8 had mild anxiety, 16 had moderate anxiety and 30 had severe anxiety, and in the luteal phase, 2 patients had no anxiety, 5 had mild anxiety, 9 had moderate anxiety and 12 had severe anxiety. There is no difference in the severity of anxiety between the two groups (p= 0.92).

STAI-X scores were not associated with education level (p=0.192) and procedure type (p=0.485). Anesthetic drug doses used in sedoanalgesia were similar between the two groups (p=0.96) "(Table 1).

 Table 1. Characteristics of patients in the follicular and luteal phase

	Follicular Phase (n=58)	Luteal Phase (n=28)	Р	
	Mean±SS	Mean±SS	r	
Age (years)	28.86 ± 6.25	27.86 ± 7.32	0.54	
Воу	163.78 ± 5.91	160.36 ± 19.08	0.36	
Weight	70.21 ± 18.46	67.89 ± 14.78	0.53	
Cycle days	27.93 ± 3.30	27.29 ± 3.15	0.39	
Sedatives	99.66 ± 30.15	99.29 ± 30.66	0.96	
STAI score	44.81 ± 9.30	40.71 ± 11.60	0.11	
Education Status	n (%)	n (%)		
Primary education	21 (36.2)	8 (28.6)		
High School	19 (32.8)	12 (42.9)	0.64	
University	18 (31.0)	8 (28.6)		
Procedure				
Endoscopy	31 (32.4)	17 (60.7)	0.52	
Colonoscopy	12 (10.1)	3 (10.7)		
Endoscopy + Colo- noscopy	15 (15.5)	8 (34.8)		
Co-morbidity				
Yes	8 (13.8)	2 (7.1)	0.74	
No	50 (86.2)	26 (92.9)		

STAI: Spielberger State-Trait Anxiety Inventory

Co-morbidity: Hypertension, Diabetes mellitus, Asthma, Rheumatoid arthritis, Crohn's disease, Dysrhythmia

# Discussion

In this study, the follicular and luteal phases of the menstrual cycle had similar effects on pre-procedural anxiety. The need for sedative medication is also similar in patients in both phases. The mean pre-procedural anxiety score for patients in the follicular phase was 44.81 and 40.71 for those in the luteal phase. These values are in line with previous studies in which preoperative anxiety levels were measured using the STAI anxiety scale. Sargin et al. investigated pre-procedural anxiety levels for upper gastrointestinal endoscopy in a study of 300 patients and found a mean anxiety score of 44 according to the STAI scale (16). Deliktaş et al. reported a mean anxiety score of 40.8±5.1 in their study including 250 patients (17).

Procedural sedoanalgesia for GI endoscopy is also strongly recommended by major international scientific guidelines. Among all invasive procedures, GI endoscopic procedures cause the most patient discomfort, fear, and pain (18). There are also studies indicating that endoscopy-related anxiety is higher in women than in men (19, 20). Anxiety disorders are generally more prevalent in women than men. There is strong evidence for sex hormone fluctuations in women as the major biological factor leading to gender differences in anxiety risk (21). Research indicates that the menstrual cycle modulates the severity and expression of anxiety symptoms (1, 9). Women prone to experience anxiety showed more panic responses during the luteal phase, when progesterone levels are elevated, compared to the follicular phase, when progesterone levels are lower (9). In contrast to these results, in our study women in the luteal phase and follicular phase had similar STAI-X1 scores. Most human studies have shown a positive relationship between progesterone and anxiety, while some studies have shown that progesterone increases in response to stressors (22-24). For example, Wirth et al. showed that fear of social rejection increased progesterone levels in their study (24). In a study that divided the cycle into menstrual, proliferative, and secretory and examined preoperative anxiety scores in patients undergoing tooth extraction, it was reported that patients in the secretory phase (the phase when progesterone is high) had the highest anxiety (25). Unlike our study, in this study, the luteal phase was taken as 14 days, while we only included patients between 18-24 days. The difference in methodology in the determination of menstrual cycle days in the studies on this subject in the literature causes the results to be different (1).

It has been reported that psychological symptoms are

usually exacerbated during the late luteal/premenstrual and early follicular phases of the menstrual cycle when estradiol and progesterone are low or decreased (13). In our study, patients in the late luteal/premenstrual phase were excluded but those in the early follicular phase were included. This may explain the relatively high STAI-X1 score of follicular phase patients in our study, which was not statistically significant.

While some studies have reported that anxiety increases with increasing educational levels, some studies have reported that educational status does not affect the degree of anxiety. In our study, no relationship was found between educational level and anxiety (26, 27).

Similar to our study results, studies comparing anxiety scores in upper gastrointestinal endoscopy and colonoscopy did not find any difference in anxiety between both procedure groups (28, 29).

There is a growing demand by both clinicians and patients to perform the procedure with sedoanalgesia to reduce the anxiety and pain associated with these invasive procedures and make them tolerable. Propofol and fentanyl are generally preferred for sedoanalgesia in our clinic. In our study, the need for sedoanalgesia in patients in the luteal phase was found to be similar to the follicular phase although there are studies showing that the need for anesthesia decreases during the luteal phase when progesterone levels are high (2, 3).

# Conclusion

Pre-procedure anxiety levels are not different in the follicular and luteal phases of the menstrual cycle.

### Conflict of interest

No conflict of interest was declared by the authors.

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