ORIGINAL RESEARCH ARTICLE

The effect of stress ball on anxiety and pain levels during endometrial biopsy: A randomized controlled trial

DOI: 10.29063/ajrh2025/v29i11.4

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Abstract

This study aims to evaluate the effect of using a stress ball on anxiety and pain levels during the endometrial biopsy procedure. The impact of stress ball use on vital sign scores was also assessed as a secondary objective.The sample of this randomized controlled study design consisted of 70 women (stress ball group n = 35 and control group n = 35). Data collection tools included the Personal Information Form, Visual Analog Scale (VAS) for Pain and Anxiety, State-Trait Anxiety Inventory (STAI), and a Satisfaction Form. The primary outcome showed no statistically significant difference in mean anxiety scores between the stress ball and control groups during the procedure (Wilcoxon test, W = -1.045, p = 0.296). As a secondary outcome, a significant decrease in heart rate was observed in the control group before and after the procedure. Additionally, reductions in anxiety levels were associated with corresponding decreases in pain scores. The reduction in anxiety levels during endometrial biopsy correspondingly decreased the pain that was experienced. Nonetheless, the utilization of a stress ball shown no statistically meaningful impact on decreasing anxiety, stress, or pain. *(Afr J Reprod Health 2025; 29 [11]: 47-56).*

Keywords: Endometrial biopsy, stress ball, anxiety, pain, nursing

Résumé

Cette étude vise à évaluer l'effet de l'utilisation d'une balle anti-stress sur l'anxiété et la douleur pendant la biopsie endométriale. L'impact de l'utilisation d'une balle anti-stress sur les signes vitaux a également été évalué comme objectif secondaire. L'échantillon de cette étude contrôlée randomisée était composé de 70 femmes (groupe balle anti-stress n = 35 et groupe témoin n = 35). Les outils de collecte de données comprenaient le formulaire de renseignements personnels, l'échelle visuelle analogique (EVA) pour la douleur et l'anxiété, l'inventaire d'anxiété état-trait (STAI) et un formulaire de satisfaction. Le critère d'évaluation principal n'a montré aucune différence statistiquement significative des scores d'anxiété moyens entre le groupe balle anti-stress et le groupe témoin pendant l'intervention (test de Wilcoxon, W = -1,045, p = 0,296). Comme critère d'évaluation secondaire, une diminution significative de la fréquence cardiaque a été observée dans le groupe témoin avant et après l'intervention. De plus, la réduction de l'anxiété était associée à une diminution correspondante des scores de douleur. La réduction de l'anxiété pendant la biopsie endométriale a également diminué la douleur ressentie. Néanmoins, l'utilisation d'une balle anti-stress n'a montré aucun impact statistiquement significatif sur la réduction de l'anxiété, du stress ou de la douleur. *(Afr J Reprod Health 2025; 29 [11]: 47-56).*

Mots-clés: Biopsie endométriale, balle de stress, anxiété, douleur, soins infirmiers

Introduction

Endometrial biopsy is a safe and effective method used to evaluate the endometrium for various indications.[1,2]This procedure, which is particularly specific for diagnosing atypical hyperplasia and endometrial cancer in women, is typically performed using an endometrial biopsy catheter (pipel) inserted through the cervix into the uterine cavity.[2]Although often a routine office procedure conducted on an outpatient basis, an endometrial biosy can cause discomfort and pain, which many women describe as moderate to severe.[1]

Since the pain experienced by a woman during the procedure can be influenced by numerous factors, ongoing research continues to explore ways to manage this pain through both pharmacological and non-pharmacological treatment methods.[3] For groups experiencing high levels of pain, intrauterine anesthesia is suggested as an appropriate pain management option, though it is noted that there is insufficient evidence from

studies designed for longer procedures to fully support this approach.[4,5]

Whether an event is perceived as stressful depends on the nature of the event and the individual's coping and defense mechanisms.[6] As stress affects many aspects of life, people require strategies to manage it.[7,8]

The use of a stress ball is a non-pharmacological method employed to distract attention, reduce stress and anxiety, and assist with anger management.[2,7,8,9] This tool, approximately seven centimeters in diameter, has become a popular choice for stress relief.[7,8,10] By serving as a distraction tool, it helps reduce stress in much the same way as activities like pencil breaking, meditation, listening to music and Video-based Multimedia .[7,10,11] Although limited in number, studies supporting such a mechanism suggest that the stress ball acts as a stimulus for consciously focused individuals.[7,8,9,12,13]The stress ball, an inexpensive and simple method believed to protect mental health, also helps improve circulation.[7,8,9,14] In light of this information, the current study was designed to evaluate the effect of using a stress ball on anxiety and pain levels during endometrial biopsy . The impact of stress ball use on vital sign scores was also considered a secondary objective.

Methods

This randomized controlled trial was conducted at a hospital in Zonguldak, Turkey, which houses the Departments of Obstetrics and Gynecology, Pediatric Health and Diseases, Pediatric Surgery, and Child and Adolescent Mental Health. On average, 15 endometrial biopsies are performed each week. The study procedures were carried out by two experienced physicians.

The study population included women who presented to the institution where the study was conducted for an endometrial biopsy between August and October 2023. The sample consisted of women willing to participate, were 18 years or older, could read and write in Turkish, and had no condition preventing them from squeezing a ball (for the Stress Ball group). Exclusion criteria included having an active mental illness that would interfere with data collection or the development of an emergency or risky condition during the procedure that would prevent data collection.

This randomized trial has been registered (ClinicalTrials.gov Identifier: NCT06171581).

The sample size was calculated using G*Power based on Sert's (2020) study, which reported an effect size of 0.39 for state anxiety scores. With an alpha of 0.05 and a power of 0.80, a total of 54 participants (27 per group) were required. [6] To account for potential dropout, 35 women were assigned to each group, resulting in a total planned sample of 70 participants.

Randomization

The sample was randomized using the 'Research Randomizer' computer program. A simple randomization method was applied: numbers between 1 and 70 were generated and participants were sequentially assigned to the Stress Ball group (n = 35) or the Control group (n = 35) (Figure 1).

Data collection

The stress ball intervention was chosen based on the anticipation that women might experience significant anxiety and stress during the endometrial biopsy procedure. The study was conducted at a single center, specifically in a gynecology ward of a maternity hospital, where conditions were standardized by using a standard gynecological examination table in the delivery room under the supervision of two specialist physicians in the research team. No medication was used for cervical ripening, and no analgesics were administered during the procedure. The stress ball used in this study is a handheld toy made of closed-cell polyurethane foam, approximately 7-8 cm in diameter, with a soft texture that can be squeezed by fingers to relieve muscle tension. Each ball was disinfected after use in the Stress Ball group, and any worn or damaged ball was replaced with a new one.

Stress ball group*:* Participants in the Stress Ball group were instructed to squeeze the stress ball as often as they wished during the endometrial biopsy procedure, which typically lasted 8-10 minutes. During this process, the stress ball intervention was applied. Prior to the procedure, women completed pre-test forms, including the "Personal Information Form," "State and Trait Anxiety Inventory," and "Visual Analog Scale (VAS-A)."

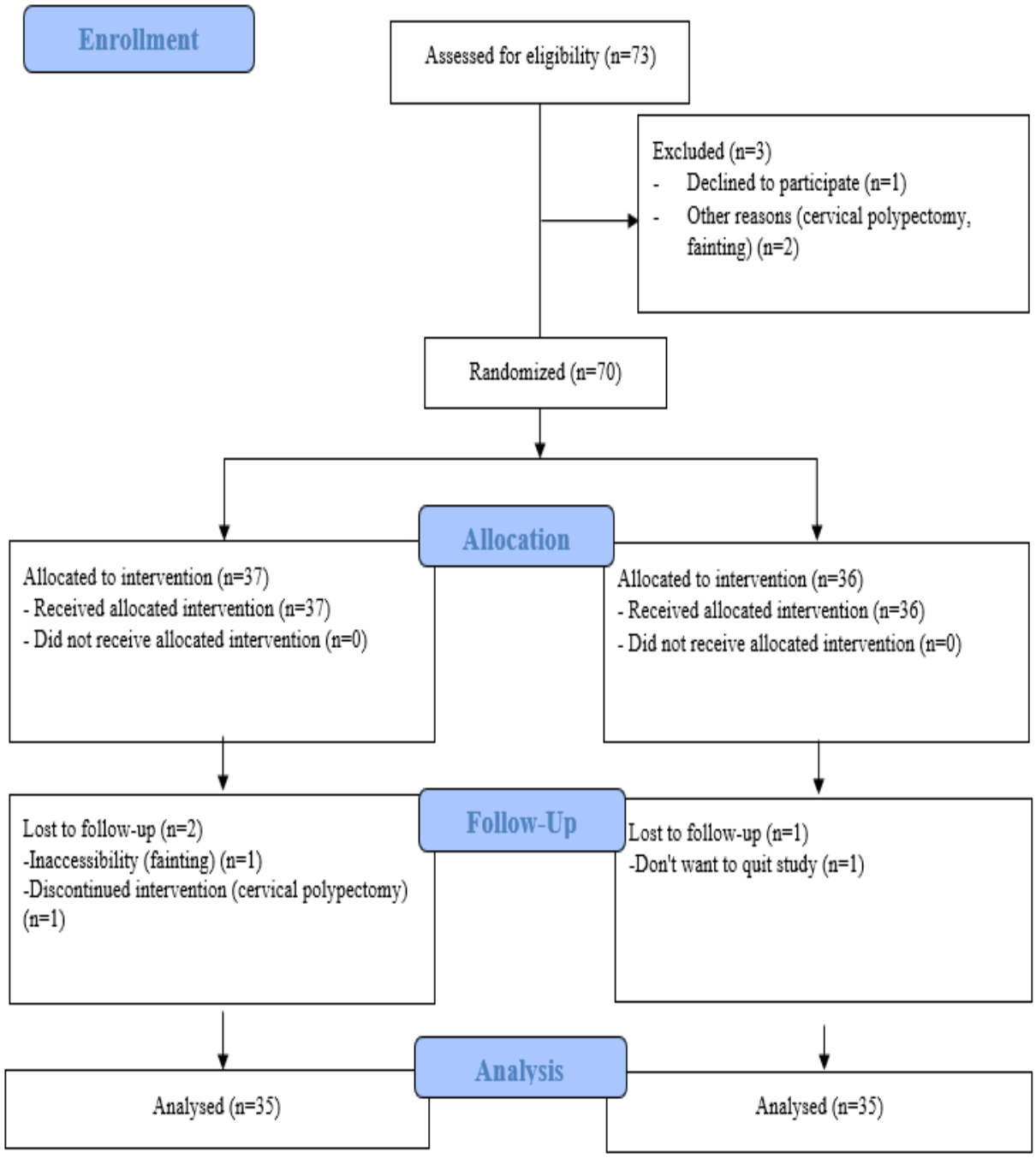

Figure 1: Consort flow diagram of women participating in the survey

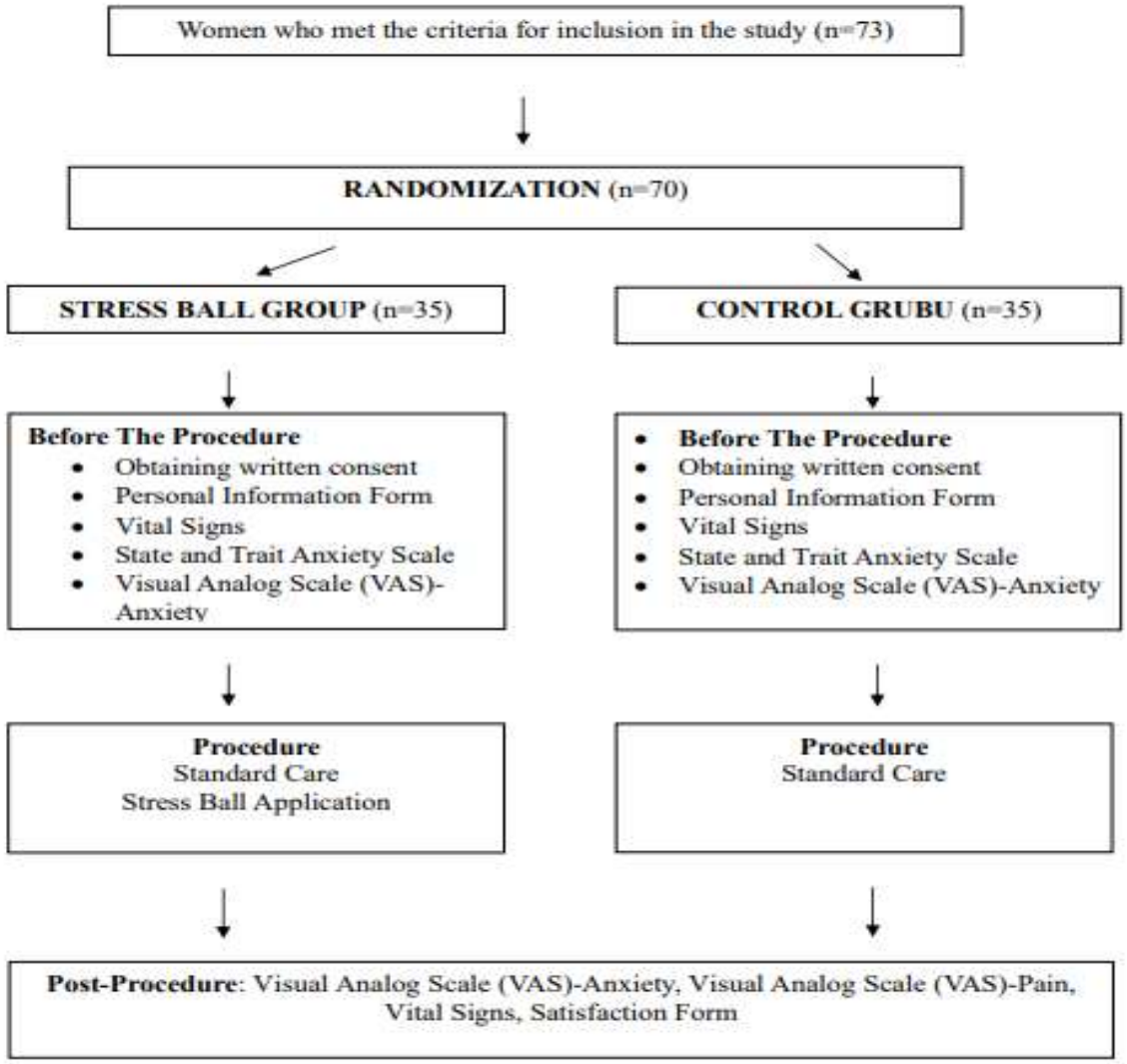

Figure 2: Intervention steps of the research

The "Visual Analog Scale (VAS, VAS-A)" and vital signs were assessed as post-test measures during and after the biopsy. Women were accompanied by a nurse standing beside the gynecological examination table during the procedure, who reminded them to squeeze the ball and provided standard nursing care. After the procedure, the "Satisfaction Form" was administered to assess the women's satisfaction levels (Figure 2).

Control group*:* No intervention was applied beyond standard nursing care during the endometrial biopsy procedure in the control group. Women completed pre-test forms, including the "Personal Information Form," "State and Trait Anxiety Inventory," and "Visual Analog Scale (VAS-A)," before the procedure. The control group's post-test measures included a reassessment of the "Visual Analog Scale (VAS, VAS-A)" and vital signs during and after the biopsy procedure. Women were accompanied by a nurse standing beside the gynecological examination table during the procedure, where standard nursing care was provided. After the procedure, the "Satisfaction Form" was administered (Figure 2).

Data collection tools

Personal ınformation form*:* This form, It includes socio-demographic, obstetric, gynecological history

as well as vital signs before and after the procedure.[8,15]

Visual Analog Scale (VAS): The VAS is a straight line used for approximately 60 years to measure the variability of pain, indicating the continuity of pain. The same scale has also been used to determine anxiety levels (VAS-A) . The distance in centimeters between the marked point and the lowest end of the line (0=no pain) provides a numerical value representing the intensity of the patient's perceived pain. A score of 0 indicates the lowest pain level, while a score of 10 indicates the highest pain or anxiety level. [16,17]

State-trait anxiety ınventory (STAI): The State Anxiety Inventory was developed by Spielberger, Gorsuch, and Lushene in 1970 and was validated and adapted into Turkish by Öner and Le Compte (1985)[18]. The STAI consists of two parts, each containing 20 questions, for a total of 40 questions. The first 20 questions measure state anxiety, while the last 20 questions measure trait anxiety. In this study, the results from the state anxiety section were used. The State Anxiety Inventory requires individuals to describe how they feel at a particular moment and under specific conditions. The scale includes ten reverse-scored items (Items 1, 2, 5, 8, 10, 11, 15, 16, 19, and 20). The Cronbach's alpha value for this scale was calculated as 0.89 in the current study.

Satisfaction form: This form, created by the researchers, valuates the satisfaction of the participants regarding the applications performed.

Statistical analysis

The data obtained from the study were analyzed using the SPSS (Statistical Package for Social Sciences) version 25.0 software. Descriptive statistics—such as frequency, percentage, arithmetic mean, standard deviation, and minimum and maximum values—were calculated. The normality of continuous variables was assessed using the Shapiro-Wilk test and visual inspection of histograms and Q-Q plots. Homogeneity of categorical variables between groups was examined using the chi-square test. Since the data were not normally distributed, the Mann-Whitney U test was used to compare the means of the two groups. The Wilcoxon test was applied for repeated measurements within dependent groups to analyze the VAS-Anxiety total and vital sign scores. Spearman's rank correlation coefficient was used to determine the correlation between the mean VAS-Anxiety and VAS-Pain total scores during the procedure. The results obtained from the data analysis were evaluated at a significance level of $p < 0.05$ with a 95% confidence interval.

Ethical approach

Before the study was conducted, ethical approval was obtained from the Non-Interventional Clinical Research Ethics Committee of the relevant university and the hospital (Date: 19.07.2023, No: 2023/14). Institutional permission dated 11.08.2023 was obtained from the institution where the study would be conducted. Written informed consent was obtained from the women participating in the study

Results

The chi-square analysis conducted to examine the homogeneity of the research groups revealed a statistically significant difference between the Stress Ball and control groups regarding employment status ($X^2=9.130$, $p=0.003$). While there was no significant difference between the groups in terms of other characteristics, it was homogeneously distributed. (Table 1).

Within the Stress Ball group, no significant change in anxiety was observed during the procedure ($W = -1.045$, $p = 0.296$), whereas the Control group showed a significant increase from pre- to post-procedure ($W = -2.877$, $p = 0.004$). Despite this, no significant difference was found between the Stress Ball and Control groups in anxiety levels before or after the procedure. Total mean scores of the State-Trait Anxiety Inventory (STAI) before the biopsy did not differ between groups ($z^a = 583.500$, $p = 0.733$). Similarly, pain scores during the procedure were not significantly different between groups ($z^a = 503.000$, $p = 0.195$) (Table 2).

Table 3 summarizes vital sign results. Repeated measures analysis indicated no significant within-group differences. However, post-procedural pulse was significantly lower in the Stress Ball group compared to the Control group ($z^a = 438.500$, $p = 0.041$). (Table 3). A statistically significant correlation was found between the post-procedural VAS-Anxiety and VAS-Pain mean total scores in the Stress Ball group ($r=0.35$, $p=0.040$) (Table 3).

Table 1: Comparison of identifying characteristics of women

Identifying Characteristics	Stress Ball Group Mean±SD		Control Group Mean±SD		X^2	p-value
Age, Years	45.94±9.66		44.89±7.73		13.900	0.974
	n	**%**	**n**	**%**		
Education Status						
Primary school	16	45.7	25	71.4	5.147	0.076
High school	10	28.6	4	11.4		
Bachelor's degree and Master's degree	9	25.7	6	17.1		
Employment Status						
Yes	18	51.4	6	17.1	**9.130**	**0.003***
No	17	48.6	29	82.9		
Income Levels						
Low	4	11.4	7	20.0	1.836	0.399
Middle	3	8.6	1	2.9		
High	28	80.0	27	77.1		
Operation Experience						
Yes	13	37.1	14	40.0	0.060	0.806
No	22	62.9	21	60.0		
Curettage Experience						
Yes	8	22.9	6	17.1	0.357	0.550
No	27	77.1	29	82.9		
Gynecological Operation Experience						
Yes	6	17.1	7	20.0	0.094	0.759
No	29	82.9	28	80.0		
Biopsy Experience						
Yes	11	31.4	9	25.7	0.280	0.597
No	24	68.6	26	74.3		
	Mean±SD		**Mean±SD**			
Pregnancy Count	2.46±1.24		2.86±1.51		3.733	0.810
Stillbirth Count	0.14±0.35		0.06±0.23		1.429	0.232
Curettage Count	0.17±0.38		0.17±0.45		1.417	0.492
Abortion Count	0.20±0.47		0.34±0.72		1.405	0.704
Normal/Vaginal Delivery Count	1.43±1.19		1.51±1.44		3.111	0.795
Cesarean Delivery Count	0.54±0.78		0.80±1.05		2.296	0.681
	n	**%**	**n**	**%**		
Knowledge of the Reason for and Procedure of the Endometrial Biopsy						
Yes	31	88.6	30	85.7	0.128	0.721
No	4	11.4	5	14.3		
Reasons for Endometrial Biopsy* **						
Abnormal uterine bleeding	20	57.1	24	68.6	2.134**	0.536
Endometrial thickening	5	14.3	3	8.6		
Presence of polyps or fibroids	5	14.3	2	5.7		
Cancer screening	1	2.9	1	2.9		

Note: *p<0.05, **Fisher's exact test, *** n values not evaluated based on 100%.

Table 2: Distribution of pre- and post-procedure mean total scores of VAS-Anxiety, STAI, and VAS-pain in the stress ball and control groups

	Measurements	Stress Ball Group Mean±SD	Control Group Mean±SD	z^a	p-value
VAS-Anxiety Mean Total Score	Pre-Procedure	6.51±2.99	6.94±3.37	537.500	0.370
	Post-Procedure	5.51±3.60	4.69±2.54	527.000	0.312
		W=-1.045, p=0.296	**W=-2.877, p=0.004***		
STAI Mean Total Score	Pre-Procedure	39.06±6.15	38.60±5.45	583.500	0.733
VAS-Pain Mean Total Score	Post-Procedure	6.06±2.79	5.11±3.15	503.000	0.195

Note: SD: Standard Deviation, z^a: Mann-Whitney U test, W: Wilcoxon test,*p<0.05

Table 3: Distribution of pre- and post-procedure mean total scores of vital signs in the stress ball and control groups

	Measurements	Stress Ball Group Mean±SD	Control Group Mean±SD	z[a]	p-value
Systolic Blood Pressure	Pre-Procedure	113.14±12.312	116.57±13.49	518.500	0.256
	Post-Procedure	113.03±22.22	112.46±22.94	604.000	0.918
		W=-0.952, p=0.341	W=-0.340, p=0.734		
Diastolic Blood Pressure	Pre-Procedure	73.43±8.72	76.03±9.74	496.500	0.147
	Post-Procedure	77.14±8.59	74.80±15.47	550.000	0.432
		W=-1.696, p=0.090	W=-0.034, p=0.973		
Pulse	Pre-Procedure	81.51±10.15	81.69±15.38	561.000	0.545
	Post-Procedure	80.23±12.31	84.31±19.16	**438.500**	**0.041***
		W=-0.664, p=0.507	W=-1.093, p=0.274		
Respiration	Pre-Procedure	18.89±2.29	19.57±2.46	493.000	0.141
	Post-Procedure	20.74±7.89	19.14±3.41	610.500	0.980
		W=-1.418, p=0.156	W=-0.747, p=0.455		

Not: SD: Standard Deviation, z[a]: Mann-Whitney U test, W: Wilcoxon test, *p<0.05

Table 4: Correlation between post-procedure vas-anxiety and vas-pain mean total scores in the stress ball and control groups

VAS-Anxiety		Stress Ball Group	Control Group
VAS-Pain	Post-Procedure	**r=0.35, p=0.040***	r=0.06, p=0.747

Note: r: Spearman Correlation Coefficient, *p<0.0

A statistically significant correlation was found between the post-procedural VAS-Anxiety and VAS-Pain mean total scores in the Stress Ball group (r=0.35, p=0.040) (Table 4).

Both groups reported 100% satisfaction with the care and support received during the procedure and reported no discomfort during the procedure.Women in the Stress Ball group expressed that the intervention was effective in reducing their stress and recommended that others benefit from this practice.

Discussion

While there are some experimental studies in the literature focusing on pain, anxiety, and stress levels during hysteroscopy a procedure some what similar to endometrial biopsy,[5,19,20-22]experimental studies explicitly focusing on pain, stress, and anxiety during endometrial biopsy are limited.[3,6,11,23] This study is the first known study to evaluate the effects of using a stress ball on anxiety, state-trait anxiety, pain, and vital signs during an endometrial biopsy procedure.

According to the results of the current study, it was found that the post-procedural anxiety scores of women in the control group were significantly lower than those in the Stress Ball group. Anxiety and pain are variables that can influence each other. In a meta-analysis by Vitale *et al*., it was found that the pain experienced during hysteroscopy was negatively affected by pre-procedural anxiety and the waiting period.[5] Another study indicated that previous biopsy experience influenced the pain and procedural processes.[1]

Our study observed that a higher percentage of women in the Stress Ball group were employed compared to the control group.. The prevalence of unreliable sources on the internet can make it difficult to access accurate information, while exposure to platforms that share negative experiences on the subject may further contribute to increased anxiety. This situation may have contributed to an increase in women's knowledge and awareness of gynecological screening, diagnosis, and treatment methods due to their employment status. However, the extent of these women's access to the internet and information, as well as their internet usage skills, remains unknown. The abundance of unreliable sources on the internet can hinder access to accurate information. Moreover, anxiety may result from exposure to platforms where negative experiences on the subject are shared. Therefore, it is assumed that the anxiety levels of women in the stress ball group increased during the endometrial biopsy process.

In our study, it was determined that the use of a stress ball during the endometrial biopsy procedure did not make a significant difference in terms of anxiety, pain, and state-trait anxiety before and during the procedure. However, as expected, it was found that as the anxiety level of the women decreased, the level of pain they experienced also decreased. Contrary to our results, a study focusing on developing a vibrating stress ball prototype involving tactile coordination found that squeezing the stress ball for 20 seconds had a stress-relieving effect and reduced anxiety.[24]

Limited number of studies with different designs show positive effects of stress ball use on anxiety, pain and discomfort.[7-10,24-26] In Tosun *et al*.'s study it was reported that the effectiveness of the ball on pain intensity increased with the prolongation of ball use in multiple sessions.Pain and discomfort are not always emotionally neutral experiences; they can often be accompanied by emotional distress and discomfort.[22, 27,28, 29]

In our study, some women may have experienced increased anxiety due to the decision to perform a biopsy during a routine examination, receiving insufficient information, and being kept waiting for a long time due to institutional workload. For women who believed or experienced that the procedure might be painful or frightening, squeezing the ball may have raised expectations for pain relief. Additionally, it is thought that the women in the control group who tended to grip the arms of the gynecological table during the procedure may have experienced a similar effect to squeezing the stress ball.

While it was determined that there was no significant difference in terms of vital signs between the two groups, when assessing post-procedural pulse readings, it was found that the control group had higher pulse values compared to the stress ball group. In a study design applying stress ball use and hand-holding techniques during skin cancer excision, no changes in physiological markers were observed before and after the procedure.[30] Since no studies on the impact of stress ball use on vital signs during endometrial biopsy were found in the literature, a direct comparison could not be made.While there are studies reporting that nurse support and listening to music during hysteroscopyreduces heart rate and blood pressure,[22,31] the opposite result was reported with a virtual reality glasses study.[19]

Similar to previous studies, this study also determined that nursing support has a positive effect on patient satisfaction.[6,31,32] In the institution where this study was conducted, patients are not accompanied by a nurse to provide explanation and support during the endometrial biopsy. Instead, a midwife assists the physician during the procedure. However, because the procedure is usually very quick, patients often receive little psychological preparation or support. These results highlight the importance of informing patients about the procedure and offering supportive care to reduce their anxiety and ensure comfort.

Limitations

The primary limitation of our study is that it was conducted in a single region and institution. As a result, our findings cannot be generalized to all women due to Turkey's geographic and cultural diversity. It is recommended that this study be replicated with similar sample groups, in different designs, and over a more extended period.

Conclusıon

According to the results of this study, the use of a stress ball during the endometrial biopsy procedure has no significant effect on anxiety, pain, or situational anxiety levels and on vital signs before and after the procedure.

There were no significant changes in vital signs before and after the endometrial biopsy procedure, although the control group showed higher pulse rates after the procedure. Given this potential effect, stress balls could be considered a complementary tool in practice, and further comprehensive studies are needed to explore this issue.

In terms of national health policies, the disproportionate number of patients compared to the available physicians and nurses reduces the effectiveness of interventions. Delivering individualized patient education in societies with diverse geographic and cultural contexts is crucial for improving the quality of care. Moreover, informing outpatient healthcare teams in ways that account for patients' sociocultural backgrounds will facilitate safer and more effective implementation of screening and diagnostic interventions.

Health policies should also be strengthened and expanded to ensure the consistent provision of effective care and education.
Health policies should be developed to ensure effective care and education during interventions.

Competing interests

The authors report no actual or potential conflicts of interest.

Funding

No external or intramural funding was received.

Acknowledgements

We thank all the women who agreed to participate in the study.

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Editing and approval of final draft: Dinçer Y, Şanlı Y, Aypar Akbag NN, Karadeniz M, Dalay O.

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