

ORIGINAL RESEARCH

Effects of Valsalva Maneuver, EMLA Cream, and Stress Ball for Pregnant Women's Venipuncture Pain

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ABSTRACT

Context • Peripheral intravenous catheter (PIVC) practice is a common invasive procedure used in the diagnosis and treatment of pregnant women admitted to the hospital. Difficulties experienced during PIVC application are among the most common problems encountered in a medical facility.

Objective • The study intended to evaluate the effects of the Valsalva maneuver, the application of eutectic mixture of local anesthetics (EMLA) cream, and use of a stress ball in controlling the pain and discomfort that developed due to PIVC administration for pregnant women.

Design • The research team designed the study as a randomized, controlled, single-blind trial.

Setting • The research took place at the obstetrics clinic at the Practice and Research Hospital at Yozgat Bozok University in Yozgat, Turkey, between January 2019 and February 2020.

Participants • Participants were 120 pregnant women who visited the obstetrics clinic and were admitted to the maternity ward of the hospital during that time.

Intervention • Participants were divided into four groups of 30 women each: (1) the Valsalva maneuver group, (2) the EMLA group, receiving an application of the cream, and (3) the stress-ball group, and (4) the control group.

Outcome Measures • Data were collected through the use of a pregnancy information form and a visual analog scale. In the assessment of the data, variance analysis was used with the Kruskal Wallis and Dunn test.

Results • Only the pain scores of the Valsalva maneuver group were found to be significantly lower than those of the control group, whereas the pain scores of the EMLA and stress-ball groups were similar to those of the control group.

Conclusions • The current study can generate awareness in pregnant women in terms of choosing between pharmacological and nonpharmacological practices that nurses use during PIVC insertion. As the only randomized controlled blind study that has been performed on the topic, the current study offers nurses evidence of a way to reduce PIVC pain in pregnant women. (*Altern Ther Health Med.* 2021;27(5):108-114).

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Peripheral intravenous catheter (PIVC) practice is a common invasive procedure used for diagnosis and treatment of pregnant women admitted to the hospital.¹ PIVC is often conducted to collect blood samples from pregnant women, to

provide frequently required intravenous hydration, to stop bleeding during delivery, and to administer antibiotics and oxytocin.² Difficulties experienced during PIVC application are among the most common problems encountered in a medical facility.

If patients have existing pathologies, pain can increase their levels of anxiety,^{3,4} which can affect homeostasis.⁵ To reduce the pain and discomfort from PIVC practice, meticulous evaluation of an individual, taking various measures and implementing an efficient method should occur. These may include diverting attention or using pain-relieving pomades to comfort individual.^{6,7}

According to the Infusion Nurses Association (INS), special groups—such as newborns, children, pregnant women, and older people—should receive appropriate and customized treatment.² The dilatation of distal veins in

pregnant women due to peripheral edema in the later phases of pregnancy and the anatomical and physiological differences between women could increase pain during PIVC practice. Pregnant women's differences should be considered when performing PIVC practice to ensure the successful insertion of PIVCs, avoid the experience of pain, lower the anxiety of both the nurse and the patient, and increase in the safety of pregnant patients.

Pharmacological and complementary and alternative medicine (CAM) can be used to control the pain and discomfort experienced during PIVC administration. Pharmacological methods mostly consist of the application of a eutectic mixture of local anesthetics (EMLA) cream, such as ethyl chloride or lidocaine, that a physician requests.⁸⁻¹⁰ These pharmacological methods are effective in controlling pain but also may produce negative consequences, such as side effects, additional time, and higher costs. It takes a certain period of time for the pain relieving pomade to show its effectiveness and it takes cost to obtain the cream.^{11,12}

On the other hand, CAM can be part of a comprehensive pain-reduction approach, in support of standard pharmacological treatments for pain relief. While pharmacological treatments can have an impact upon somatic pain, CAM methods mostly affect the emotional, cognitive, behavioral, and sociocultural dimensions of pain.^{13,14} In addition, these methods can have positive impacts on reducing the anxiety of individuals undergoing PIVC insertion and on providing mental support to those individuals.¹³

Nurses within a health team have a vital and indispensable role in pain control. They learn methods of coping with pain of nursing undergraduate education and previous pain experience of patients, teach patients coping strategies, guide patients in use of the strategies, practice the planned treatment, monitor the effects and results of treatment, and provide an empathic approach and offer sympathy.¹³

Because of this role, nurses must be able to correctly evaluate effective and advanced practices and pain reduction and relief methods in terms of patient outcomes.^{15,16}

Some CAM methods that can help reduce pain and anxiety during PIVC insertion include squeezing a stress ball and the Valsalva maneuver. The Valsalva maneuver is a breathing method that can slow the heart when it's beating too fast. In this maneuver, the individual breathes out strongly through his or her mouth while holding his or her nose tightly closed. This creates a forceful strain that can trigger the heart to react and go back into normal rhythm.

The number of studies that show a decrease in pregnant women's pain during PIVC administration is quite limited and not at a level that has generated compelling evidence for clinical application. Suren et al's randomized controlled study found that the Valsalva maneuver showed results similar to EMLA cream in reducing pain during PIVC insertion.⁹

The technique of drawing attention in another direction, such as by squeezing a stress ball, is a nonpharmacological method based on the assumption that individuals can

participate in a stimulus only if they consciously focus on it.¹⁷ Another potential mechanism of this method, which is assumed to reduce pain by directing an individual's attention toward a nonpainful stimulus, is the activation of segmental pain inhibitor mechanisms. In this form of pain inhibition, pain is decreased based on motion. For example, pain is responded by moving the aching area. The motion created in the joints is create an inhibitory response to the pain.

However, Agarwal et al's randomized controlled study with seventy-five adult patients examined the effects of squeezing a stress ball and blowing sphygmomanometers during PIVC administration. In this blowing sphygmomanometers the individual breathes out strongly through his or her mouth while holding his or her nose tightly closed. The same as vallalva maneuver to blowing sphygmomanometers mechanism. Those researchers found that 100% of the control group and the stress ball group and 72% of the sphygmomanometer group experienced pain during the practice.¹⁸

Kilic and Oztunc's controlled study with pregnant women compared the use of a stress ball and the Valsalva maneuver.¹² That study found that the pain score of the stress ball group was similar to that of the control group, but the pain scores in the Valsalva group were lower.

Gupta et al's randomized controlled study examined the effects on stress and anxiety of balloon inflation based on the Valsalva maneuver and those of drawing attention in another direction during the insertion of PIVC; 100% of the participants in the control group and the stress ball group and 56% of patients in the balloon inflator group experienced pain during the intervention.¹⁹

Vijay et al evaluated the benefits of sphygmomanometer blowing based on the Valsalva maneuver for 20 seconds during PIVC insertion and found that the Valsalva group's pain score, at 2.98 cm on a Visual Analog Scale VAS, was significantly lower than the control group's pain score, at 4.7 cm.²⁰ Kumar et al found that a cough application based on Valsalva maneuver had a positive impact on reducing pain.²¹

The current study intended to evaluate the effects of the Valsalva maneuver, the application of EMLA cream, and use of a stress ball in controlling the pain and discomfort that developed due to PIVC administration for pregnant women.

METHODS

Participants

The research team designed a randomized, controlled, single-blind study. It was performed in the obstetrics clinic at the Practice and Research Hospital at Yozgat Bozok University in Yozgat, Turkey, between January 2019 and February 2020. The participants were pregnant women who visited the obstetrics clinic and were admitted to the maternity ward of the hospital during that time.

Potential participants were included in the study if they: (1) were pregnant, (2) would be able to complete a visual analogue scale (VAS) accurately, and (3) were willing to participate in study.

Potential participants were excluded from the study if they: (1) had heart or lung disease; (2) had been diagnosed with glaucoma; (3) had phlebitis, scar tissue, dermatitis, an incision, or an infection in the insertion area; (4) had any disease that could affect the perception of pain; (5) had a vision and/or hearing problem; or (6) had adaptation of location and time.

The research team found 203 potential participants, of whom 57 were excluded, 32 for not meeting the inclusion criteria, 17 for declining to participate, and 8 for other reasons.

All participants were informed about the type, purpose, and application process of the research before the PIVC application and were asked for permission for participation verbally and in written form.

Approval for the research was received from the ethics committee of the Clinical Research Ethics Committee of the Faculty of Medicine, and institutional approval was received from the Health Practice and Research Center.

Procedures

Sample size. The number of participants was computed with reference to a similar study in the literature, based on a 0.80 power level, 0.05 error level, and 0.25 effect level.⁹ It was determined that 56 participants should be included in the sample. The research team sought 203 pregnant women, which was determined to be within the scope of the study.

Randomization. The assignment of pregnant women to one of four groups was determined by a randomization program that generated a randomization list on the computer.²²

PIVC insertion. PIVC application is a peripheral venous catheter placement for drug administration into the vein. The nurse chooses the vein he deems appropriate for this procedure and applies the catheter to the vein with the skill he gained in his undergraduate education. It is always the most successful to enter the vein in the first attempt. because the more the number of trials, the more pain the patient feels.

Intervention. Participants were divided into four groups of 36 women each: (1) the Valsalva group, who performed the Valsalva maneuver; (2) the EMLA group, who received an application of the cream, (3) the stress-ball group, who squeezed a stress ball, and (4) the control group, who received no cream and performed no action during the PIVC insertion. The stress ball was approximately 6 cm in diameter with a soft texture that was made of polyurethane (PU) material; a yellow ball with a smiley-face pattern was used.

Outcome measures. The participants completed the outcome measures after the performance of the interventions and PIVC insertion was successfully completed. The implementation of each data-collection tool lasted about 15 minutes. The measures included the Pregnancy Identification Form and the Pain Severity and Satisfaction Perception Evaluation.

Intervention

In each group, at 10 minutes before cannulation, the participant's blood pressure and pulse were checked and

recorded, and the relevant intervention method was taught by the research team to each participant or the EMLA cream was applied. In the operating room, participants were placed in the supine position.

Valsalva maneuver. Participants in the Valsalva group performed the Valsalva maneuver during PIVC administration.

Stress ball. Participants in the stress-ball group were asked to squeeze and loosen the stress ball in the hand on the side of the intravenous administration, two minutes before the administration, and to continue this process until the PIVC insertion was completed.

EMLA cream. Following admission to the ward, the medical practitioner determined the location of the PIVC insertion for participants in the EMLA group, and 5% EMLA cream was applied and covered with a gauze patch. After waiting 60 minutes for the cream to take effect, the PIVC was applied to the same location after antiseptic cleaning.

Control group. Participants in the control group had no EMLA cream applied and performed no action during the PIVC insertion.

Outcome Measures

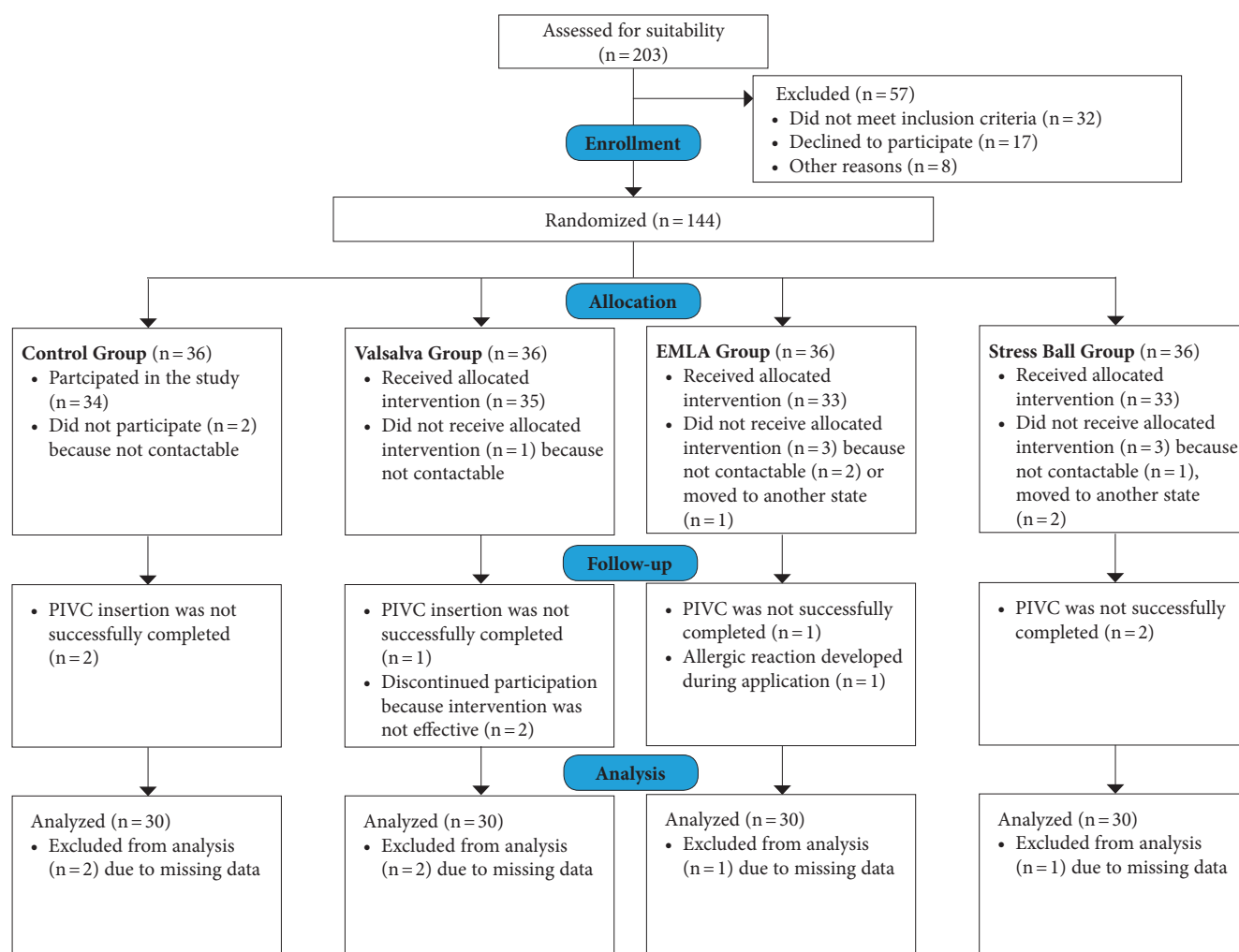
Pregnancy Identification Form. The first section of the pregnancy identification form, which consisted of two subsections, comprised questions that included age, gender, height, weight, BMI, medical diagnosis, gestational week, number of pregnancies, and admission and discharge dates. The form's second section, which the research team had prepared in line with the relevant literature,^{19,23-25} included such information as the anatomical location where the PIVC was inserted, the number of insertions, the number of insertions in the location used, and the antibiotics and fluids that were requested.

Pain Severity and Satisfaction Perception Evaluation. A visual analog scale (VAS) was used in the evaluation of pain severity and the perception of satisfaction. The VAS is a simple, effective, and repeatable tool, requires minimal material, and enables rapid measurement in a clinical setting. The VAS entails a 10-cm line, which is drawn horizontally or vertically. Subjective descriptive categories reside at both ends of the line—no pain or no satisfaction versus worst pain possible or satisfaction, respectively. The participant is asked to tick a mark on this line wherever the severity of pain or perception of satisfaction matches. The numerical value of the pain severity or the satisfaction level is obtained in cm or mm by measuring the distance between the lowest VAS level and the participant's mark with a ruler.²⁶

Statistical Analysis

The Statistical Package for Social Science for Windows (SPSS) 21.0, version 21.0, was a package program licensed by Bozok University for the analysis of the data. The results were found to have a confidence interval of 95% and a significance level of $P < .05$. The conformity of the numeric data to the normal distribution was analyzed with the Shapiro-Wilk test.

Figure 1. Participants' Flow Diagram for Peripheral Intravenous Catheter (PIVC) Insertion



Descriptive analyses—arithmetic mean, standard deviation, number, and percentile slice—were conducted in the analysis of sociodemographic data. One-way analysis of variance (ANOVA) was used for data with normal distribution in the comparisons of more than two groups, and the Kruskal Wallis test was used for nonnormally distributed data.

RESULTS

Participants

The study analyzed the data of 120 participants (Figure 1). Of the 36 participants in the control group, two weren't contactable after inclusion in the group, and for two others, PIVC insertion was not successfully completed. Of the remaining 32 participants, two were excluded from analysis due to missing date.

Of the 36 participants in the Valsalva group, one didn't receive the allocated intervention due to not being contactable after inclusion in the group. For one participant, PIVC insertion wasn't successfully completed, and two others discontinued participation because the intervention wasn't

effective. Of the remaining 32 participants, two were excluded from analysis due to missing data.

Of the 36 participants in the EMLA group, three didn't receive the allocated intervention, with two not being contactable after inclusion in the group and one having moved to another state. For one participant, PIVC insertion wasn't successfully completed, and one other discontinued participation because an allergic reaction developed during application. Of the remaining 31 participants, one was excluded from analysis due to missing date.

Of the 36 participants in the Stress Ball group, three didn't receive the allocated intervention, with two not being contactable after inclusion in the group, one having moved to another state. For two participants, PIVC insertion wasn't successfully completed. Of the remaining 31 participants, one was excluded from analysis due to missing data.

The characteristics of the pregnant women who participated in the study are presented in Table 1.

The mean age in the Valsalva group was 32.1 ± 9.14 years, with a mean BMI of 27.17 ± 3.21 kg/m² and a mean

Table 1. Distribution of Pregnant Women in Intervention and Control Groups According to their Descriptive and PIVC Characteristics

	Valsalva Group Mean ± SD Min-Max	Stress Ball Group Mean ± SD Min-Max	EMLA Cream Group Mean ± SD Min-Max	Control Group Mean ± SD Min-Max	KW Test P Value
Age, y	32.1 ± 9.14 20-48	28.2 ± 8.20 17-44	30.3 ± 8.86 18-48	29.4 ± 7.87 17-45	3.224 .358
BMI, kg/m²	27.17 ± 3.21 20-31	27.67 ± 3.04 20-34	28.61 ± 4.63 19-38	29.13 ± 4.47 19-38	4.352 .226
Gestational age	32.3 ± 4.59 24-40	33.5 ± 4.44 20-58	34.0 ± 5.46 26-40	33.6 ± 5.68 24-40	2.869 .412
	N (%)	N (%)	N (%)	N (%)	
Location of PIVC insertion					
Inner face of left forearm	17 (56.7)	17 (56.7)	19 (63.3)	13 (43.3)	1.917 .590
On the left hand	6 (20.0)	6 (20)	2 (6.7)	8 (26.7)	
Inner face of right forearm	4 (13.3)	2 (6.7)	6 (20.0)	6 (20.0)	
On the right hand	3 (10.0)	5 (16.6)	3 (10.0)	3 (10.0)	
Nurse success					
Trial 1	26 (86.6)	20 (66.7)	24 (80.0)	17 (56.7)	16.931 .001
Trial 2	4 (13.4)	9 (30.0)	5 (16.7)	11 (36.7)	
Trials 3 or more	0 (0.0)	1 (3.3)	1 (33.3)	2 (6.7)	

Abbreviations: PIVC, peripheral intravenous catheter; EMLA, eutectic mixture of local anesthetics; SD, standard deviation; KW, Kruskal-Wallis; BMI, body mass index.

Table 2. Distribution of Means for Postinsertion Pain in Intervention and Control Groups

Characteristics	Valsalva Group Mean \pm SD Min-Max	Stress Ball Group Mean \pm SD Min-Max	EMLA Cream Group Mean \pm SD Min-Max	Control Group Mean \pm SD Min-Max
VAS (0-10)	3.10 \pm 1.60 1-6	4.10 \pm 1.51 2-8	3.70 \pm 1.82 1-9	4.40 \pm 1.92 1-9
KW Test, P Value	8.442, .038 ^a			

^a $P < .05$

Abbreviations: EMLA, eutectic mixture of local anesthetics; SD, standard deviation; KW, Kruskal-Wallis; VAS, visual analog scale.

gestational age of 32.3 \pm 4.59 weeks. The inner face of left forearm was used for the PIVC insertion in 56.7% of participants in that group, and PIVC was performed in 86.6% of participants in that group at the first attempt.

The mean age in the stress ball group was 28.2 \pm 8.20 years, with a mean BMI of 27.67 \pm 3.04 kg/m² and a mean gestational age of 33.5 \pm 4.44 weeks. The inner face of the left forearm was used for the PIVC insertion in 56.7% of participants in that group, and PIVC was performed in 66.7% of participants in that group at the first attempt.

The mean age of the EMLA cream group was 30.3 \pm 8.86 years, with a mean BMI of 28.61 \pm 4.63 kg/m² and a mean gestational age of 34.0 \pm 5.46 weeks. The inner face of the left forearm was used for the PIVC insertion in 66.3% of participants in that group, and PIVC was performed in 80% the group at the first attempt.

The mean age in the control group was 29.4 \pm 7.87 years, with a mean BMI of 29.13 \pm 4.47 kg/m² and a mean gestational age of 33.6 \pm 5.68 weeks. The inner face of the left

forearm was used for the PIVC insertion in 43.3% of participants in that group, and PIVC was performed in 56.7% of participants at the first attempt.

When the intervention and control groups were compared in terms of the locations of introductory and PIVC insertion, it was determined that no statistically significant difference existed between the groups ($P = .590$), and in terms of nurse success, a difference existed between the intervention and control groups ($P = .001$).

Pain Scores

The mean pain scores after PIVC insertion are presented in Table 2. The mean pain score for the Valsalva group was 3.10 \pm 1.60, for the stress ball group was 4.10 \pm 1.51, for the EMLA cream group was 3.70 \pm 1.82, and for the control group was 4.40 \pm 1.92. The differences between the mean scores of the three intervention groups and the control group were found to be statistically significant (KW = 8.442, $P = .038$).

Table 3. Test Results for Multiple Comparisons of Postinsertion Pain Scores of Pregnant Women in the Intervention and Control Groups. An advanced analysis using Dunn's test was conducted as a multiple comparison test for the p value, which was found to be significant as a result of Kruskal-Wallis test. The corrected *P* value for this test is shown as *P*^a.

Groups	Valsalva Group	Stress Ball Group	EMLA Cream Group	Control Group
Valsalva group		a		a
Stress ball group	a			
Emla cream group				
Control Group	a			

^a*P* < .001

Abbreviations: EMLA, eutectic mixture of local anesthetics.

Table 4. Distribution of Means of Postinsertion Satisfaction Scores of Pregnant Women in Intervention and Control Groups

Characteristics	Valsalva Maneuver Group Mean ± SD Min-Max	Stress Ball Group Mean ± SD Min-Max	EMLA Cream Group Mean ± SD Min-Max	Control Group Mean ± SD Min-Max
Satisfaction score (VAS) 0-10	5.93 ± 2.33 2-10	4.63 ± 1.42 1-8	5.50 ± 2.47 1-10	5.46 ± 2.40 1-10
KW Test, <i>P</i> Value	4.975, .174 ^a			

^a*P* > .05

Abbreviations: EMLA, eutectic mixture of local anesthetics; SD, standard deviation; KW, Kruskal-Wallis; VAS, visual analog scale.

A significant difference existed in the mean pain scores between the Valsalva group and the control and stress ball groups, at *Z* = -2573, *P* < .001, and *Z* = -2346, *P* < .001, respectively (Table 3). No significant differences existed in the mean pain scores between the Valsalva and EMLA, EMLA and stress ball, EMLA and control, and stress ball and control groups, at *Z* = -1.242, *P* = .214; *Z* = -1.020, *P* = .308; *Z* = -1.351, *P* = .177; and *Z* = -0.462, *P* = .644, respectively.

Satisfaction

The mean scores for satisfaction in the intervention and control groups after the PIVC insertion are presented in Table 4. For the mean satisfaction score in each group, the score for the Valsalva group was 5.93 ± 2.33, for the stress ball group was 4.63 ± 1.42, for the EMLA group was 5.50 ± 2.47, and for the control group was 5.46 ± 2.40. No statistically significant difference existed between the mean satisfaction scores of the three intervention groups and the control group (KW = 4.975, *P* = .174).

DISCUSSION

In the current study, a significant difference was found only between the pain scores of the control group and those of the Valsalva group, similar to the findings of Vijay et al.²⁰

The current study found no significant differences in the pain scores between the EMLA and control groups and the stress ball and control groups. The Valsalva and EMLA groups did have similar scores, which is similar to the

findings of Suren et al.⁹ No other study comparing the Valsalva maneuver and EMLA practice has been found in the literature.

The most striking finding of the current study is that the Valsalva maneuver group had lower pain scores than the control group, unlike the EMLA and stress ball groups. It's also intriguing that no differences existed in the current study between the pain scores of the EMLA and control group, perhaps because of the high level of anxiety due to the pregnancy in the last trimester and the fear of PIVC administration.

Limitations of study

The most important limitation of our study is the limited number of similar studies in the literature. This situation caused the discussion part to be limited. Therefore, there is a need to compare pharmacological and non-pharmacological methods in peripheral intravenous catheter pain.

CONCLUSIONS

The current study can generate awareness in pregnant women in terms of choosing between pharmacological and nonpharmacological practices that nurses use during PIVC insertion. As the only randomized controlled blind study that has been performed on the topic, the current study offers nurses evidence of a way to reduce PIVC pain in pregnant women.

AUTHORS' DISCLOSURE STATEMENT

The authors have no conflicts of interest related to the study.

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