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# Research Article

# Effects of a Thermoelectric Element Band on Venipuncture-associated Pain and Anxiety: A Randomized Controlled Trial



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#### SUMMARY

*Purpose:* Venipuncture is an invasive procedure for diagnosis and treatment, which is often attributed to pain and anxiety. In this study, a thermoelectric element (TEE) band was developed to apply heat therapy  $(40~45^{\circ}\text{C})$ , cold therapy  $(0~10^{\circ}\text{C})$ , or thermal grill illusion (TGI) therapy  $(40~45^{\circ}\text{C}, 0~10^{\circ}\text{C})$  to cause an illusion of pain by simultaneously applying heat and cold. This band was subsequently used to investigate its effect on patient pain, anxiety, and satisfaction.

*Methods:* This was a randomized controlled study. Participants, who were to undergo venipuncture, were randomly assigned to the heat therapy, cold therapy, TGI therapy, or control groups. Each group had 30 participants. The interventions were employed for 10 seconds during venipuncture, and the pain, anxiety, and satisfaction were measured before and after the procedure.

Results: Subjective pain, anxiety, and physiological responses after TEE band intervention were not significantly different between the four groups. However, there was a significant difference in satisfaction (F = 4.21, p = .007) between the four groups, and the cold therapy group showed the highest satisfaction. Conclusion: In this study, when heat, cold, and TGI therapy were applied with a TEE band, pain and anxiety relief effects were not confirmed, but satisfaction was high. TEE band is a newly developed product that can easily apply hot and cold treatments without using ice packs or hot water packs. Further studies with various individual characteristics of chronic pain or repeated venipuncture are warranted to evaluate the effect of TEE.

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# Introduction

Venipuncture is an essential process in the examination and treatment of individuals in various healthcare settings. It involves the access of a vein for obtaining blood samples and intravenous medication administration for a quick onset of action. Venipuncture is, however, often also a source of anxiety and pain [1,2]. Attempting this procedure on hard-to-find veins has been associated with increased psychological pressure and workload on the staff [2]. Consequently, the novel job position of the "intravenous (IV) nurse," whose work scope includes IV care (including peripheral IV injections and blood draws), was created

to alleviate the patients' pain and anxiety associated with venipuncture and to boost the nurses' job satisfaction [3]. Therefore, pain relief associated with venipuncture is an important topic of interest, requiring simple and effective methods to relieve both the psychological (fear, anxiety) and physical aspects of this procedure.

Pain serves as both a warning for potential danger as well as an index of recovery. Despite these positive aspects, pain itself is an unpleasant experience, which coupled with psychological torment, such as anxiety and fear, is further aggravated. Nursing interventions are, therefore, mostly focused on pain and anxiety relief, since the two are closely related to each other [4]. The gate control theory can explain the relationship between pain and anxiety. This posits that a pain sensation can increase or decrease during the process in which the pain stimulus travels up the nerve fibers along the pain pathway. At this point, psychological factors, such as cognition, motivation, and emotional state, affect the stimulation of the large fibers (A-beta fibers) of the spinal cord and alter the experience of the pain stimulus [5].

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Based on this understanding, many studies have explored nursing interventions, which are effective at alleviating the pain and anxiety associated with punctures and injections. Previous studies have included children vulnerable to pain [6–8], patients undergoing hemodialysis requiring punctures regularly [9–13], and patients with diabetes mellitus who undergo regular insulin therapy [14]. Nursing interventions that have been studied include heat and cold therapy [15,16], topical anesthetic cream [6,7,12], distraction therapy [8], aromatherapy [9], and vibration therapy [17,18], all of which have been reported to be effective in pain relief. However, topical anesthetics and aromatherapy are limited in terms of systemic absorption through the skin and the onset of action. Additionally, few studies have attempted to reduce the pain and anxiety associated with venipuncture in adults [17,18], since venipuncture is considered a simple procedure that causes only temporary pain. However, nurses who perform venipuncture are responsible for the patients' sense of wellbeing. Therefore, it is important to continuously strive to identify effective methods of pain and anxiety relief in patient care.

Among the various simple, independent, nursing interventions conducted to relieve pain and anxiety, heat and cold therapies are effective [10]. Heat therapy effectively relaxes the muscles and lowers the pain by increasing the rate of blood flow [15], while cold therapy reduces pain by decreasing the rate of nerve conduction and increasing the pain threshold [19]. Healthcare facilities may have different techniques for heat and cold therapies, which use gel packs, ice cubes, and heat pads [15,19]. Nurses, while remaining within their specialty of patient care, need to expand the scope of independent nursing interventions, as well as to keep abreast of medical technological advances to utilize effective devices for patient care.

A thermoelectric element (TEE) is a module that converts heat energy into electric energy or vice versa. TEEs can be easily used for heating and cooling and are currently utilized in a wide range of appliances and products used in daily life, including cold water dispensers, cooling car seats, and heating and cooling beauty products. Owing to the recent development of a flexible TEE, the range of potential applications has expanded. In this study, we developed a TEE band for the easy application of heat and cold therapy during nursing interventions. This TEE band contains a flexible TEE plate inside the band, and heat and cold can be applied by pressing a button on the power unit. Further, we applied thermal grill illusion (TGI), which simultaneously applies warm and cool stimuli to trigger a sensory illusion of pain relief.

In 1896, Torsten Thunberg first described TGI as the sensation resulting from the simultaneous application of warm and cool stimuli to the skin [20]. The TGI device causes an illusory sensation of pain at a temperature that does not actually cause warm or cool injuries to the body [21], and paradoxically has been reported to be effective in reducing pain [22], particularly neuropathic and chronic pain [23,24]. We decided to investigate whether TGI application would be effective in reducing the level of acute pain experienced during venipuncture.

This study, therefore, aimed to examine the pain and anxiety-relief effects of a flexible TEE band generating instant heat, cold, or TGI therapy during venipuncture, and to determine the patients' satisfaction with it to explore the device applications in various healthcare settings.

#### Methods

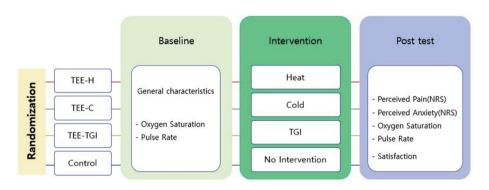
Study design

This study was a randomized controlled trial, designed to evaluate the effects of a TEE band applied during venipuncture for a blood test at a healthcare center. The participants were divided into either a control group, who wore a TEE band without any intervention, or into one of the following intervention groups: the heat, cold, or TGI therapy (simultaneous heat and cold stimuli) groups (Figure 1).

#### **Participants**

The participants were recruited from among adults requiring venipuncture for blood tests. The inclusion criteria were 1) aged 20–75 years, 2) history of venipuncture in the past 6 months; a study comparing recalls of pain experiences found that recalling a previous pain experience within 6 months accurately remembered pain and emotions with no difference [25], and 3) no wound present at the venipuncture site. Individuals who were consuming drugs that could have influenced the pain and/or anxiety measures, and those who were incapable of effective communication were excluded.

The sample size was determined using the G-power 3.1.9 program. The calculation parameters were four groups, an effect size of 0.3 [17], an  $\alpha$  value of 0.05 and power of 0.80, which resulted in a sample size estimate of 111. Consideration a potential withdrawal rate of 10%, we recruited 120 participants for this study. In order to



TEE-H:Thermoelectric element band-Heat group; TEE-C:Thermoelectric element band-Cold group; TEE-TGI:Thermoelectric element band-Thermal Grill Illusion group; Control: Control group; TGI:Thermal Grill Illusion; NRS:Numeric Rating Scale

Figure 1. Study design.

prevent allocation bias, random numbers were generated using Excel's random number generation function before recruitment, and information on each allocation group was placed in a clear envelope and arranged in an orderly manner. Participants were recruited using a recruitment poster as per the recruitment list, the author (HC) opened the envelope and assigned each person accordingly to the TEE-H, TEE-C, TEE-TGI, and control groups. Either heat, cold, or TGI was applied to the participants by means of the TEE band. In the control group, the TEE band was applied without operating the machine. In the course of the research, the author (HC) operated the machine, while the phlebotomist was unaware of the participant's allocation group; the study participant was not aware of the temperature stimulus until the machine was operated. Thirty participants were assigned to each group, and there were no dropouts; therefore, a total of 120 participants completed the study (Figure 2).

Measurements and instruments

# 1) TEE band

The TEE band refers to a wristband developed for this study (Tegway, Daejeon, South Korea). A flexible TEE plate patented in Korea (10-1989908, 10-1829709, 10-1689308) was inserted in the band (5.5  $\times$  3.5 cm), through which heat and/or cold stimuli could be applied using electric energy by pressing the HOT/COLD button on the power unit.

# 2) Subjective pain

Subjective pain was measured using the Numeric Rating Scale (NRS). The NRS is valid, reliable, and appropriate for pain measurement in clinical practice. It has good sensitivity and generates

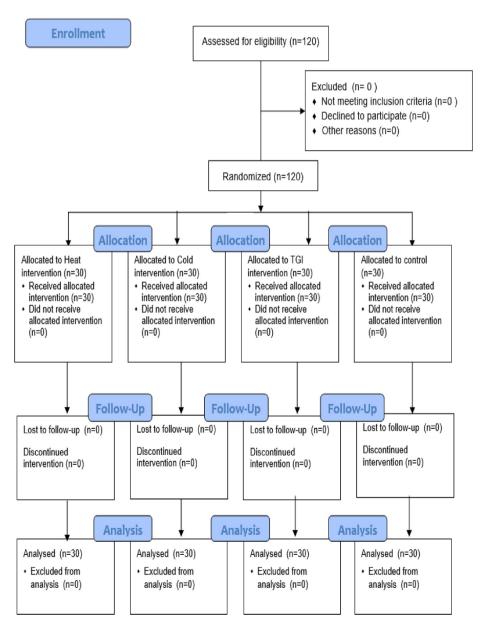


Figure 2. Flow diagram.

data that can be analyzed for audit purposes [26]. Pain was measured in centimeters from 0 "no pain at all" to 10 "very severe pain".

# 3) Anxiety

Anxiety was measured using the NRS. The NRS is also effective in evaluating anxiety because it is validated and self-evaluated by the subjects [27]. In this study, anxiety was measured in centimeters from 0 "no anxiety at all" to 10 "very severe anxiety."

# 4) Physiological response

Pain induces alterations in the autonomic nervous system. Physiological responses include biological and behavioral reactions to pain. Physiological changes are parameters that support the measurement and evaluation of pain [28]. Among the physiological parameters, pulse rate and oxygen saturation are used as indicators of pain in various studies due to their objectivity, and changes can be quickly and easily measured through pulse oximeter [6,28–30]. These were determined using the peripheral oxygen saturation rate and the pulse rate, which were measured using a pulse oximeter (MD300 C22, ChoiceMMed).

# 5) Satisfaction

To measure the participants' satisfaction with the TEE band, we developed six preliminary items based on a questionnaire used in a previous study assessing satisfaction [31], and a literature review. The preliminary items were reviewed by an expert panel comprising two nursing professors and three nurses with a minimum of 10 years of clinical phlebotomy experience. After some modifications and improvements, the final version of the questionnaire had 10 items. The content validity of these 10 items was evaluated by an expert panel comprising two Fundamentals of Nursing professors and four nurses with a minimum of 10 years of clinical phlebotomy experience. The content validity index (CVI) for each item ranged from 0.8 to 1.0, with a mean CVI of 0.98. The 10 items used to assess satisfaction were rated on a five-point Likert scale, with a higher score indicating greater satisfaction. The reliability (Cronbach's  $\alpha$ ) of the tool was .87 in this study.

# Interventions

# Thermoelectric band development

A TEE is a module that converts heat energy into electric energy and vice versa. TEE is effectively used to produce electricity with heating and cooling features, especially in thermoelectric cooling equipment and parts [32]. While TEE has been utilized in health-care for heat and cold therapies, the firm and flat structure of the device hinders the immediate expression of cool and warm sensations. A flexible TEE was therefore developed with small pieces of thermoelectric chips to address these shortcomings. This flexible TEE is lighter than a firm TEE and features a rapid temperature response, making it convenient for application on curved body parts, such as a wrist, to provide warmth, cold, and simultaneous warm and cold stimuli instantly.

We utilized this flexible TEE to administer heat and cold therapy to patients since these are independent nursing interventions used in venipuncture. We developed the TEE band through several rounds of discussions with venipuncture experts and flexible TEE developers, focusing on the shape of the band, application method, temperature settings, and patient convenience (Tegway, Daejeon, South Korea) (Figure 3). The TEE band, which was designed to be

wrapped around the skin, contains a 5.5  $\times$  3.5 cm flexible TEE plate within.

The appropriate temperature for thermotherapy for pain-control is based on the contents presented at an average of  $41.22 \pm 9.77^{\circ}\text{C}$  according to the literature review [10,17]. To identify the most effective and safe temperature for cold therapy based on previous randomized controlled trial studies, ice packs of -4 to  $4^{\circ}\text{C}$  and cooling gel packs of 0 to  $10^{\circ}\text{C}$  were recommended [19,33]. This study also aimed to induce TGI in terms of the most suitable degree of temperature difference between the simultaneous cold and warm temperatures. Smaller differences (e.g.,  $10-15^{\circ}\text{C}$ ) are sufficient for illusory heat, while larger differences (e.g.,  $\geq 20^{\circ}\text{C}$ ) are required for illusory pain sensations [34]. To summarize, the TEE band set the temperature for heat and cold therapy at  $40~45^{\circ}\text{C}$  and  $0~10^{\circ}\text{C}$ , respectively, to prevent skin burns or other injuries.

# Data collection and procedures

Participants were recruited, using a recruitment poster, from a population of adults who were required to undergo a blood test with venipuncture during a health examination from March to April 2021. The volunteers were explained that they would have to wear a wristband during the venipuncture and that the stimulation received would not cause skin damage. All the participants signed an informed consent form prior to participating in the study. The participants completed a questionnaire to gather information on the general characteristics and perceived pain and anxiety experience during their previous venipuncture. Additionally, their peripheral oxygen saturation and pulse rate were measured using a pulse oximeter.

Venipuncture was performed with the participants sitting comfortably in an environment maintained at 23~25°C. A consistent treatment stimulus was maintained to minimize the error in the experiment, and the puncture site was set to the antecubital fossa for all the participants; syringes with the same needle size (5 cc, 22-gauge) and identical serum separator tubes were prepared. A single nurse with more than 5 years of clinical experience was designated the phlebotomist in order to prevent any variability in the characteristics of the experimenter and puncture skills; the phlebotomist was blinded to participant allocation.

We placed the allocation number results, which were generated using the randomization function of Excel and created by the investigator, in a sealed envelope stored in a drawer. Prior to the experiment, each participant was given an allocation envelope to open, at which point we checked the participant's group allocation.



Figure 3. Thermoelectric element (TEE) band.

Group allocation was written in numbers; thus, both the participant and the phlebotomist were blinded to the assigned number and could not anticipate group assignment. When the phlebotomist was ready for venipuncture, we wrapped the TEE band around the wrist of the patient's arm such that the plate was in close contact with the skin, 10 s of the corresponding stimulus was provided: heat (40~45°C), cold (0~10°C), or TGI (simultaneous administration of 40~45°C and 0~10°C). The participants of the control group wore the TEE band but did not receive any stimulation. We turned on the power unit and 10-s timer as soon as the phlebotomist had pulled the skin tautly below the needle injection site such that the corresponding stimuli would be generated. The phlebotomist inserted the needle, collected the 5-cc blood sample, and then removed the needle. The entire process took approximately 10 s. We turned off the power unit of the TEE band following the completion of the 10-s timer. Immediately after needle removal and stimuli elimination through the TEE band, we measured the participants' peripheral oxygen saturation and pulse rate using the connected pulse oximeter and removed the TEE band. The participants were subsequently asked to complete the questionnaires regarding their perceived pain and anxiety following the venipuncture, and their satisfaction with the TEE band.

#### Data analysis

Data were statistically analyzed using the IBM SPSS Statistics 26.0 software. The participants' general characteristics and dependent variables were analyzed as the frequency, absolute number, percentage, and mean with standard deviation; homogeneity was tested using the  $\chi^2$  test and one-way ANOVA. The effects of the TEE band were analyzed using ANOVA.

Significant results (p < .05) were tested using the Bonferroni post-hoc test.

#### Ethical considerations

This study was approved by Institutional Review Board at Eulji University (Approval No. EU21-001), and the protocol was registered with a clinical trials registry (KCT0006176) before any data were collected. We explained the purpose of the study and informed the participants that the collected data would only be used for research purposes and that they were free to withdraw from the study at any time. All the participants signed the written informed consent form. Participants were provided approximately \$10 as a token of appreciation for their participation.

#### Results

# Baseline homogeneity

A total of 120 participants who were divided into four groups of 30 as heat therapy, cold therapy, TGI therapy, and control groups. The baseline homogeneity of the four groups was no statistically significant differences in sex, age, height, weight, exercise, baseline pain, anxiety, peripheral oxygen saturation, or pulse rate (Table 1).

Effects of the TEE band on variables with venipuncture

# 1) Subjective pain

There were no significant differences in subjective pain among the four groups (F = 1.69, p = .173) (Table 2).

**Table 1** Homogeneity Test for General Characteristics and Dependent Variables between Groups (N = 120).

Variables	Category	TEE-H ( $n = 30$ )	TEE-C $(n = 30)$	TEE-TGI ( $n=30$ )	Control $(n = 30)$	$\chi^2/F$	р
		$\overline{\text{Mean} \pm \text{D or } N(\%)}$	Mean $\pm$ SD or $N(\%)$	Mean ± SD or N (%)	Mean ± SD or N (%)		
Gender	Female	23 (76.7)	24 (80.0)	22 (73.3)	26 (86.7)	1.77	.622
	Male	7 (23.3)	6 (20.0)	8 (26.7)	4 (13.3)		
Age (yr)		$28.40 \pm 12.28$	$26.10 \pm 10.59$	$24.43 \pm 8.44$	$27.83 \pm 11.94$	0.81	.490
Height (cm)		$163.67 \pm 6.16$	$163.10 \pm 5.96$	$164.21 \pm 6.81$	$161.33 \pm 7.18$	1.09	.356
Weight (kg)		$61.77 \pm 11.44$	$60.10 \pm 10.90$	$60.92 \pm 12.15$	$57.38 \pm 9.80$	0.88	.456
Exercise	None	9 (30.0)	13 (43.3)	9 (30.0)	12 (40.0)	4.19	.652
	Often	18 (60.0)	15 (50.0)	15 (50.0)	15 (50.0)		
	Daily	3 (10.0)	2 (6.7)	6 (20.0)	3 (10.0)		
Pain <sup>a</sup> (NRS)	•	$4.07 \pm 1.98$	$4.43 \pm 1.77$	$4.14 \pm 2.00$	$3.82 \pm 1.81$	0.54	.656
Anxiety <sup>a</sup> (NRS)		$3.09 \pm 2.55$	$3.70 \pm 2.63$	$3.12 \pm 2.53$	$3.35 \pm 2.42$	0.32	.814
SpO <sub>2</sub> (%)		$98.20 \pm 1.28$	$98.30 \pm 1.21$	$98.10 \pm 1.35$	$98.60 \pm 1.19$	0.88	.455
Pulse Rate (bpm)		$92.43 \pm 13.86$	$85.80 \pm 13.90$	$90.33 \pm 15.88$	$84.03 \pm 16.65$	1.99	.119

Note. TEE-H = Thermoelectric element band-Heat group; TEE-H = Thermoelectric element band-Cold group; TEE-TGI = Thermoelectric element band-Thermal Grill Illusion group; Control = Control group; Mean  $\pm$  SD = Mean  $\pm$  Standard Deviation; NRS = Numeral rating scale.

 Table 2
 Effects of TEE Band on Pain, Anxiety, Oxygen Saturation, Pulse Rate, and Satisfaction between Groups after Intervention (N = 120).

Variables	$TEE-H^{a}(n=30)$	TEE- $C^b$ ( $n=30$ )	TEE-TGI $^{c}$ ( $n=30$ )	$Control^d (n = 30)$	F	р
	Mean ± D	Mean ± SD	Mean ± SD	Mean ± SD		
Pain (NRS)	3.30 ± 2.28	2.71 ± 2.10	3.96 ± 2.27	3.57 ± 2.14	1.69	.173
Anxiety (NRS)	$1.87 \pm 1.63$	$2.03 \pm 1.92$	$2.63 \pm 2.52$	$1.73 \pm 1.82$	1.16	.327
SpO <sub>2</sub> (%)	$98.20 \pm 1.19$	$98.03 \pm 1.00$	$97.93 \pm 1.36$	$98.43 \pm 1.17$	1.05	.375
Pulse Rate (bpm) Satisfaction	$85.70 \pm 11.67$	$80.23 \pm 13.31$	$86.43 \pm 14.27$	$83.33 \pm 16.85$	1.17	.324 .007 b > d <sup>†</sup>
Satisfaction	$32.90 \pm 8.09$	$35.30 \pm 9.83$	$32.53 \pm 7.13$	$28.20 \pm 6.03$	4.21	.007 b > a

Note. TEE-H = Thermoelectric element band-Heat group; TEE-H = Thermoelectric element band-Cold group; TEE-TGI = Thermoelectric element band-Thermal Grill Illusion group; Control = Control group; Mean  $\pm$  SD = Mean  $\pm$  Standard Deviation; NRS = Numeral rating scale.

<sup>&</sup>lt;sup>a</sup> Previous venipuncture experience.

<sup>†</sup> Bonferroni.

#### 2) Anxiety

There were no significant differences in anxiety among the four groups (F = 1.16, p = .327) (Table 2).

# 3) Peripheral oxygen saturation

There were no significant differences in peripheral oxygen saturation among the four groups (F = 1.05, p = .375) (Table 2).

#### 4) Pulse rate

There were no significant changes in pulse rate among the four groups (F = 1.17, p = .324) (Table 2).

Effects of the TEE Band on satisfaction with venipuncture

Satisfaction significantly differed among the four groups (F = 4.21, p = .007), with the TEE-C group expressing the highest satisfaction compared to the control group, as confirmed by the post-hoc test (Table 2).

#### Discussion

This study aimed to investigate whether a TEE band developed with flexible thermoelectric modules generating heat, cold, and simultaneous heat and cold stimulation would improve the pain, anxiety, and satisfaction in adults undergoing venipuncture. Our study results demonstrated that providing cold therapy with the TEE band during venipuncture resulted in the highest satisfaction, and greatest intention to reuse the device. Previous studies have reported that cold therapy reduced pain during injections and was associated with the highest satisfaction [17,31]. Although previous studies applied cold therapy for 1–13 min for a puncture [11,17], our results confirmed that even a short application of 10 s resulted in satisfaction, a finding which could help enhance the efficiency of cold therapy in clinical practice.

We examined the pain-relief effects of TGI generated using the TEE band during venipuncture. In a previous study, TGI has been confirmed to reduce the pain in patients with persistent pain [23,24]. However, no previous study has examined the effects of TGI on pain during venipuncture. We hypothesized that TGI would be effective in reducing acute pain such as that associated with venipuncture. This was based on the findings that electric stimulation produced by devices, such as an electromyogram, effectively reduced pain by increasing the pain threshold and reducing the pain awareness [35], and that massaging the injection site using pressure following an intramuscular injection also effectively reduced pain [36]. Furthermore, as described by the gate control theory, pain can be controlled by activating the large fiber that will close the gate of the spinal cord and inhibiting the transmission of pain information through small fibers. We, therefore, hypothesized that heat and cold sensations would stimulate the muscle fibers and thus relieve pain. Thus, we designed the TGI by simultaneously generating heat and cold stimuli using the TEE band and we developed a prototype of the TEE band. However, TGI did not reduce pain and anxiety during venipuncture in this study. We speculate that pain was not controlled since the simultaneous heat and cold sensation is a novel sensation, and hence, the body may fail to distinguish between the heat and cold stimuli and therefore fail to close the gate that inhibits pain. Another possibility may be that the intended sensation was not delivered to the participants owing to the differences in skin thickness and sensory processing. Hence, further research is needed to identify the optimal TEE band temperature settings to produce the ideal TGI for each sex and age group.

Also, the post-intervention reduction in pain and anxiety was not significant. This is consistent with previous findings [16,17] and can be attributed to the different properties of anxiety across individuals. In addition, the participants of this study were healthy adults aged 20-75 years, the age range was too wide, and the baseline for pain and anxiety were relatively low, so it seems that the appropriate effect could not be confirmed. Furthermore, the TEE band developed in this study is only a prototype with a focus on the functional aspect rather than the esthetical quality. Therefore, the application of an emotional design to relieve anxiety could help alleviate the participants' psychological anxiety during invasive procedures and facilitate the treatment process [37]. Hence, attractive and emotionally appealing design components would also be essential when developing devices for use in patients in healthcare facilities.

Generally, the sympathetic nervous system is stimulated in the early phase of acute pain, which in turn increases the pulse rate and oxygen demand; these parameters are widely used as markers of pain and anxiety owing to their objectivity [28]. In our study, there was no significant difference in the post-intervention period concerning peripheral oxygen saturation between the four groups, since 10 s was not sufficient for appearance of changes in the peripheral oxygen saturation. In addition, the other physiological response variable, pulse rate, did not show a significant difference, as in a previous study [7,9,30]. These results show that an insignificant physiological response may be insufficient to indicate pain. We, therefore, need to assess more than the physiological response variables.

Heat, cold, and TGI stimuli application with a TEE band is a novel intervention; hence, we interviewed some participants following the experimental treatment. A participant who received cold therapy stated that "It felt cold, and I didn't know that a needle was being inserted." A participant who received heat therapy commented that "I felt the needle coming in and it hurt, but I felt relaxed." While heat and cold stimuli were familiar sensations, participants who received TGI stated that simultaneously feeling heat and cold was an unfamiliar sensation: "It was weird and unpleasant, where it suddenly felt cold and suddenly felt hot" and "I was startled because I had never felt this before." As shown here, most participants felt the intended sensation after 10 s of TGI generated by the TEE band.

Through the interview, both heat and cold therapies applied with the TEE band were effective in reducing pain, and the warmth from heat therapy tended to be more effective than the coolness from cold therapy in promoting psychological relaxation. In this study, heat therapy did not show a statistically significant difference in the reduction of pain and anxiety; however, it was the most effective intervention method experienced by participants during the interview. Moreover, the unfamiliar sensation from the TGI resulted in some individuals experiencing an unpleasant sensation, and thus the pain was not masked at all. Nevertheless, this was the first attempt at using this device in clinical practice and follow-up research is required to further evaluate this method.

Our study has some limitations. First, we compared the pain level during venipuncture by selecting healthy adults without disease who had venipuncture experience within 6 months. Considering that there are individual variations in pain, the pain and anxiety of venipuncture within 6 months were measured by memory of the previous venipuncture experience. In addition, since the TEE band was first created to relieve the pain of venipuncture, it was not possible to reflect individual characteristics by setting the temperature in advance as a pilot study. In addition, there was no study applying TGI to venipuncture; hence, it was difficult to compare the pain relief effect of TGI to venipuncture. Considering the individual variations in pain, a

follow-up study is warranted to target patients who are repeatedly punctured, and it is necessary to investigate the effects on pain and anxiety after applying a TEE band that reflects the individual characteristics.

#### **Conclusion**

This study showed that heat, cold, and TGI stimuli application with a TEE band is a novel intervention. It is important to apply nursing interventions to reduce venipuncture-associated pain and anxiety, and efforts are warranted for convenient application. Since pain and anxiety are subjective measures, they differ across individuals. Hence, heat, cold and TGI therapy to relieve pain and anxiety should be tailored to individual characteristics and preferences.

The TEE band composed of TEEs, which have been commonly used in daily life, was developed as a novel TEE band that can be used in healthcare. The TEE band developed in this study is safe because the electric energy delivers a consistent temperature to the user, and the hot and cold settings can be switched easily using the hot and cold buttons, allowing users to choose their preferred setting. Since TEE band is a newly developed product that can easily apply hot and cold treatments without using ice packs or hot water packs, it is necessary to conduct research to devise more application methods for effective use in patient care.

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# **Conflict of interest**

The authors have no conflicts of interest to declare.

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