

Comparison Valsalva maneuver and auriculotherapy on pain intensity of peripheral intravenous cannulation in adults: A randomized clinical trial

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Abstract

Introduction: Effective pain management during peripheral intravenous cannulation (PIVC) poses a significant challenge for medical practitioners in the emergency department. A range of non-pharmacological interventions have been advanced to address this concern. This study aimed to compare the effects of the Valsalva maneuver (VM) and auriculotherapy on pain intensity during PIVC in adults.

Methods: A randomized clinical trial was conducted on 99 adult patients referred to Emergency department Hospital in Gonabad, Iran. Patients were randomly assigned into three groups VM ($n=33$), auriculotherapy ($n=33$), and control ($n=33$). Pain levels were assessed using the Visual Analog Scale (VAS) immediately after PIVC. Data analysis was performed using SPSS version 25, with a significance level of less than 0.05.

Results: The mean pain scores in the VM, auriculotherapy, and control groups were 2.88 ± 3.81 , 2.57 ± 3.45 , and 7.13 ± 2.39 , respectively. Kruskal–Walli's test revealed a significant difference among the groups ($p < 0.001$). Pairwise comparisons indicated no significant difference between VM and auriculotherapy groups in pain intensity ($p = 0.67$). However, significant differences were observed between the control group and the VM group ($p < 0.001$) as well as between the control group and the auriculotherapy group ($p < 0.001$).

Conclusion: The results of this study demonstrate that both auriculotherapy and the Valsalva maneuver effectively reduce pain during PIVC in adults. Healthcare providers can consider incorporating these methods to help alleviate pain during PIVC procedures.

Keywords

Valsalva maneuver, auriculotherapy, ear acupressure, pain, peripheral vein cannulation, adult

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Introduction

Peripheral intravenous cannulation (PIVC) is a commonly performed procedure in emergency departments.^{1,2} One significant adverse effect of PIVC is pain, recognized as the fifth vital sign, encompassing an unpleasant emotional experience that elicits both emotional and physiological responses.^{3,4} This procedure not only induces discomfort in patients but also generates considerable stress among healthcare providers.⁵ The resulting pain experience can detrimentally impact the therapeutic alliance between healthcare professionals and patients.⁶ However, effective pain management has been shown to enhance patient satisfaction levels.⁷

Current pain management strategies encompass a spectrum of pharmaceutical and non-pharmacological interventions. While pharmaceutical approaches are efficacious, they often come with notable side effects and financial burdens.⁸ Conversely, non-pharmacological modalities, although comparatively less potent, have garnered considerable attention from healthcare providers due to their favorable safety profiles, ease of application, and cost-effectiveness.⁹ Noteworthy among these non-pharmacological interventions are the Valsalva maneuver (VM) and auriculotherapy, which have recently emerged as subjects of interest within the research community.^{3,10}

The VM exerts its analgesic effects through the elevation of mediastinal pressure, which stimulates pressure receptors located in the carotid sinus and aortic arch. This stimulation results in vagal activation, leading to the inhibition of spinal pain receptors and the attenuation of pain signal transmission.¹¹ Additionally, the VM is recognized for its potential role as a distraction technique.^{12,13} A meta-analysis investigating the efficacy of the VM revealed a significant reduction in pain intensity during PIVC in adults compared to control groups.³

Also, auriculotherapy, a non-pharmacological method increasingly utilized for pain relief, involves the stimulation of specific points on the external ear using a probe.¹⁴ This alternative medicine technique operates on the principle that the ear serves as a microsystem mirroring the entire body, with distinct auricular points corresponding to specific organs or systems. By manipulating these points, auriculotherapy aims to restore the body's energy balance and facilitate natural healing processes.¹⁵ Noteworthy for its ease of application and minimal patient complications, this approach has garnered limited attention from pain management practitioners in the realm of PIVC, and existing research remains sparse. While investigations into its efficacy for various types of pain are ongoing, preliminary studies have shown promising results, particularly in reducing pain intensity during childbirth.¹⁶

To date, there is a marked scarcity of research examining the comparative effectiveness of the VM and auriculotherapy in alleviating the pain associated with PIVC. These

two innovative modalities offer distinct mechanisms of pain management, ease of application, and a cost-effective approach. Therefore, the present study seeks to evaluate the effect of the VM and auriculotherapy on the level of pain experienced during PIVC procedures among adult patients presenting at the emergency department.

Methods

Study type and place

This study conducted a randomized clinical trial, three-group, and open label. The study was registered under the clinical trial code IRCT20240106060628N1. This study was conducted in the emergency department of Allama Bahloul Gonabadi Hospital in Gonabad, Iran, in March 2023. CONSORT guidelines for reporting randomized controlled trials were followed.¹⁷

Inclusion and exclusion criteria

The study population comprised all adult patients referred to Allama Bahloul Gonabadi Hospital. Inclusion criteria consisted of patients aged 18 and above, categorized as triage level 4 and 5 based on Emergency Severity Index (ESI), requiring PIVC, exhibiting a level of consciousness of 15 based on Glasgow Coma Scale, free from a history of heart disease, addiction, trauma, and acute pain, expressing willingness to participate in the study, and not having taken sedatives within the last 6h. Exclusion criteria encompassed failure PIVC in the first attempt, patient non-compliance during study procedures, and patient withdrawal from study participation.

Randomization and concealment

Eligible patients meeting the inclusion criteria were enrolled in the study. Subsequently, participants were randomly assigned to one of three groups: VM group, auriculotherapy group, and control group. Random allocation was performed using a permuted block randomization method with six possible sequences (ABC, ACB, BAC, BCA, CAB, CBA). The random allocation was concealed using sealed envelopes, where the allocation sequence was placed inside numbered envelopes. Eligible patients were then assigned to each group based on the envelope they opened, thereby reducing potential selection bias.

Sample size estimate

The sample size was estimated by analyzing the mean and standard deviation from Akarsu et al.'s study with a confidence level of 95% and a statistical power of 80%, following the formula for comparing means.¹⁸ Considering a 10% allowance for potential sample dropout, a final total

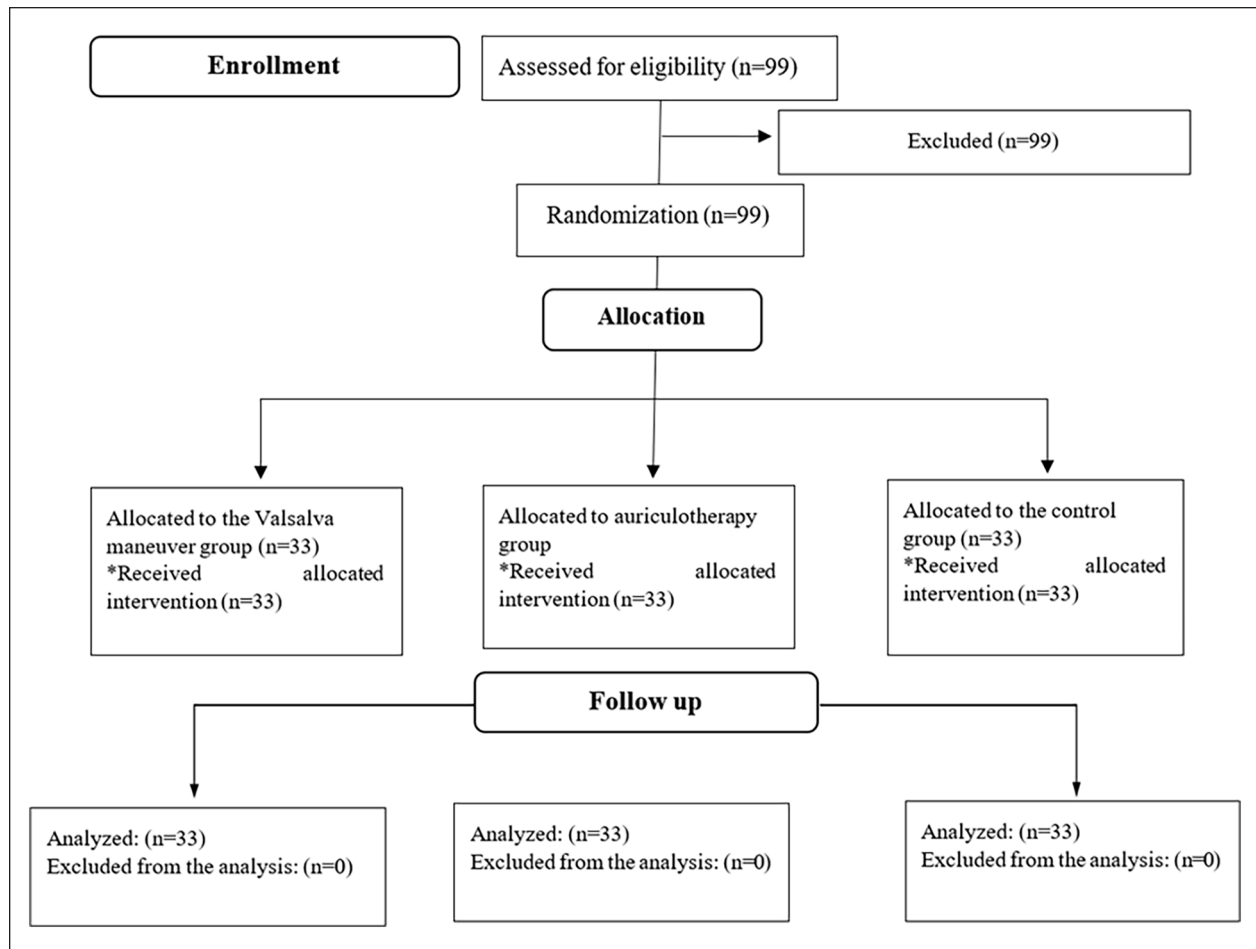


Figure 1. CONSORT flow diagram.

of 33 participants were included in each of the three study groups. Thus, the study included 99 patients, and the final analysis was conducted with the same number, with no instances of sample dropout observed throughout the study (Figure 1).

Interventions

In the VM group, a tourniquet was applied 10 cm above the catheter insertion site at the antecubital fossa. The site was then disinfected with an alcohol-based solution. Following this preparation, the patient was instructed to press the tip of their nose with the opposite hand to effectively close both nostrils and exhale against a closed glottis for 20 s prior to cannulation. Subsequently, a 20-gauge PIVC was inserted into the antecubital fossa.

In the auriculotherapy group, a tourniquet was similarly applied 10 cm above the catheter insertion site at the antecubital fossa, and the site was disinfected using an alcohol-based solution. The researcher applied pressure to a specific point on the earlobe using a specialized probe for

2 min until the patient's pain threshold was reached. Following this intervention, a 20-gauge PIVC was inserted into the antecubital fossa.

In the control group, a tourniquet was applied 10 cm above the antecubital fossa, and the site was disinfected using an alcohol-based solution. Subsequently, a 20-gauge PIVC was inserted into the antecubital fossa. All catheters were inserted by a nurse with 12 years of experience, and all insertions were successful on the first attempt.

Data collection tools

Following successful catheter insertion in all groups, pain intensity was immediately assessed using a Visual Analog Scale (VAS). Subsequently, the catheter was secured in place with a specialized adhesive. Pain intensity was evaluated using the VAS, with scores ranging from 0 (indicating no pain) to 10 (indicating the highest level of pain). Also, demographic data of the patients, such as age, gender, body mass index, marital status, residence area, and history of hospitalizations, were meticulously documented.

Table 1. Socio-demographic characteristics of patients.

Variables	Valsalva (n=33)	Auriculotherapy (n=33)	Control (n=33)	p-Value
Age, mean (SD)	32.48 ± 9.09	33 ± 12.67	35.88 ± 13.004	0.45
Body mass index, mean (SD)	42.55 ± 3.92	23.76 ± 3.4	24.86 ± 4.25	0.55
Gender, n (%)				
Female	(57.6) 19	(51.5) 17	(48.5) 16	0.75
Man	(42.4) 14	(48.5) 16	(51.5) 17	
Marital status, n (%)				
Single	(24.2) 8	(24.2) 8	(21.3) 7	0.94
Married	(75.8) 25	(75.8) 25	(78.7) 26	
Residence area, n (%)				
Urban	(93.9) 31	(90.6) 29	(48.8) 28	0.46
Rural	(6.1) 2	(9.4) 3	(15.2) 5	
History of hospitalizations, n (%)				
Yes	(6.1) 2	(12.1) 4	(15.2) 5	0.46
No	(93.9) 31	(87.9) 29	(84.8) 28	

Table 2. Results of Post hoc analysis for pain intensity.

Pairwise comparison	Mean ± SD	p-Value
VM vs auriculotherapy	2.88 ± 3.81 vs 2.57 ± 3.45	0.67
VM vs control	2.88 ± 3.81 vs 7.13 ± 2.39	<0.001
Auriculotherapy vs control	2.57 ± 3.45 vs 7.13 ± 2.39	<0.001

Ethical consideration

Ethical approval was granted by the Ethics Committee at Gonabad University of Medical Sciences (IR.GMU. REC.1402.145). Following the identification of the intervention, the researcher briefed the patient on the study's objectives, procedural steps, and methods for assessing pain levels. A written informed consent form was obtained from each patient.

Data analysis

After inputting the data into version 25 of the statistical software SPSS, the normality of the quantitative data was assessed using the Kolmogorov-Smirnov test. Pain intensity was reported using the mean and standard deviation. Given the non-normal distribution of the data, the Kruskal-Wallis non-parametric test was employed to compare the intensity levels across the three groups under investigation. Bonferroni's post hoc test was subsequently applied for pairwise comparisons within each group. The Chi-square test was utilized for analyzing nominal and categorical demographic variables, while the one-way ANOVA test was performed for continuous variables assuming normal distribution. In cases of non-normality, the Kruskal-Wallis's test was applied.

Results

In each of the three groups of VM, auriculotherapy, and control, the average ages were 32.48 ± 9.09, 33.0 ± 12.67,

and 35.85 ± 13, respectively. There was no significant difference in age among the three groups ($p=0.80$). The study included 47 men (47.48%) and 52 women (52.52%). The distribution of gender in each group is presented in Table 1. Additional demographic variables are detailed in Table 1.

The mean pain score in the VM, auriculotherapy, and control groups were 2.88 ± 3.81, 2.57 ± 3.45, and 7.13 ± 2.39, respectively. There was a statistically significant difference in pain intensity among the three groups ($p < 0.001$). Pairwise comparisons indicated no significant difference between VM and auriculotherapy groups in pain intensity ($p=0.67$). However, significant differences were observed between the control group and the VM group ($p < 0.001$) as well as between the control group and the auriculotherapy group ($p < 0.001$; Table 2).

Discussion

This study aimed to compare the effects of the VM and auriculotherapy with a control group on pain intensity resulting from PIVC in adult patients. The analysis revealed a statistically significant difference among the three groups concerning pain intensity. Post-hoc tests indicated no significant difference between the VM and auriculotherapy interventions regarding pain intensity during PIVC. However, both interventions groups exhibited a statistically significant decrease in PIVC pain intensity compared to the control group.

Agarwal et al. examined the effects of the VM and the distraction technique in alleviating PIVC pain, with results showing a significant reduction in pain intensity in the VM group compared to the control group (15), aligning with findings from the current study.¹⁹ Notably, Agarwal employed a 16-s VM involving blowing into the Sphygmomanometer, whereas our study implemented a 20-s VM technique by pressing the nasal tip and exhaling with a closed glottis. The varying durations of the Valsalva maneuver underscore the need for future research to address this crucial aspect.

Yilmaz and Güneş investigated the effects of three non-pharmacological methods—coughing, blowing into a spirometer, and squeezing a rubber ball—compared to a control group in 30–40-year-old men.⁸ The study revealed a statistically significant difference among the four groups, with pain intensity ranking from lowest to highest in the cough group, blowing into the spirometer group, squeezing the ball group, and the control group. This study employed two VM techniques—coughing and blowing into a spirometer—both of which demonstrated superior pain reduction compared to the squeezing the ball group and the control group. In our investigation, the VM exhibited a greater reduction in average pain intensity compared to both auriculotherapy and control groups. Notably, while Yilmaz and Güneş focused on men aged 30–40 years, our study included participants over 18 years of both genders.

Shivashankar et al. demonstrated that the VM, performed by blowing into a sphygmomanometer, significantly decreased pain intensity PIVC in patients admitted to the surgical department compared to the control group.²⁰ This investigation, similar to our present study, involved adult participants, with pain intensity assessed using the VAS. While Shivashankar's study focused on patients hospitalized in the surgical department, our study examined patients referred to the hospital's emergency department.

In a study by Akdas et al., the impact of EMLA ointment and the VM on venipuncture pain severity in children was investigated. The results indicated that the average pain level in the VM group did not show significant differences compared to the control group, which contrasts with the findings of our current study.²¹ The discrepancies observed could potentially be attributed to differences in age groups, as the Akdas study was conducted on children 5–15 years old, where incomplete or incorrect execution of the technique may have influenced the results. Our study, on the other hand, focused on adults, considering that pain responses may vary across different age groups.²²

Although previous studies have not evaluated the impact of auriculotherapy on the severity of PIVC pain, our study addresses a notable research gap by investigating the impact of auriculotherapy on the severity of catheter insertion pain. Rastegarzade et al. examined the effects of auriculotherapy on pain intensity during active labor and demonstrated a significant reduction in pain levels compared to the control group.²³ Similarly, the findings of the current study confirm that auriculotherapy effectively

reduces pain associated with PIVC insertion compared to the control group.

In the study by Khloobagheri et al., auriculotherapy was shown to significantly reduce pain intensity during cesarean sections compared to the control group.²⁴ Notably, the pressure points in both ears were stimulated for 24 h in their study. In contrast, our present study employed a distinct approach where auriculotherapy was administered for 2 min before PIVC, offering a novel perspective on the application of this technique in pain management during medical procedures.

While no previous studies have directly compared the VM with auriculotherapy for pain management, our investigation revealed that the average pain intensity in the VM group did not significantly differ from the auriculotherapy group. In our study, patients self-performed the VM for 20 s, whereas auriculotherapy was administered by a researcher for 2 min. Both interventions are believed to inhibit pain receptors in the spinal cord, albeit through distinct mechanisms. Our findings suggest the need for further research to comprehensively compare the efficacy, application, and underlying mechanisms of the VM and auriculotherapy in pain modulation.

Current study had some limitations. The study focused solely on pain intensity and did not assess other important outcomes such as patient satisfaction, anxiety levels, or procedural complications. Furthermore, we evaluated pain levels using the VAS based on patient self-reports. Incorporating measurements of hemodynamic parameters such as heart rate, blood pressure, and respiratory rate can enhance validity of findings in future research.

Conclusion

The present study compared the pain intensity experienced during PIVC among three groups: VM, auriculotherapy, and control. The results revealed a statistically significant difference in pain intensity across the three groups. Although post-hoc analyses indicated no significant difference between the VM and auriculotherapy groups, both interventions significantly reduced pain intensity compared to the control group. These findings suggest that healthcare providers can effectively utilize these methods to manage PIVC pain in adult patients. Further studies are recommended to validate and expand upon the findings of this study, potentially enhancing our understanding of optimal pain management strategies in clinical settings.

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References

1. Álvarez-Morales L, Gómez-Urquiza JL, Suleiman-Martos N, et al. Ultrasound-guided peripheral intravenous cannulation by emergency nurses: a systematic review and meta-analysis. *Int Emerg Nurs* 2024; 73: 101422.
2. Firooz M, Karkhah S and Hosseini SJ. The effect of transillumination device on successful peripheral venous catheter placement in children: a systematic review and meta-analysis. *J Vasc Access* 2024; 25: 703–712.
3. Hosseini SJ, Manzari ZS, Karkhah S, et al. The effects of Valsalva maneuver on pain intensity and hemodynamic status during short peripheral cannula insertion in adults: a systematic review and meta-analysis. *J Vasc Access* 2024; 25: 1051–1062.
4. Hosseini SJ, Firooz M, Yazdi K, et al. The efficacy of technology-based devices on the first-attempt success rate for difficult intravenous access in pediatrics: a systematic review and network meta-analysis. *J Vasc Access*. Epub ahead of print 17 June 2024. DOI: 10.1177/11297298241259843.
5. Cooke M, Ullman AJ, Ray-Barruel G, et al. Not “just” an intravenous line: consumer perspectives on peripheral intravenous cannulation (PIVC). An international cross-sectional survey of 25 countries. *PLoS One* 2018; 13: e0193436.
6. Fusco N, Bernard F, Roelants F, et al. Hypnosis and communication reduce pain and anxiety in peripheral intravenous cannulation: effect of Language and Confusion on Pain During Peripheral Intravenous Catheterization (KTHYPE), a multicentre randomised trial. *Br J Anaesth* 2020; 124: 292–298.
7. Omkar Prasad R, Chew T, Giri JR, et al. Patient experience with vascular access management informs satisfaction with overall hospitalization experience. *J Infus Nurs* 2022; 45: 95–103.
8. Yılmaz D and Güneş ÜY. The effect on pain of three different nonpharmacological methods in peripheral intravenous catheterisation in adults. *J Clin Nurs* 2018; 27: 1073–1080.
9. Yu Z, Zhou Y, Xu X, et al. Pharmacological and non-pharmacological interventions in management of peripheral venipuncture-related pain: a randomized clinical trial. *BMC Pediatr* 2023; 23: 58.
10. Morais BX, Ongaro JD, Almeida FO, et al. Auriculotherapy and reducing chronic musculoskeletal pain: integrative review. *Rev Bras Enferm* 2020; 73: e20190394.
11. Villa G, Chelazzi C, Giua R, et al. The Valsalva manoeuvre versus tourniquet for venipuncture. *J Vasc Access* 2018; 19: 436–440.
12. Shi S, Zhu R, Huang X, et al. Comparison of the effects of Valsalva maneuver, EMLA cream, and the combination of both in relieving pain of needle insertion on totally implantable access port: a randomized controlled study. *J Vasc Access* 2024; 25: 1576–1583.
13. Shi H, Li X, Huang X, et al. Efficacy and safety of the Valsalva maneuver in relieving venipuncture pain in children and adults: a systematic review and meta-analysis. *J Vasc Access*. Epub ahead of print 23 February 2024. DOI: 10.1177/11297298241231903.
14. Vahedi M, Hasanpoor-Azghady SB, Amiri-Farahani L, et al. Comparison of effect of auriculotherapy and mefenamic acid on the severity and systemic symptoms of primary dysmenorrhea: a randomized clinical trial. *Trials* 2021; 22: 655.
15. Tesser CD, Moré AOO, Santos MC, et al. Auriculotherapy in primary health care: a large-scale educational experience in Brazil. *J Integr Med* 2019; 17: 302–309.
16. Alimoradi Z, Kazemi F, Valiani M, et al. Comparing the effect of auricular acupressure and body acupressure on pain and duration of the first stage of labor: study protocol for a randomized controlled trial. *Trials* 2019; 20: 766.
17. Cuschieri S. The CONSORT statement. *Saudi J Anaesth* 2019; 13: S27–S30.
18. Akarsu RH, Kuş B and Doğukan Akarsu G. Effects of Valsalva maneuver, EMLA cream, and stress ball for pregnant women’s venipuncture pain. *Altern Ther Health Med* 2021; 27: 108–114.
19. Agarwal A, Sinha PK, Tandon M, et al. Evaluating the efficacy of the Valsalva maneuver on venous cannulation pain: a prospective, randomized study. *Anesth Analg* 2005; 101: 1230–1232.
20. Shivashankar A, Nalini K and Rath P. The role of nonpharmacological methods in attenuation of pain due to peripheral venous cannulation: a randomized controlled study. *Anesth Essays Res* 2018; 12: 7–10.
21. Akdas O, Basaranoglu G, Ozdemir H, et al. The effects of Valsalva maneuver on venipuncture pain in children: comparison to EMLA® (lidocaine–prilocaine cream). *Ir J Med Sci* 2014; 183: 517–520.
22. El Tumi H, Johnson MI, Dantas PBF, et al. Age-related changes in pain sensitivity in healthy humans: a systematic review with meta-analysis. *Eur J Pain* 2017; 21: 955–964.
23. Rastegarzade H, Abedi P and Valiani M. The effect of auriculotherapy on labor pain intensity in nulliparous women. *Anesthesiol Pain* 2015; 6: 54–63.
24. Khloobagheri E, Kazemi M, Loripoor M, et al. Effect of foot reflexology with auriculotherapy on pain after elective cesarean section: a randomized clinical trial. *Iran J Obstet Gynecol Infertil* 2020; 23: 67–78.