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The Effect of Vibration Maneuver on Pain Relief during Cannulation Insertion for Cancer Patients: A Randomized Controlled Trial

Alaa Kareem Azeez MSc.*; Alaa Jawad Kadhim, Ph.D.**. Hadi Ahmadi Chenari, Ph.D.***.
*MSC, University of Baghdad, College of Nursing, Department of Adult Nursing, Baghdad, Iraq.
E: Mail: aalaa.aziz2202m@conursing.uobaghdad.edu.iq
** University of Baghdad, College of Nursing, Department of Adult Nursing, Baghdad, Iraq.
E: mail: alaaj@conursing.uobaghdad.edu.iq
*** PhD, Assistant professor, Department of Nursing, Ferdows School of Paramedical and Health, Birjand University of Medical Sciences, Birjand, Iran.
E: mail: ahmadi.h@bums.ac.ir.

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ABSTRACT

Objective(s): To measure the effect of using vibration maneuver on the level of pain during intravenous cannulation.

Methods: A randomized controlled trial was carried out in the oncology unit of AL- Al-Haboubi Teaching Hospital in Thi-Qar governorate from November 22nd, 2023 to June 5th, 2024. After the sample was selected among patients, 105 patients were divided into two groups, 50 in the control group and 55 in the experimental. In the experimental group, a vibrating device was used, and the pain was assessed using a visual analogue scale of a 10-cm line. The researcher used two white envelopes inside which there was a colored card to facilitate the random selection and a self-report method was used for data collection.

Results: The results of the statistical analysis showed highly significant differences between the two groups in pain intensity during cannulation in the post-test. The control group recorded a high average pain intensity of (M+SD 76.54+20.427), While the experimental group showed a significant decrease in pain intensity with an average (M+SD 27.25+22.788). These results indicate that the intervention based on applying vibration technology contributed effectively to reducing the level of pain, as the difference between the two groups was highly statistically significant (p=0.001).

Conclusion: The study concluded that vibration maneuver had a positive relationship and highly effective in reducing pain for intravenous cannulation.

Recommendations: The study recommended that the vibration experience be applied to patients during cannulation insertion in adult segments.

*Corresponding author at: University of Baghdad, College of Nursing, Department of Adult Nursing, Baghdad, Iraq.MSC. (Azeez A. K.). Email: aalaa.aziz2202m@conursing.uobaghdad.edu.iq. ORCID: https://orcid.org/0009-0005-2735-177X. **DOI:** https://doi.org/10.58897/392y5639

تأثير مناورة الاهتزاز على تخفيف الالم أثناء إدخال القنية لمرضى السرطان: تجربة منضبطة معشاة

المستخلص

الأهداف: ان تقليل الانزعاج الناجم عن إدخال القنية في الوريد من شأنه أن يحسن رضا المرضى، ويقلل من القلق، ويخفف من الآثار الفسيولوجية السلبية للألم لدى الأفراد ، لذلك تهدف الدراسة الحالية إلى قياس مدى تأثير استخدام الاهتزاز على مستوى الألم أثناء إدخال القنية الوريدية.

المنهجية: أجريت هذه التجربة المنضبطة المعشاة في وحدة الأورام في مستشفى الحبوبي التعليمي في محافظة ذي قارللمدة من ٢٢ تشرين الثاني ٢٠٢٣ إلى ٥ حزيران ٢٠٢٤ . وبعد اختيار العينة بين المرضى، تم عشوائيا تقسيم ١٠٥ مريضا إلى مجموعتين، ٥٠ مريضا في المجموعة الضابطة و٥٥ في المجموعة التجريبية. في المجموعة التجريبية، تم استخدام جهاز الاهتزاز، وتم تقييم الألم باستخدام المقياس التناظري البصري. واستخدم الباحثون مظروفين أبيضين معشيان بداخلهما بطاقات ملونة لتسهيل الاختيار العشوائي، كما تم استخدام أسلوب التقرير الذاتي لجمع البيانات.

النتائج:. أظهرت نتائج التحليل الإحصائي وجود فروق ذات دلالة معنوية عالية بين المجموعتين في شدة الألم أثناء إدخال القنية في الاختبار البَعدي. فقد سجلت المجموعة الضابطة متوسطاً مرتفعاً لشدة الألم بلغ (٧٦,٥٤±٢٠,٤٢٧)، في حين أظهرت المجموعة التجريبية انخفاضاً ملحوظاً في شدة الألم بمتوسط (٢٧,٢٥±٢٢,٧٨٨). وتشير هذه النتائج إلى أن التدخل المعتمد على تطبيق تقنية الاهتزاز أسهم بفاعلية في تقليل مستوى الألم، حيث كان الفارق بين المجموعتين ذا دلالة إحصائية عالية.(p=0.001) .

الاستنتاجات: خلصت الدراسة إلى أن مناورة الاهتزاز فعالة للغاية في تقليل الألم أثناء عملية إدخال القنية الوريدية.

التوصيات: أوصت الدراسة بتطبيق مناورة الاهتزاز على المرضى أثناء إدخال القنية في شرائح البالغين.

الكلمات المفتاحية: مناورة الاهتزاز، الألم، إدخال القنية في الوريد.

Introduction

In the past ten years, there has been a rise in cancer incidence among individuals in the Middle East, particularly in Iraq [(1)]. In 2022, the Iraqi Cancer Board registered 39,068 newly diagnosed cases of cancer in Iraq. In this report, breast cancer was a particularly common type of cancer in both males and females [(2)].

A large number of chemotherapy medications are used through intravenous administration [(3)], which involves invasive nursing procedures such as setting up an intravenous catheter (IV). This is done in around 70%-80% of patients who are admitted to the hospital. Nurses frequently perform peripheral venous catheter (PVC) in chemotherapy units as a core treatment [(4)].

Over the past few years, there has been a rise in the use of PVC in patients who are treated in oncology units due to the increased administration of high-dosage chemotherapy [(5)]. Of equal importance, pain is a complex feeling that combines physical as well as psychological components. [(6,7)], patients with cancer typically have higher levels of anxiety than others with different medical conditions [(8,1)]. Nurses play a crucial role in effectively managing pain and reducing its intensity [(9,10)]. PVC is reported to be a painful and uncomfortable procedure for patients [(11)]. Therefore, both pharmacological and non-pharmacological methods are used to manage the pain resulting from the insertion of needle into the vein [(12,13)].

However, studies have shown that pharmaceutical methods for pain control have drawbacks, such as the possibility of adverse reactions, longer onset times, and higher costs [(11)]. A literature review shows that many non-pharmacological treatments are used to manage discomfort associated with venipuncture [(14-16)].

Studies have shown that using mechanical vibration on both young children and older adults can successfully alleviate acute and chronic pain, including needle insertion-associated pain. Vibratory devices are also used for to produce analgesia in both adults and children [(17-19)].

Buzzy, developed by Labs in Atlanta, is a dependable device designed to decrease pain

during invasive medical procedures. This device makes the concurrent use of external cold and vibration to relieve pain and discomfort. Studies have shown that the use of Buzzy is a good way to reduce pain experienced during venipuncture. The device operates on the principles of Gate Control theory [20-22].

Thus, reducing the discomfort caused by intravenous cannulation would improve patient satisfaction, decrease anxiety, and alleviate the negative physiological effects of pain in individuals [23].

In Iraq, non-pharmacological techniques are not commonly employed to manage pain caused by the injection [12].

The current study was conducted as a clinical trial of non-pharmacological techniques for patients during intravenous cannulation. It aimed to determine the effect of vibration on patients' pain during intravenous cannulation

Methods

Study design and setting

A randomized controlled trial was used, as it provides the highest level of evidence for intervention studies. Randomization reduces selection bias, and the use of a control group enables valid comparisons, ensuring that observed differences in pain outcomes are attributable to the intervention [24]. The study was conducted between November 22nd, 2023 to June 5th, 2024. The study was carried out at the Oncology Unit of AL- Al-Haboubi Teaching Hospital in Thi-Qar.

Study sample and sampling

A simple random sampling (probabilistic sampling) was used to select a sample of 105 patients undergoing cannulation in an oncology center. Participants were given a chance to choose one of the two envelopes. According to Slovin's formula a total population size of 157, the sample size was estimated at 113:

$$n = N / [1 + (N) (E2)]$$

$$n = 112.7$$

$$n \approx 113.$$

The two groups are shown in Figure 1.

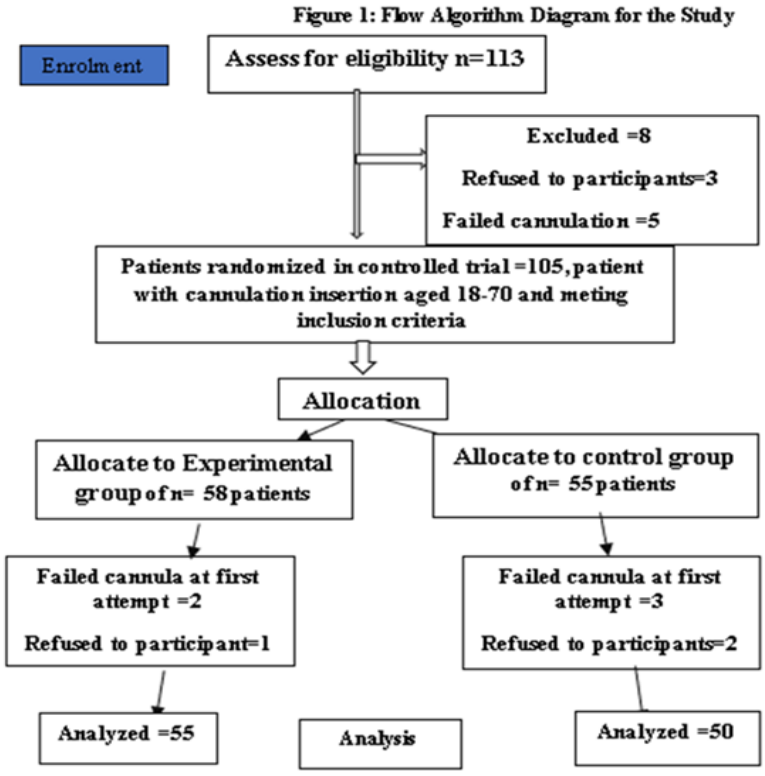

Figure1. CONSORT diagram flow chart.

Data Collection and study Instruments

The data were collected from January 4, 2024, to February 7, 2024. The participants were interviewed and were informed about the purpose of study. Their demographic data were collected. The researchers got permission from all participants to record their answers and save them for data analysis.

The total samples of 105 subjects were randomly divided into two groups. The data collection instruments were self-report, as well as the self-report for Visual Analog Scale (VAS) scale was used after the successful intravenous cannulation. Next, data were collected for the two groups (experimental and control groups) for the post-test measure by asking the patient to mark a point on the line that most correctly represented his or her pain level.

There were two parts in the questionnaire; part (I): Demographic information: It included three items to explore age, sex and level of education. Questionnaire; part (II): VAS for pain: The VAS is a widely used instrument for screening and evaluating the severity of pain at a specific moment, employing a measurement system. Reliability of the VAS for acute pain measurement as assessed by the Intra-class correlation coefficient (ICC) appears to be high at 0.97, and the validity of scale was 95%, VAS consists of a 10 cm line for marking the severity of pain.

Ethical Considerations

The researchers distributed the informed letters of consent to all patients actively involved in the oncology unit, to gain a full permission to participate in the current study. Furthermore, they received a notification of their right to withdraw from the study or choose not to answer a certain question during the study course at any time. The study protocol was approved by the Ethics Committee of Baghdad University, the College of Nursing, Baghdad, Iraq in 22/11/2023.

The trial was registered in the Iranian Clinical Trial Registery (IRCT) and the IRCT ID was (20230310057672N3). All guidelines set by the Worldwide Medical Association Declaration of Helsinki were followed.

The Intervention

Before the cannulation, it is common to cleanse the area surrounding the vein with an alcohol swab and let it dry. It happens following the application of a tourniquet to the patient's wrist and finding the right vein on the back of hand. In this study, the vibration device was placed about 3-5 cm proximal to the body. The device attachment was taped to the wrist 30-60 seconds before the intravenous cannulation and kept in place until the procedure was done. The pain intensity was measured immediately after the successful cannulation, using the VAS. The patient marked a point on the VAS line that represented his/her perceived level of pain.

Data analysis

Statistical Package for the Social Sciences (SPSS) was used to analyze the data. Descriptive and inferential statistics (frequency, percentage, mean of score, standard deviation, Kolmogorov Smirnov Test, and Mann-Whitney U test) were used to analyze the data. The data was not normally distributed, so the Mann-Whitney test was used. The reporting style was CONSORT 2010 diagram flow chart in this study.

Results

Table 1. The Distribution of Participants' Demographic Variables (n=105).

Variable	group	Control group		Experimental group	
		f	%	f	%
Age group/year	< 20	1	2	0	0
	20-29	3	6	1	1.8
	30-39	4	8	5	9.2
	40-49	12	24	17	30.9
	50-59	13	26	17	30.9
	60-69	14	28	13	23.6
	≥ 70	3	6	2	3.6
	Mean ± SD	51±13		51±10.9	
Sex	male	7	14	12	21.8
	female	43	86	43	78.2
Educational level	Primary school or lower	32	64	34	61.8
	Middle school and higher	18	36	21	38.2

F= Frequency, **%**= Percentage, **M**= Mean, **SD**= Standard deviation.

Table (1) presented that mean age of the study group was 51+10.9 years old while the mean age for the control group was 51+13 years old. In relation to sex, most of the study groups were females with (86%) and in the control group was (78.2%). The majority of patients in the control group (64%) had a level of education corresponding to primary school or lower. A comparable proportion was observed in the study group, where 61.8% of patients reported the same educational level.

Table 2. Pain score for control and experimental groups (No. 100)

Pain (VAS control)	f	%	Assessment	Pain (VAS study)	f	%	Assessment
No pain	0	0	Severe	No pain	9	16.4	Mild
Mild pain	2	4		Mild pain	31	56.4	
Moderate pain	14	28		Moderate pain	12	21.8	
Severe pain	34	68		Severe pain	3	5.5	
M+SD	76.54±20.427			M±SD	27.25±22.788		

VAS= Visual Analogue Scale, **F**= Frequency, **%**= Percentage, **M**= Mean, **SD**= Standard Deviation, Ass: Assessment No pain= 0-4, Mild= 5-44, Moderate= 45-74, Severe= 75-100.

Table (2) shows that patients experienced severe pain during cannulation as reported by 68% of patients (M±SD= 76.54±20.427) in the control group. Moreover, patients experienced mild pain during cannulation insertion after using the vibration maneuver as reported by 56.4% of patients (M±SD= 27.25±22.788).

Table 3. Comparison of Pain Severity between Intervention and Control Groups During Peripheral Intravenous Insertion

Groups	Pain					
	M.	SD	Mann-Whitney U	Z-score	P-value	Sig.
Control	76.54	20.427	173.500	-3.008	.001	S.
Experimental	27.25	22.788				

M= Mean, **SD**= Standard Deviation, **P value**= 0.001, **Sig**= Significance.

The Mann Whitney U test indicated a significant difference in pain severity between the experimental and control groups during cannulation insertion. The experimental group had a lower mean rank (Mean Rank= 27.25) compared to the control group (Mean Rank= 76.54), and the difference was statistically significant (U= 173.500, P value= 0.001). These results demonstrate that the vibration maneuver was highly effective in reducing pain."

Discussion

The current study aimed to determine the effect of using vibration on the level of pain during intravenous cannulation. Section 1 of the discussion will present and discuss the results of the descriptive tables. The finding of present study indicated that most sample study was female. M±SD= 51+13 5 of control group, and 1+10.9for experimental group. While the section 2 will present and discuss the results of inferential tables. The severe pain reported in 68% of patients in control group while, there's mild pain after application the vibration in experimental group reported in 56.4%. There's highly effective in lowering pain in vibration group at p-value of .001 and the vibration maneuvers was a highly effective in relieving pain during cannulation insertion.

The study findings agree with research done in Turkey, the mean ratings of pain for those in the experimental group were lower than those in the control. As the findings showed, using vibration and cold gel packs could be recommended for alleviating pain in intravenous cannulation of adults [19].

Another study aimed to assess the effect of vibration stimulation on intramuscular injection pain and patient satisfaction. A total number of 84 injections were analyzed and most participants (53.6%) were female. Most participants (44.4%) in the sample held a primary school education and pain and satisfaction were assessed via VAS. The results showed that vibration decreased the severity of pain and increased patient satisfaction [25].

A recent study in Turkey investigated the effect of the vibration technique at the injection site and squeezing a stress ball during administration on pain severity of COVID-19 vaccination. The study included 120 adults divided into three groups. The study showed that the application of local vibration using the Buzzy® device effectively reduced pain levels associated with the administration of vaccination [26].

Another study was conducted in Turkey to investigate the effect of Buzzy® on phlebotomy satisfaction and pain experienced during the phlebotomy process in healthy adult blood donors. A statistically significant difference was found between the average level of pain and satisfaction level with the phlebotomy procedure. The study showed that the Buzzy® device proved to be effective in alleviating the pain associated with phlebotomy and enhancing phlebotomy satisfaction among healthy adult males [20].

In contrast, the study conducted in Turkey, to assess the efficacy of vibration device on pain during and after venipuncture procedures in infants. The study concluded that the device

did not reduce pain scores in infants during and after venipuncture procedure [27].

The vibration maneuver reduces pain primarily through the Gate Control Theory, where stimulation of large-diameter sensory fibers inhibits pain signal transmission from small nociceptive fibers. It also activates mechanoreceptors, triggers endorphin release, engages descending inhibitory pathways, and provides cognitive distraction, all of which collectively decrease the perception of pain during procedures [28].

The present study has certain limitations, primarily because it was conducted at a single center and due to the limited number of existing studies on the use of vibrating devices for pain reduction. Consequently, the findings may have limited generalizability to other settings or populations. Nevertheless, this study was undertaken to address the urgent need to enhance nursing skills, minimize patient pain, and contribute to the advancement of nursing research, particularly given the scarcity of controlled trial studies within the nursing profession. Future multicenter studies with larger and more diverse samples are recommended to validate these findings and enhance their generalizability.

Conclusion

The findings of this study suggest that the vibration maneuver is an effective non-pharmacological strategy for alleviating pain in patients with cancer during intravenous cannulation. Incorporating this technique into routine nursing practice has the potential to enhance patient comfort and improve the overall quality of care. Further research, particularly multicenter studies with larger and more diverse samples, is recommended to validate these results and expand the applicability of this intervention across different clinical settings.

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Conflict of interest

None to declare.

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Data availability

The data supporting the findings of this study are not publicly available due to ethical and privacy considerations but may be made available from the corresponding author upon reasonable request and with appropriate approval.

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