Original Article

Effectiveness of using a vibration device to ease pain during upper extremity injections: A randomized controlled trial

ABSTRACT

Objectives: The current study aimed to evaluate the effectiveness of using a vibration device to ease pain during upper extremity injections. Specifically, the study aims to compare the pain levels of patients who receive the injection with and without the use of vibration therapy. The results of this study may have implications for improving patient outcomes and satisfaction during routine injection procedures.

Material and Methods: This randomized controlled trial included patients aged 18 years or older who were scheduled to receive an injection in the upper extremity. A total of 60 patients were enrolled and randomized to either the intervention group or the control group using a computer-generated randomization sequence. The level of satisfaction and pain levels were assessed using a visual analog scale. The study was conducted in accordance with the Declaration of Helsinki and approved by the institutional review board.

Results: The mean pain score immediately after the injection was 4.03 ± 2.11 out of 10 in the vibration group (n = 30), compared to 7.4 ± 1.37 out of 10 in the control group (n = 30) ($P < 0.001$). Patients in the vibration group also reported higher levels of satisfaction and comfort during the injection ($P < 0.001$). No adverse events were reported in either group.

Conclusion: Our study proves that using a vibration device during upper extremity injections can effectively reduce postinjection pain and improve patient satisfaction. Further research is needed to explore this intervention's long-term effects and feasibility in different clinical settings.

Key words: Pain comfort, pain reduction, randomized controlled trial, vibration therapy, visual analogue scale, upper extremity injections

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Introduction

Injection-related pain is a common issue that can cause significant discomfort and anxiety for patients.[1] Pain during injections can lead to decreased adherence to necessary treatments and, in some cases, can even result in needle phobia.[2] While some patients may experience only mild pain during injections, others may experience more severe pain that can persist for hours or even days after the procedure.[3] Thus, it is essential to identify effective methods for reducing injection-related pain to improve patient comfort and adherence to necessary treatments.[4]

In 1965, Melzack and Wall presented the "gate control" hypothesis, which suggests that pain perception might be mitigated by stimulating nerve fibers that convey non-noxious signals.[5] The hypothesis suggests that stimulation of the larger-diameter Ab fibers (e.g. with sufficient pressure or vibration) can seal a brain "gate" to nociceptive signals, thereby reducing the pain sensation. Vibration specifically stimulates mechanoreceptors, including the Pacinian corpuscles and main terminals of the muscular spindle.[6,7] Incorporating insights from Sá-Caputo *et al*.,[8] our understanding of pain mitigation extends to mechanobiomodulation, which explains how mechanical vibration influences physiological responses through mechanisms beyond the 'gate control' theory. This suggests vibration devices could reduce pain by activating a broader network of mechanosensors, including Piezo1 and Piezo2 ion channels, with implications for their clinical use in reducing injection-related discomfort.

Vibrational stimulation is one of many nonpharmaceutical methods for managing pain. Local vibration therapy generates vibrations that can penetrate up to 6 cm into the tissue, manage muscle tone, alleviate localized pain, and increase blood and lymphatic circulation.[9-11] The newly introduced guidelines for whole-body vibration (WBV) research aim to unify and enhance reporting standards across both clinical and preclinical studies. By expanding upon previous guidelines, they cover a wider array of WBV research aspects, offering explanations and examples to aid in reporting. Designed to complement general reporting standards without imposing rigid application recommendations, these guidelines advocate for flexibility due to the diverse nature of WBV studies.[12] Recent research highlights the potential of local vibration (LV) as an effective technique for neuromuscular conditioning, offering a practical alternative to WBV in clinical settings. By applying vibrations directly to specific muscles or tendons, LV can induce significant neuromuscular adaptations without the need for active patient participation. Studies suggest that even short-term LV sessions can impact muscle performance, with improvements largely driven by changes in the central nervous system. This positions LV as a promising approach for enhancing muscle conditioning and rehabilitation efforts.[13]

Vibration devices have emerged as a potential solution to reduce pain associated with various medical procedures.[14-16] These devices are noninvasive and easy to use. Additionally, they are cost-effective and have few, if any, reported adverse effects. Previous research has investigated the application of microvibratory stimulation during digital blocks of the hand using the DentalVibe device, aiming to evaluate its impact on injection pain scores. The study revealed a statistically significant difference in mean injection pain scores when the DentalVibe device was utilized for vibration anesthesia during digital blocks of the hand. This finding suggests that using microvibratory stimulation can potentially reduce the discomfort associated with these procedures.[17] Vibration devices have been used during injections to reduce pain in dental procedures,[18] facial surgeries,[19] and plastic surgery clinical practice settings,[15] with limited information available regarding their use in upper extremity injections.

Moreover, the sample sizes in some studies were relatively small, and the study populations were often limited to specific patient populations, which may limit the generalizability of their findings. Therefore, there is a need for further research on the effectiveness of vibration devices in reducing injection-related pain, particularly in upper extremity injections, using larger sample sizes and diverse patient populations. The current study aimed to evaluate the effectiveness of using a vibration device to ease pain during upper extremity injections. Specifically, the study aims to compare the pain levels of patients who receive the injection with and without the use of vibration therapy. The results of this study may have implications for improving patient outcomes and satisfaction during routine injection procedures.

Methods and Materials

Study design and clinical setting

This prospective clinical trial was conducted in a tertiary center and spanned the duration between October 2022 and February 2023. The authors recruited 60 patients aged 18 and older who were scheduled to receive an injection in their upper extremities in the plastic surgery department. The inclusion criteria included (1) adult patients aged 18 years and older, (2) those scheduled to receive local anesthesia or corticosteroid injections in their upper extremities, (3) those free from peripheral sensory loss conditions (i.e., stroke,

multiple sclerosis, diabetic peripheral neuropathy, etc.), and (4) those free from infection, abscess, or necrosis at the injection site. Exclusion criteria included (1) those on analgesic medications (such as opioids), (2) alcoholics and substance use disorders, (3) pregnant patients, (4) patients with reported allergies, (5) patients with acute infections, (6) patients with chronic pain, (7) patients with a psychiatric condition, and (8) declined to participate. Simple randomization was used in this study to assign participants to either the intervention (vibration arm) or control group (nonvibration arm). A random number generator was used to ensure that each participant had an equal chance of being assigned to either group [Figure 1].

Injection technique

In this study, the chosen vibration device was the 24K Gold Energy Beauty Bar Electric Vibration Facial Massage Roller Waterproof. It was operated at a fixed frequency setting of 6000 rotations per minute (RPM), which corresponds to 100 Hz, with a vibration. Furthermore, following the guidelines provided by van Heuvelen MJG *et al*.,[12] we also report the peak-to-peak displacement of the mechanical vibration, which was set to 1.0 mm. This specification ensures adherence to comprehensive reporting standards for mechanical vibration parameters, enhancing the reproducibility and comparability of our findings with other studies in the field of whole-body vibration research. This specific setting was applied consistently throughout the study for all participants. The injection technique used in this study followed standard clinical practice for upper extremity injections. The preparation for injection began with the thorough cleaning of the injection site using an antiseptic solution. The medication was administered with a 30 gauge (30 G), ½ inch length sterile needle attached to a standard syringe. The needle was inserted perpendicularly into the target area at a 90-degree angle to the skin surface. The medication was then slowly injected as the needle was carefully withdrawn, ensuring even distribution and minimizing tissue disruption. In the intervention group, the vibration device was placed proximal to the injection site for

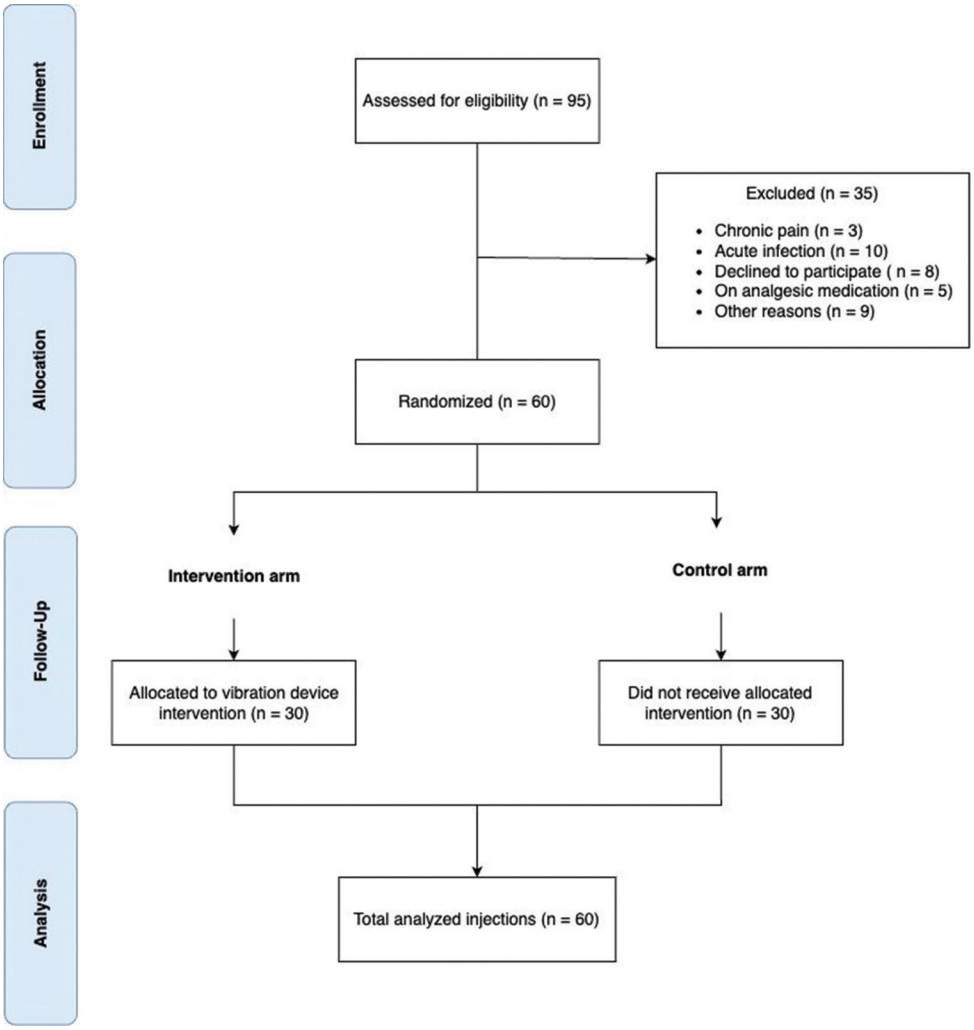

Figure 1: Flow diagram for this study (CONSORT statement)

a few seconds before the injection, and the medication was then injected at the injection site while the vibration device was still functioning [Figure 2]. Immediately following the injection, the vibration device was turned off and cleaned with an alcohol swab. Patients were evaluated for their level of pain and satisfaction after each injection. The control group did not receive any intervention and underwent the standard injection procedure without using a vibration device. A single investigator performed all injections on all enrolled patients to avoid bias. The injection sites were selected based on the specific clinical indication for each injection, including (1) the wrist, (2) the A1 pulley of the middle finger, (3) the A1 pulley of the ring finger, and (4) other sites within the upper extremity. This fourth category encompasses locations not explicitly listed but within the upper extremity. The injected material was varied based on indications of injection; the materials included (1) lidocaine, (2) lidocaine with epinephrine, or (3) triamcinolone with lidocaine.

Outcome measures and data collection tool

After the injection was administered, patients were requested to fill out a form regarding their experience. The primary outcomes of this study included the level of pain experienced by patients during the injection and their satisfaction with the procedure. The pain was assessed using a visual analog scale (VAS), with patients indicating their level of pain on a scale from 0 to 10, with 0 indicating no pain and 10 indicating the worst possible pain. In our study, patients were asked to report their pain levels immediately after the injection and again at a follow-up time point between 2 and 5 minutes. Patient satisfaction with the injection procedure was assessed using a Likert scale, a method widely recognized for its reliability and simplicity in gauging subjective experiences and opinions. Patients indicated their level of satisfaction on a scale from 1 to 5, where 1 signifies 'very dissatisfied' and 5 'very satisfied'.[20] Additionally, the secondary outcomes of this study included collecting basic demographic information such as age, gender, and smoking status and information on previous injections, the site of injection, the injected material, and the indication of injection. Furthermore, patients were asked if they experienced any complications related to the injection procedure, such as bleeding, numbness, or infection. Those who received a vibration device were also asked if the vibration device helped to reduce their pain during injection and whether they would request the use of a vibration device for any future injections of their upper extremities. Data were collected immediately following the injection procedure. All data were recorded on a secure, password-protected electronic database.

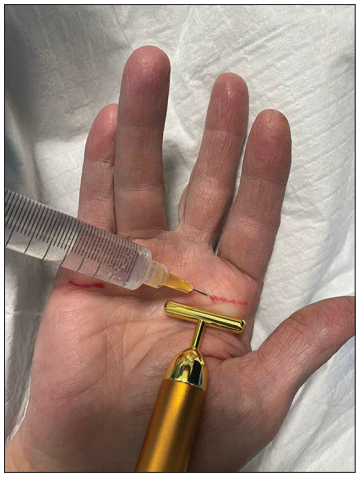

Figure 2: Image demonstrating the use of a vibration device during upper extremity injections. The vibration device is placed proximal to the injection site and used for a few seconds before the medicine is injected at the injection site while the vibration device is still functioning

Ethical considerations

The patients were informed about the use of study data and assured of their privacy, in accordance with the Helsinki Declaration. They provided written consent prior to participating in the study. The study was registered on Clinical Trials with the registration number "NCT05651139" (14/12/2022) prior to recruiting the first participant and has been reported in accordance with the Consolidated Standards for Reporting Trials (CONSORT) Statement for reporting parallel group randomized trials.[16] The clinical trials were full-board approved by the Institutional Review Board (Ref. No. 23/0032/IRB-A).

Statistical analysis

Data were analyzed using Statistical Package for Social Studies (SPSS 22; IBM Corp., New York, NY, USA). Continuous variables were expressed as mean ± standard deviation, and categorical variables were expressed as percentages. T-test calculation for two independent means was used to estimate the efficacy of the vibration device in easing the pain after the injection with a P value < 0.05 considered statistically significant. Univariate analysis was used to seek the correlation between different subjects' variables and the mean scores of the VAS alongside the injection satisfaction with a P value < 0.05 considered statistically significant with a confidence interval of 95%. The randomization process was performed by a researcher not involved in the recruitment. The calculation of the sample size for this study was guided by preliminary data and studies in similar domains that explored the effectiveness of vibration devices in reducing pain during medical procedures. To ensure sufficient power to detect a significant difference between the intervention and control groups, we employed a power analysis. This analysis was based on expected pain score differences observed in previous research, assuming a standard deviation as per similar prior studies. We aimed for a power of 80% and an

alpha level of 0.05 to detect clinically meaningful differences in pain scores using a two-sided *t*-test. Considering these parameters and accounting for a potential dropout rate of 10%, the required sample size was calculated to be 60 participants (30 per group).

Results

In this clinical trial, a total of 60 patients were included, with 30 patients randomly assigned to the vibration arm and 30 patients to the nonvibration arm. This allocation was achieved through simple randomization using a computer-generated random number sequence. The maximum age in our trial was 75 years, with a mean age of 51.00 ± 13.98 years. 51.7% of the included patients were male in gender, 80% were nonsmokers, 53.3% had prior injections, and the commonest noticed comorbidity was hypertension. Furthermore, the commonly injected material was lidocaine with epinephrine as that accounted for 51.7% of our cohort; the commonest injection side was volar (80%), the wrist constituted the most familiar site (25%), and the trigger finger was the commonest indication for the injection (53.3%). Further details about the demographic traits of the two arms are presented in Table 1.

Table 1: Two arms subjects' demographics

Variable	Category	Data (%)
Age	Mean (± Std Dev)	51.00 (±13.98) years old
Gender	Male	31 (51.7%)
	Female	29 (48.3%)
Smoking status	Smoker	9 (15.0%)
	Nonsmoker	48 (80.00%)
	Ex-Smoker	3 (5.0%)
Previous injections	Yes	32 (53.3%)
	No	28 (46.7%)
Comorbid conditions	Diabetes mellitus	31
	HTN	40
	Others*	14
	Healthy	18
Randomization	Vibration used	30 (50%)
	No-vibration	30 (50%)
Site of the injection	Wrist	15 (25%)
	A1 pulley of middle finger	13 (21.7%)
	A1 pulley of ring finger	12 (20.0%)
	Other sites within the upper extremity**	20 (33.3%
Injected material	Lidocaine	12 (20%)
	Lidocaine with epinephrine	31 (51.7%)
	Triamcinolone with lidocaine	17 (28.3%)
Volar\dorsal	Dorsal	12 (20%)
	Volar	48 (80%)
Reason of injection	Trigger finger	32 (53.3%)
	Carpal Tunnel syndrome	11 (18.3%)
	Mass excision	4 (6.7%)
	Other reasons**	13 (21.66%
Has this injection been less painful than previous injections?	Yes	28 (46.6%)
	No	4 (6.7%)
	No previous injections	28 (6.7%)

We calculated the VAS outcomes from each patient and analyzed the outcomes and found that the mean score immediately after the injection for the vibration arm was 4.03 (±2.11) out of 10, and the mean score after 2–5 minutes of the injection was 2.66 (±1.89); as for the injection satisfaction for the vibration arm, we found that 50% were very satisfied, 43.3% were extremely satisfied, and none expressed their dissatisfaction. The mean score immediately after the injection for the nonvibration arm was 7.4 (±1.37) out of 10, and the mean score after 2–5 minutes of the injection was 5.95 (±1.78); as for the injection satisfaction for the nonvibration arm, we found that 53.33% were neutral and only 33.33% were slightly satisfied.

We further analyzed the VASs to reach a consensus about the efficacy of the vibration device in easing injection pain. The *t*-test showed a statistically significant difference between the two arms with a *P* value *of* <.*00001* and a t-value of 7.31736 (immediately after the injection) and a statistically significant difference between the two arms with a *P* value *of* <.*00001* and a t-value of -6.64501 (2–5 minutes after the injection). Further details are presented in Table 2 and depicted in Figure 3. Figure 4 displays the different indications that were included in our study for injection. Patients who had injections with vibration were asked if they would request to have the injection with the vibration again, and 95% responded yes. Overall, 93% of patients claimed the vibration device reduced their pain significantly. Among patients with vibration arms, no complications were observed. Among those without vibration, one patient developed persistent numbness.

We further analyzed the data utilizing a univariate analysis to seek the correlation between different demographic variables and injection satisfaction alongside the mean scores of the VAS. All the analyzed variables did not show any statistical significance except for the "Used Vibration" variables. It showed a statistical significance with a *P* value *of* <.*00001* in injection satisfaction and the mean score of the VAS. Further details are presented in Table 3 and Table 4. No statistically significant differences were found in visual analog mean scores between the case groups and the control group when considering basic demographics, injection type, or injection site ($P > 0.05$). In terms of satisfaction levels, there were no significant differences between the case groups and the

Table 2: Outcomes from the two arms to compare the intervention significance

Variable	Category	Data		*P*	Confidence Interval
		Vibration arm	Nonvibration arm		
VAS immediately after injection	Mean (±Std Dev)	4.03 (± 2.11)	7.4 (± 1.37)	<0.00001	[2.29, 4.45]
VAS after 2–5 minutes	Mean (±Std Dev)	2.66 (± 1.89)	5.95 (± 1.78)	<0.00001	[2.361,4.219]
Injection satisfaction	Extremely satisfied	13 (43.3%)	0 (0%)	-	-
	Very satisfied	15 (50.0%)	1 (3.33%)	-	-
	Slightly satisfied	0 (0%)	10 (33.33%)	-	-
	Neutral	2 (6.7%)	16 (53.33%)	-	-
	Not satisfied	0 (0%)	3 (10.0%)	-	-
Complications	None	30 (100%)	29 (96.66%)	-	-
	Numbness	0 (0%)	1 (3.33%)	-	-

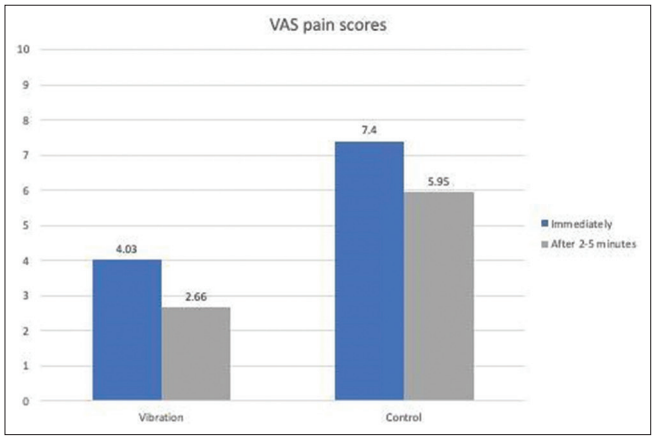

Figure 3: VAS of the two arms immediately and after 2–5 minutes after the injection

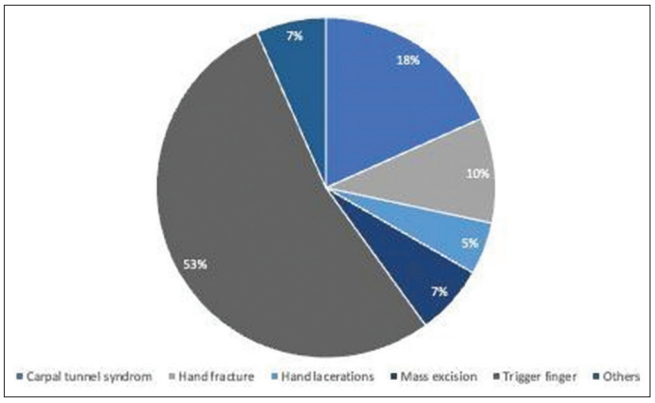

Figure 4: Various indications for injection among the included patients

control group in relation to basic demographics, injection type, or injection site ($P > 0.05$).

Discussion

This prospective clinical trial aimed to evaluate the efficacy of the vibration device on easing the pain during injections in the upper extremities by recruiting 60 patients and stratifying them into two arms, (1) vibration arm and (2) nonvibration arm, in which each patient's pain scores were calculated and then a mean of the scores were analyzed statistically to find a consensus about the benefit of the vibration device in such intervention.

The analysis showed a statistically significant benefit of vibration device in easing the pain of injection with a *P* value of <.00001. This significance was observed immediately after the injection and 2–5 minutes after the injection. Furthermore, the authors recorded the patients' injection satisfaction and found that 53.33% were neutral and only 33.33% were slightly satisfied in the nonvibration arm, while in the vibration arm patients, we found that 50% were very satisfied, 43.3% were extremely satisfied, and none expressed their dissatisfaction. The findings of these clinical trials go in line with previously published trials in different areas and settings.[4,14-19] A 2020 study published in The Journal of PeriAnesthesia Nursing found that using a vibration device prior to injections significantly reduced pain in children. The findings of this study indicate that the use of external cooling and vibration applied to the site of local anesthesia had a notable impact on reducing injection pain experienced by children during dental treatment.[21] A study conducted by Kearl *et al*.[22] examined the use of the Buzzy® device combined with the J-tip® device for pain management during venipuncture or intravenous starts in pediatric patients. The findings indicated that both interventions resulted in lower pain scale scores compared to no analgesia. However, combining the two interventions did not lead to a significant reduction in pain scale scores compared to using the J-tip® device alone. Another study has explored the use of microvibratory stimulation during digital blocks of the hand, specifically employing the DentalVibe device to assess its effects on injection pain scores. Consistent with prior findings, our study demonstrated a statistically significant difference in mean injection pain scores when utilizing the DentalVibe device for vibration anesthesia during digital blocks of the hand. These results further support the notion that microvibratory stimulation has the potential to effectively reduce the discomfort commonly associated with such procedures.[17]

Table 3: Univariate analysis of different demographic traits correlated to the injection satisfaction

Variable	Category	*P*
Injection satisfaction		
Used vibration	Yes	<0.00001
	No	
Age	Mean of ages	0.142
Gender	Male	0.156
	Female	
Site of the injection	Wrist	0.158
	A1 pulley of middle finger	
	A1 pulley of ring finger	
	Other sites**	
Volar\dorsal	Dorsal	0.127
	Volar	
Reason of injection	Trigger finger	0.173
	Carpal Tunnel syndrome	
	Mass excision	
	Other reasons**	

Table 4: Univariate analysis of different demographic traits correlated to visual analog mean scores

Variable	Category	*P*
Visual analog mean scores		
Used vibration	Yes	<0.00001
	No	
Age	Mean of ages	0.372
Gender	Male	0.633
	Female	
Site of the injection	Wrist	0.712
	A1 pulley of middle finger	
	A1 pulley of ring finger	
	Other sites**	
Volar\dorsal	Dorsal	0.070
	Volar	
Reason of injection	Trigger finger	0.031
	Carpal Tunnel syndrome	
	Mass excision	
	Other reasons**	

Drawing from the evidence provided in earlier studies, the use of a vibration device has shown a notable effect on reducing pain associated with injections. These observations lend robust support to the results we have documented in our clinical trial. The mechanism behind why the vibration device eases the pain after the injection could be explained by reducing the sensation of pain and discomfort in the area around the injection site. The vibration may work by stimulating sensory nerves in the skin, which can help to override the pain signals sent to the brain by the injection.[23] This increased blood flow may help to reduce inflammation and promote healing, which can further help to ease pain and discomfort; however, the exact mechanisms by which vibration devices ease pain after an injection are not yet fully understood; it is believed that the vibration helps to reduce pain signals and promote healing, making the injection experience more comfortable for the patient.[24]

Limitations

The current study has several limitations that should be acknowledged. First, the study was conducted at a single center and included a relatively moderate sample size. Therefore, the generalizability of the findings may be limited. Further multicenter studies involving larger and more diverse patient populations are needed to validate the findings of this study. Second, we did not evaluate the effect of vibration devices on different types of injections or on patients with different levels of anxiety. The third limitation of our study is the lack of standardization in the conditions requiring the injection, the injection site, and the materials used for the injection. Future research should consider these limitations and strive for better standardization in these aspects to enhance the validity and generalizability of the findings. An inherent limitation concerning the biomechanical parameters involves the study's focus on a singular vibration setting—specifically, a fixed frequency of 100 Hz and a peak-to-peak displacement of 1.0 mm. This singular setting does not account for potential interaction effects between different biomechanical parameters, such as the interplay between frequency, amplitude, and individual patient characteristics (e.g. skin thickness, subcutaneous fat distribution) that might influence the efficacy of vibration-induced pain relief. The fixed vibration setting limits our understanding of how varying these parameters could enhance or diminish the therapeutic effects of vibration on pain mitigation. Future investigations should consider a broader range of biomechanical settings to explore these dynamics thoroughly and tailor vibration therapy more effectively to individual patient needs. Last, the cost-effectiveness of implementing vibration devices in clinical practice was not assessed in our study, and this should be considered in future research. Despite these limitations, the current study provides preliminary evidence supporting the effectiveness of using a vibration device to reduce pain during upper extremity injections. Future studies could evaluate the effectiveness of vibration devices in reducing pain during other procedures such as venipuncture, arterial puncture, and nerve blocks. Forthcoming studies should also evaluate the effectiveness of the vibration device in both adolescent and pediatric populations. Assessing the impact of the vibration device on pain management and satisfaction levels specifically in these age groups would provide valuable insights and help determine the applicability and benefits of this intervention across different age ranges. Furthermore, further research could be conducted in order to determine the optimal duration and intensity of vibration required to achieve maximum pain relief. In addition, studies could also

be conducted to evaluate the effect of vibration devices on the anxiety of patients undergoing these procedures.

Conclusion

This prospective clinical trial aimed to assess the efficacy of a vibration device in easing the pain after injections in the upper extremities and showed a significant benefit of the vibration device in easing the pain and increasing the patients' injection satisfaction. Vibration is a safe and effective means of reducing the pain among patients. We strongly encourage the routine implementation of vibration devices in clinical settings to enhance patient satisfaction and the experience in hospital settings.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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