



Efficacy of virtual reality distraction technique for anxiety and pain control in orthopedic forearm surgeries performed under supraclavicular brachial plexus block: A randomized controlled study

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ABSTRACT

Background: Virtual reality (VR) distraction has been considered an alternative to medication to treat acute pain related to different procedures. This study aimed to evaluate the safety and efficacy of VR in reducing anxiety and pain in patients having orthopedic forearm operations under supraclavicular brachial plexus block.

Methods: This was an open-label, parallel-group, randomized trial. Thirty adult patients with American Society of Anesthesiologists physical status I or II were enrolled for orthopedic forearm operations performed under supraclavicular brachial plexus block. The patients were randomized into two equal groups. In the VR group, 15 patients performed the procedure with the use of VR and administration of midazolam according to the patient's request, while in the control group, 15 patients received 2 mg midazolam followed by a titration dose according to the patient's request. The primary outcome was the total intravenous sedation needed for the patient. Secondary outcomes included total perioperative analgesic utilization, incidence of harmful effects, patient satisfaction rating, and hemodynamic parameters.

Results: Virtual distraction technique significantly reduced the intraoperative midazolam consumption (2.00 ± 0.00 vs 6.67 ± 2.09 mg, respectively, $p < 0.001$) compared to the control group. The total perioperative analgesic consumption, incidence of adverse effects, and hemodynamic parameters were not significantly different in both groups. Patients who performed the block with the VR distraction technique showed better satisfaction scores compared to the control group (9.60 ± 0.51 vs 8.53 ± 0.92 , respectively, $p = 0.001$).

Conclusion: In orthopedic forearm surgeries under supraclavicular nerve block, the VR distraction technique can reduce intraoperative sedation requirements and improve patient satisfaction.

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1. Introduction

Anxiety is a normal response that emerges from surgical operations and anesthesia. Following orthopedic injuries, anxiety problems are quite common, persistent, and may coexist with other symptoms to alter the protracted results of the damage [1]. An increase in the need for anesthesia/surgical discomfort, recovery time, and hospitalization have all been linked to perioperative anxiety [2].

Moreover, peripheral nerve blocks have been used regularly as a form of anesthesia due to the ubiquitous usage of ultrasonography in daily anesthesia practice. The preoperative anxiety level may also be impacted by the anesthetic technique used separately from the surgical procedure [3]. Intravenous sedation is frequently used to ensure patient comfort. This includes the administration of powerful opioids like fentanyl and benzodiazepines like midazolam. These drugs are not safe to take particularly opioids. Routine

administration of opioid and sedatives should be avoided due to potential side effects like respiratory depression, which are more common in patients who have sleep apnea [4] as well as the risk of long-term opioid abuse in even patients who have never used opioids before [5] and received opioids during the perioperative period. Additionally, in susceptible individuals, such as the elderly, benzodiazepines and intravenous opioids may cause postoperative delirium [6].

Virtual Reality (VR) allows users to completely immerse themselves in a "virtual world" through tactile, olfactory, visual, and other senses. This is very different from sitting and watching television or playing video games. The usage of VR technology was first restricted to entertainment uses, but it has since expanded to a wide range of healthcare fields [7]. Patients can divert their attention from the main process by participating in a freshly generated interactive, simulated world with the use of VR [8].

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Several studies were carried out to demonstrate the effectiveness and benefits of VR as well as its drawbacks [9]. Virtual reality was used in managing acute procedure-related pain [10]. It has been employed in painful procedures, including burns [11], impacted third molar teeth [12] urological [13], and orthopedic operations [14]. Virtual reality was self-administered to cure persistent low back pain during COVID-19 and has been shown in recent trials to positively modify chronic intractable pain [15,16]. Recently, the use of VR environments in the management of anxiety and phobias has received the most attention in relation to psychological treatments [9]. This study aimed to evaluate the safety and effectiveness of VR on anxiety and pain level in patients undergoing orthopedic operations on the forearm under supraclavicular brachial plexus block.

2. Methods

2.1. Ethical considerations

This trial was conducted following consent by the Ethics Committee of the Faculty of Medicine, Cairo University, Egypt. This study was listed at the ClinicalTrials.gov (ID: NCT05512728). After declaration of the aim and methods of the trial, a written informed consent was obtained from each participant. The information of each participant was kept confidential.

2.2. Study design, setting, and date

This open-label, parallel-group, randomized, clinical trial was performed at Cairo University Hospitals, Egypt between November 2020, and May 2021.

2.3. Eligibility criteria

The present study included 30 adult participants aged 18- to 60-year-old of both genders. Patients who had an American Society of Anesthesiologists physical status I or II were scheduled for elective forearm orthopedic surgeries using ultrasound-guided supraclavicular technique for brachial plexus block.

We excluded patients who had any problem preventing proper fitting of the glasses to the patient face and those with sensory impairment (blindness, deafness) and eye infection. Also, patients who had a history of allergy to the local anesthetic drugs, psychiatric disorders (claustrophobia), and cognitive impairment and those with coagulopathy or infection at the puncture site were excluded.

2.4. Randomization, allocation concealment, and blinding

Using a computer software program, randomization was done. The use of consecutively numbered, sealed,

opaque envelopes served as the means of allocation concealment [17]. The allocation was not hidden from the researchers, participants, or healthcare professionals.

2.5. Interventions

Thirty adult patients were divided into two groups by random method (15 patients each). Brachial plexus block surgery was performed on all patients using an ultrasound-guided supraclavicular approach. Patients in the control group received 2 mg midazolam then titration of midazolam (0.01 mg/kg/dose) with the patient's request. Patients in the VR group applied the VR set before performing the supraclavicular block. The block technique was fully explained to patients who were reassured that they could terminate the VR session at any time during the procedure once occurrence of any adverse effect like nausea, vomiting, and headache, then titration of midazolam (0.01 mg/kg/dose) according to the patient request. VR was removed after the surgery and prior to exiting the operating room.

The VR environment was provided by Shinecon VR (Shinecon, china) that have a large field of view and high-quality display, with aspheric lens, lens diameter 40 MM, view angle 108, sharpness 99%, visibility 100%, color 38 MM, and pupillary distance adjustment 65 MM. The Shinecon VR setup was powered by a HUAWEI Y7 prime phone running the freely available VR software. Shinecon VR provides videos for nature, forests, wind, desert, and animals. That featured noise-canceling headphones with the VR simulation's background music playing.

Detailed history taking especially for any psychiatric disorders or cognitive impairment and thorough physical examination, especially for eye, sensory impairment, and the site of puncture for local anesthetic injection were conducted in the pre-anesthetic visit. Routine laboratory investigations were carried out including complete blood count, prothrombin time, partial tissue thromboplastin time, international normalized ratio, and random blood sugar.

2.6. Intraoperative management

As soon as the patient entered the surgical room, basic monitoring was applied for the heart rate (HR), non-invasive blood pressure, respiratory rate, pulse oximetry, and Electrocardiography. A 20-gauge or wider intravenous line was secured.

2.7. Block performance

All patients received ultrasound-guided supraclavicular block. The skin was disinfected, and the transducer was placed in the transverse plane directly above the

clavicle; the transducer was tilted caudally to image the chest contents and to obtain a cross-sectional view of the subclavian artery. The brachial plexus was viewed as a group of hypoechoic oval structures posterior and superficial to the artery. Using a 25- to 27-gauge needle, 1–2 mL of local anesthetic was injected into the skin 1 cm lateral to the transducer. The distribution of local anesthetic via small-volume injections was observed as the needle advances through tissue layers (hydro-localization); small-volume injections were used to prevent accidentally inserting the needle into the brachial plexus. The block needle was then inserted in-plane toward the brachial plexus in a lateral-to-medial direction. Insertion of the needle into the sheath was frequently accompanied by a palpable “pop.” After careful aspiration, 1–2 mL of local anesthetic was administered to check the correct needle placement.

If the injection displaced the brachial plexus away from the needle, it might be necessary to advance the needle another 1–2 mm closer to the plexus to achieve sufficient local anesthetic spread. When the local anesthetic injection did not appear to cause a spread throughout the brachial plexus, needle repositioning was required. Typically, 20–25 mL of local anesthetic (Bupivacaine 0.5% plain solution) was needed for sufficient block. Brachial plexus blockade assessments were taken every 5 minutes for the next 30 minutes after local anesthetic injection [18].

To assess sensory blockade of the musculocutaneous, median, radial, and ulnar nerves, a 3-point scale using a cold test was used as 0 if there was no block, 1 if patient felt touch but didn't feel cold, and 2 if patient didn't feel touch [19]. The lateral aspect of the forearm and the dorsum of the hand as well as the volar aspect of the thumb and the fifth finger were the sites of assessment of the sensory blockade.

To evaluate motor blockade, elbow flexion (musculocutaneous nerve), thumb opposition (median nerve), thumb abduction (radial nerve), and thumb adduction (ulnar nerve) were assessed on a 3-point scale as follows: 0, no motor block (normal motor functions); 1, paresis (decreased motor strength); and 2, paralysis (complete loss of motor strength) [19]. Totally, the maximum composite score was 12 points. If the patient received a minimum composite score of 10 points and their sensory block score was equal to or higher than 5 out of 6 points, we deemed them surgically ready [20,21]. If the combined score was less than 10 points after 30 minutes, the patient was excluded from the study, and further management was taken according to the decision of the attending anesthetist.

2.8. Intraoperative management

Heart rate, systolic and diastolic blood pressure were measured at time of patient admission to OR, at 1

minute after block, then every 10 minutes till skin closure. We assessed sedation every 10 minutes. We gave midazolam (0.01 mg/kg per dose) upon patient's request, and we continued titration using the Modified Wilson sedation scale to keep the patient oriented (score 1). We did not give further doses if the patient became drowsy. In the Modified Wilson sedation scale, the patient is scored 1 if *oriented* (eyes may be closed but can respond to “can you tell me your name?”), 2 if *drowsy* (eyes may be closed, arousable only to commands like “please open your eyes”), 3 if *arousable* to mild physical stimulation (earlobe tug), and 4 if *unarousable* to mild physical stimulation [22]. Titration of fentanyl (0.5 mcg/kg per dose) was done according to numeric pain score, where the patient was asked to make pain rating on a scale from 0 (representing no pain) up to 10 (representing the worst possible pain) [23]. Among all patients, titration was administered according to the attending anesthetist's decision and the total dose of sedation and analgesia was recorded during the time from block needle entry till the end of the procedure.

The patient satisfaction was measured using a modification of a scoring system that was described in an earlier study [24]. The patient was scored from 1 to 5 depending on his response to the two questions regarding how satisfied he was with the results of his anesthesia and how strong he wished to use the technology again in anesthetic management.

2.9. Outcomes

The primary outcome was the total intravenous sedation needed for the patient. Secondary outcomes were the total perioperative analgesic consumption, incidence of adverse effects, patient satisfaction score, and hemodynamic parameters.

2.10. Sample size calculation

The sample size was determined using MedCalc software version 14.10.2 (MedCalc software bvba, Ostend, Belgium), with an alpha error of 0.05, and a power of 80%. According to a pilot study on 6 patients, the total dose of midazolam needed for intraoperative sedation was 10 ± 2.5 mg for patients undergoing ultrasound brachial plexus block in the control group. On average, 14 patients per group would be required to detect a 25% difference in midazolam dose between the 2 study groups. The ultimate sample size was 15 per group to make up for the failure to follow up (total sample size was 30 patients).

2.11. Statistical analysis

The study was carried out using the Statistical Program for Social Sciences (SPSS) version 26 for Windows from

IBM Corp. in Armonk, New York, USA. Data that were normally distributed were presented as mean \pm standard deviation (SD). The independent samples T-tests were used to compare the two groups. The ANOVA test was performed to compare serial measurements within each group. Frequencies (count and percentage) were used to summarize categorical data, and Fisher's exact or the Pearson's Chi-square tests were used to determine whether there was a relationship between the examined groups. To interpret the significance of statistical tests, a p-value of 0.05 was used.

3. Results

Thirty-eight patients were assessed for eligibility, two patients refused to participate, three patients had psychological disturbances, and three patients were excluded due to coagulation disorders. Thirty patients were included in the trial and divided into two groups

at random (15 patients each). All patients were scheduled for orthopedic forearm operations with the use of supraclavicular brachial plexus blockade. The VR group performed the procedure while wearing of the VR goggles and midazolam titration if needed. The control group performed the procedure with the midazolam administration only (Figure 1).

Regarding age, weight, height, and sex, Table 1 demonstrates no statistically relevant differences between the two groups.

Table 2 reveals that the patients who performed the procedure with VR goggles required less total midazolam compared to the control group (2.00 ± 0.00 vs 6.67 ± 2.09 mg, respectively, $p < 0.001$). The total fentanyl requirement, Wilson and numeric pain score showed no significant difference between both groups. Early disconnections, nausea, and headaches were among the adverse effects that did not statistically significantly differ within groups. Participants in the

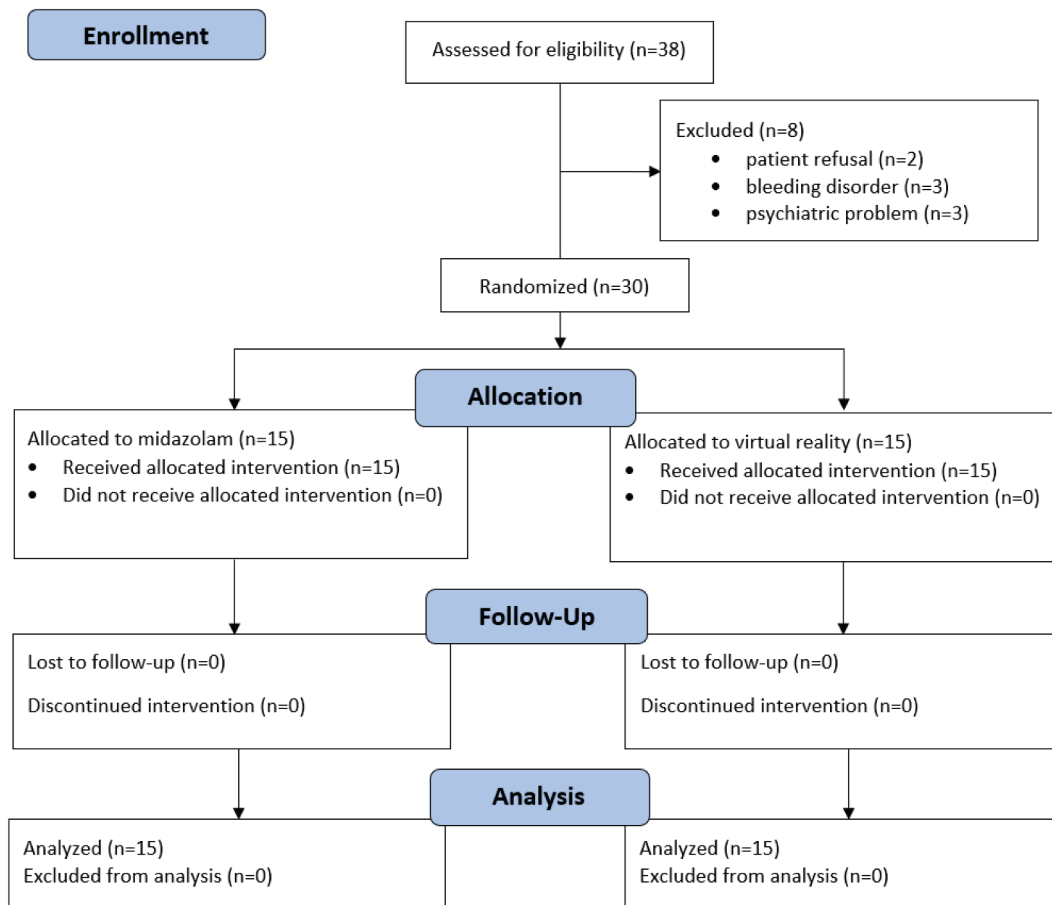


Figure 1. The CONSORT flow diagram of the trial.

Table 1. Demographic data.

Variable, mean \pm SD	Control group	Virtual reality group	P-value
Age (year)	32.53 \pm 1.50	36.87 \pm 9.36	.243
Weight (kg)	85.47 \pm 13.46	87.33 \pm 9.42	.663
Height (cm)	168.40 \pm 5.70	167.73 \pm 5.02	.737
Sex			
Male	9 \pm 6.0%	8 \pm 53.3%	
Female	6 \pm 4.0%	7 \pm 46.7%	.713

SD: standard deviation.

Table 2. Total midazolam and fentanyl requirement with Wilson, numeric pain score, and patient satisfaction score.

Variable	Control group	Virtual reality group	P-value
Total midazolam, mg, mean ± SD	6.67 ± 2.09	2.00 ± 0.00	<0.001
Total fentanyl, µg, mean ± SD	25.00 ± 10.99	20.00 ± 5.57	0.062
Wilson score, mean ± SD	1.07 ± 0.26	1.13 ± 0.35	0.559
Numeric pain, mean ± SD	0.07 ± 0.26	0.07 ± 0.26	1
Patients' satisfaction score, mean ± SD	8.53 ± 0.92	9.60 ± 0.51	0.001
Adverse events, n (%)			
Early disconnection			
Yes	0 (0%)	2 (13.3%)	—
No	0 (0%)	13 (86.7%)	
Headache	0 (0%)	1 (6.7%)	0.483
Headache and nausea	0 (0%)	1 (6.7%)	

SD: standard deviation; n: number.

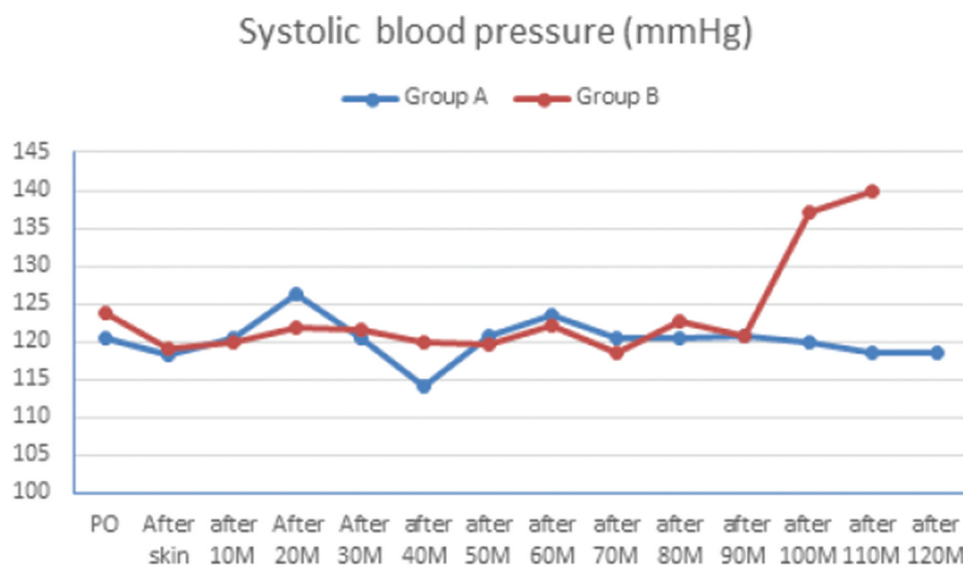


Figure 2. A line chart showing a comparison between the two groups regarding preoperative and intraoperative systolic blood pressure. Group A: control group; Group B: virtual reality group; PO: preoperative; M: minute

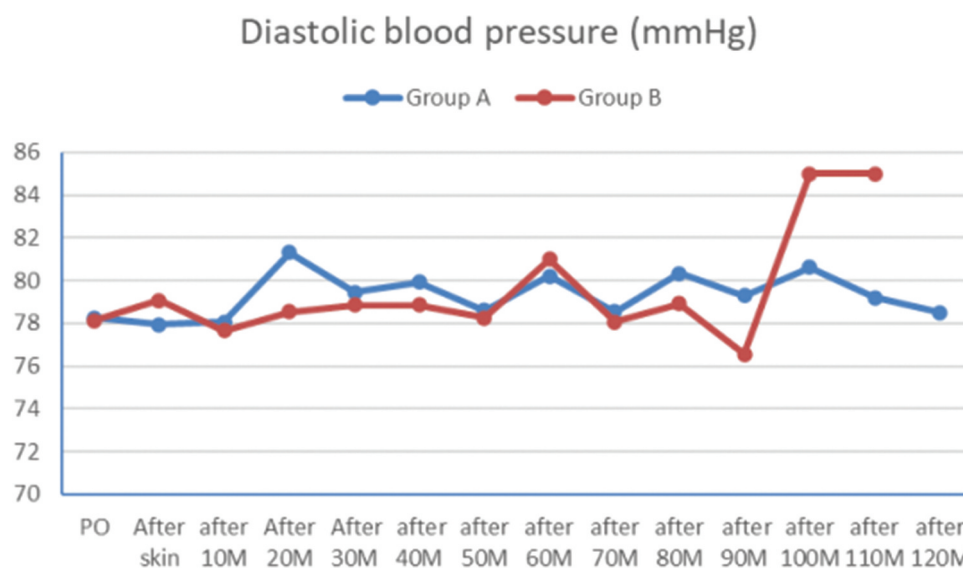


Figure 3. A line chart showing a comparison between the two groups regarding preoperative and intraoperative diastolic blood pressure. Group A: control group; Group B: virtual reality group; PO: preoperative; M: minute

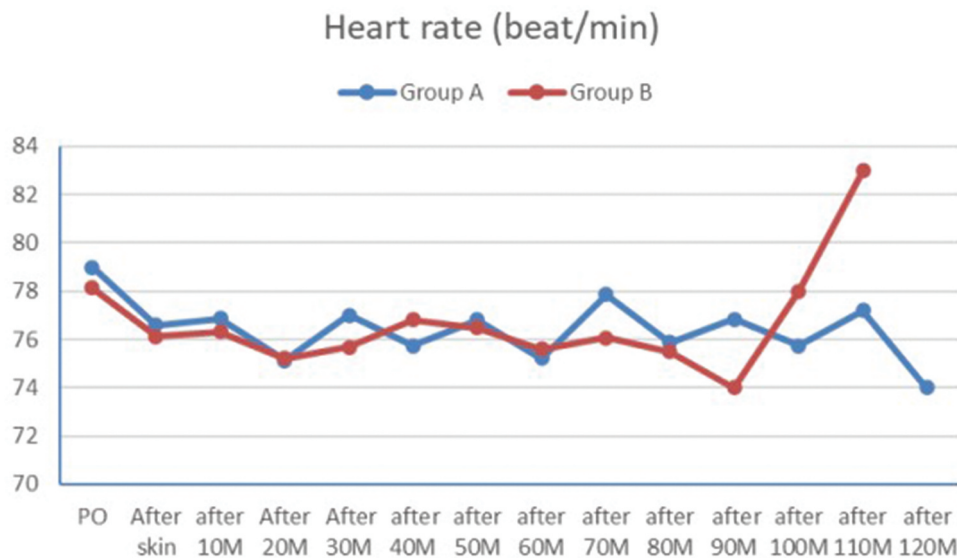


Figure 4. A line chart showing a comparison between the two groups regarding preoperative and intraoperative heart rate. HR: hear rate; Group A: control group; Group B: virtual reality group; PO: preoperative; M: minute

VR group were significantly more satisfied than those in the control group (9.60 ± 0.51 vs 8.53 ± 0.92 , respectively, $p = 0.001$).

Systolic and diastolic blood pressure, as well as heart rate, did not significantly differ between the two groups preoperatively or during surgery except one patient who performed the procedure with VR had significant elevation in blood pressure at 110 minutes intraoperatively (Figures 2, 3, and 4).

4. Discussion

In the forearm orthopedic operations, intraoperative sedation is usually administered despite having appropriate regional anesthesia, which can lead to oversedation. By diverting the mind from processing unpleasant sensations, VR may minimize the usage of sedatives and lower the danger of oversedation without having an influence on patient pleasure. This study aimed to evaluate the safety and efficacy of VR distraction technique in patients scheduled for orthopedic forearm surgeries under supraclavicular brachial plexus block.

Our findings indicated that visual reality was effective in reducing the requirement of midazolam and providing better patients' satisfaction without any significant adverse effects or hemodynamic instability compared to the conventional technique. Similarly, Pandya et al. [25] reported that VR distraction was a useful non-medical substitute for intravenous sedation for patients scheduled for the ultrasound-guided insertion of some perineural catheters. Joo et al. [26] reported that VR immersion was employed in minimizing anxiety and procedural pain during fluoroscopic pain treatments. Chan and Scharf [14] found that VR had a sedation-sparing impact and could be safely administered in an operating room setting. Moreover,

Alaterre et al. [27] suggested that VR distraction program effectively improved anxiety-reduction with better patient satisfaction in the operating room.

Our study differed from earlier reports in that we immersed the patients in a continuous, stress-free environment using a VR set during the entirety of the supraclavicular block and surgical intervention procedures. The total amount of midazolam administered was utilized as a criterion to represent their anxiety levels. Studies that utilized propofol as a sedative failed to capture the sedation-sparing effects of VR, according to their findings. Many types of VR are used to reduce procedural pain and anxiety. Fully immersive VR diversion games were effective for acute procedural pain treatment [28]. By exposing the patient to a variety of rich sensory inputs, these VR distraction games may divert the patient's attention away from harmful stimuli and instead provide him a more lifelike experience [29]. An immersive VR program commercially created for medical hypnotherapy was employed instead of VR diversion games, which led to decreased procedural pain and anxiety. Compared to VR distraction games, there are little research on how VR hypnosis program control discomfort during procedures [30].

Our study was unable to demonstrate that VR had an adjuvant effect on pain control, probably because of the usage of regional nerve block prior to the procedure to ensure that every patient would be completely pain-free. An 18-minute VR self-hypnosis program was previously employed by Konstantatos et al. [31] in burn patients receiving awake dressing changes. Their research revealed that a single session of VR hypnosis for burn patients enduring an 18-minute dressing was insufficient to alleviate procedural pain because the VR hypnosis group experienced higher pain after dressing. Mladenovic and Djordjevic [12] found no

statistically significant differences in the degree of pain experienced during extraction of impacted third molar teeth under local anesthesia.

In contrast to the previous studies, Ding et al. [32] found that immersive VR was useful as a pain distraction technique without any significant changes in the hemodynamic parameters when VR was used during dressing change in patients who had hemorrhoidectomy. In hand surgery, Faruki et al. [33] reported that VR immersion resulted in marked reductions in the amount of the propofol used intraoperatively and the time needed for post anesthesia care unit and hospital stays. Hoffman et al. [11] observed that the areas of the brain involved for the identification and signaling of pain had lowered activity while the patient was immersed in a virtual environment, even though there is currently no definitive mechanism of relieving pain due to the application of VR technology. It is thought that the diversion provided by the virtual environment and the lack of cognitive resources prevent pain receptors from processing neural signals, which results in a decrease in both the pain felt and the brain activity in the pain-sensitive area [34].

Wearing eyeglasses could cause unsatisfactory comfort when using the helmet in the supine position, our investigation found no significant signs of headache, nausea, vomiting, or early discontinuation. In terms of patients' comfort, improved patient satisfaction is essential in modern medicine since it determines how well medical services are provided. In our study, VR showed better patients' satisfaction. Also, Mladenovic and Djordjevic [12] documented that over 90% of respondents felt satisfied to VR during the procedure. Contrary to our findings, Chan and Scharf [14] found no discernible difference between the VR and the conventional treatment. This might be attributable to the limited sample size, the fact that both groups of patients received enough sedation, or the fact that the VR did not cause the patients any excessive anxiety. Joo et al. [26] noticed that there was no discernible difference in patient satisfaction across the groups. It could be explained by the interactive usage of additive local anesthetics in conscious patients in both groups, which was done in response to patients' needs at the time of the procedure. Furthermore, Joo et al. assumed that a single VR intervention session was insufficient to ascertain the severity of chronic pain.

Prior to and during our surgical intervention, the hemodynamic parameters were measured during the administration of anesthesia. There were no statistically significant differences between both groups. On the other hand, Mladenovic and Djordjevic [12] reported that heart rate values were not statistically changed before the application of anesthesia, but when VR goggles were utilized, the respondents' pulse rates were noticeably lowered both before and throughout the procedure. Surgical interventions are highly stressful

conditions for patients, resulting in elevated heart rates and blood pressures as physiological responses to stress [35]. Heart rate readings among patients wearing VR goggles were much lower before and during the surgical intervention than with traditional surgery. Even though the patients had dominating sympathetic nerve activity prior to treatment, the parasympathetic nerve's activity increased throughout VR presentations to the point where it balanced the sympathetic nerve, indicating that the patients were recovering to a stable mental state. From our findings, VR can be considered an effective and safe distraction tool that could be implemented with great success in patients scheduled for orthopedic forearm surgery under supraclavicular brachial plexus block.

4.1. Limitations

A non-immersive environment may result from a variety of potential VR technology drawbacks, such as problems with device communication. The usage of VR headsets rendered the use of a blindfolded design unfeasible. Thus, it could cause variations in how the treating anesthesiologist gave extra sedatives such as midazolam and fentanyl and skew patients' satisfaction surveys. Patients were unable to interact directly with the software and were not allowed to choose their favorite video. Due to a lack of equipment at the institutional laboratory, the plasma levels of cortisol or ACTH, the direct indicators of neurohumoral stress, were not measured. We employed patient-reported measures for anxiety and pain after patients were recovering from sedative administration where the post-amnesia impact of midazolam might have had some effect. A larger multicenter study is required because this single – center study had a tiny sample size.

5. Conclusion

The VR distraction technique was effective in reducing intraoperative sedation requirements with better patient satisfaction in patients scheduled for orthopedic forearm surgeries under supraclavicular nerve block.

Disclosure statement

There are no conflicts of interest.

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