Master's Thesis of Hyungul Song

Effectiveness of virtual reality immersion on procedure-related pain and anxiety in outpatient pain clinic: an exploratory randomized controlled trial

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Abstract

Keyword : Chronic Pain; Invasive Procedure; Procedure-related Anxiety; Procedure-related Pain; Sympathetic Block; Virtual Reality

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Background: The study investigated virtual reality (VR) immersion in alleviating procedure-related pain and anxiety in patients with chronic pain undergoing fluoroscopy-guided minimally-invasive intervention in a prone position at an outpatient clinic.

Methods: In this prospective randomized controlled study, 38 patients undergoing lumbar sympathetic ganglion block were randomized into either the VR or the control group. In the VR group, procedure-related pain was controlled via infiltration of local anesthetics while watching a 30-minute VR hypnotic program. In the control group, the skin infiltration alone was used, with the VR device put on, but the VR hypnotic program switched off. The primary endpoint was an 11-point score on the numerical rating scale (NRS), indicating procedure-related pain. Patients' satisfaction with pain control during the procedure, anxiety levels

using the 5-point patient-reported anxiety score, the need for additional local anesthetics during the procedure, hemodynamic stability, and any adverse events were assessed.

Results: Procedure-related pain was significantly lower in the VR group (3.7 ± 1.4 in the 11-pointed NRS score) than in the control group (5.5 ± 1.7; P = 0.002). Patient-reported pre-procedural anxiety score did not differ between the two groups (P = 0.288), but post-procedural anxiety was lower in the VR group (2.5 ± 0.8 in the 5-pointed score) than in the control group (3.2 ± 0.7; P = 0.001), with a significantly greater reduction from pre-procedural anxiety in the VR group than the control group (P < 0.001). Although patients' satisfaction with pain control did not differ significantly (P = 0.158) between the groups, a higher number of patients required additional local anesthetics in the control group (n = 13) than in the VR group (n = 4; P = 0.001). No severe adverse events occurred in either group during the study.

Conclusions: VR immersion can be safely used as a novel adjunct to reduce procedural pain and anxiety during fluoroscopic pain intervention.

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Chapter 1. Introduction

Pain has a negative effect on the physical and psychosocial dimensions of quality of life [1,2]. The history of medicine suggests novel strategies to alleviate pain in numerous diseases. Although pharmacological treatment is pivotal in pain management [3], non-surgical and minimally-invasive procedures play a significant role, especially in pain practice [4]. They can be rapidly conducted in an outpatient setting, lasting only a few minutes in a patient who is awake. However, in the context of medical care, it sounds paradoxical that procedural pain involving minimally-invasive procedures is intolerable beside the original pain [5]. During the procedure, insufficient pain control may result in adverse consequences for patients, such as aborted procedures, avoidance of future therapeutic intervention, poor recovery, and psychological trauma. Skin infiltration with local anesthetics (LA) could mitigate procedure-related pain; however, it is often insufficient for patients undergoing painful procedures, leading to general or unknown anxiety during the intervention. Although intravenous (IV) sedation could be used for some painful procedures, it is not always adequate in an outpatient pain setting due to respiratory depression or hemodynamic instability [6,7].

Virtual reality (VR) is a non-invasive simulation that allows

users to interact with a computer-generated artificial environment [8]. Unlike augmented reality, it is a fully digital experience that can either stimulate or alter the real world [8]. In the medical field, VR has been used to distract patients from pain during uncomfortable medical procedures, such as in patients undergoing burn and wound care. Previous studies have shown that VR was effective in reducing the patient's pain during burn dressing, and that the use of VR effectively increased the rate of burn depth recovery [9-11]. In detail, in adolescent patients with acute burn injury, patients with VR immersion showed 2.14 days faster rate of re-epithelialization compared to the standard group (P = 0.061), and significantly faster rate of 2.26 days when the analyses were adjusted for mean burn depth (P = 0.046) [9-11]. It has also been a useful option to reduce pain and anxiety during orthopedic surgeries, pediatric vascular access, and dental procedures [12-15]. In a recent study, VR immersion provided better results than IV sedation during endoscopic urologic surgery under spinal anesthesia [16]. The study reported that the anesthesiologist's and patients' satisfaction scores during the urologic surgery were significantly higher in the patients with VR immersion group than the control group who were sedated with midazolam 1-2mg every thirty minutes during the surgery. Furthermore, the incidence of

apnea was significantly lower in the VR group than in the sedation group [16]. Combined with previous findings, VR immersion may reduce procedure-related pain in patients undergoing minimally-invasive spinal interventions. However, the role of VR immersion in an outpatient pain practice setting is seldom reported.

This study hypothesized that VR might improve procedure-related experiences as an effective adjunct to conventional skin infiltration. To this end, we investigated the role of VR immersion in alleviating procedural pain intensity and mitigation of unpleasant experiences in awake patients with chronic pain undergoing fluoroscopy-guided minimally-invasive pain interventions in a prone position.

Chapter 2. Methods

2.1. Study Design

This prospective, exploratory randomized controlled trial was approved by the Institutional Review Board of Seoul National University Hospital (No. 1802-028-920) and registered in ClnicalTrials.gov (NCT03599479 released on 24 June 2018). This study complied with the Declaration of Helsinki and was conducted at a single pain management center between December 2018 and August 2019. Written informed consent was obtained from all participants before initiating the study.

Inclusion criteria were: (1) patients aged between 20 and 85 years; and (2) patients with at least a 3-month duration of chronic pain who were scheduled to undergo fluoroscopy-guided lumbar sympathetic ganglion block (LSGB) in an outpatient setting. In this study, LSGB was selected among various minimally-invasive pain interventions, a relatively painful procedure with moderate procedural pain [5]. Institutional protocol requires that patients stay in the outpatient pain operation room (OR) for at least 20 minutes to confirm a temperature increase after administering LA, which is

adequate to experience the VR immersion.

Exclusion criteria were: (1) patients with visual or hearing impairment; (2) patients who had reported with mental disorders including psychotic, uncontrolled anxiety, or major affective disorders during physician's history taking; (3) patients with cognitive defects or intellectual impairment; (4) patients with a disability that could affect adverse effect assessment or interfere with study completion when enrolled; (5) patients with a recent history of LSGB within 1 year before the randomization; (6) patients contraindicated for invasive procedures (coagulopathy, skin infection on the injection site, and allergies to LA); or (7) any patients who were considered inappropriate to register in this clinical trial.

2.2. Randomization

Randomization was conducted in an OR before starting the procedure. In the pre-operative holding room, all participants were educated in methods to handle the device with a brief experience of VR immersion for 2 minutes in a sitting position using a Samsung Gear head-mounted display compatible with the Android platform

operating on a Galaxy 7.0 device (Samsung, Seoul, Korea). After entering the OR, patients were placed in a prone position, with their neck slightly flexed, and were assisted with putting on the VR head-mounted display and headphones. A soft gel pillow and a large foam pillow supported the patient's forehead and chest to prevent any pressure or discomfort from wearing the device (Fig. 1). The VR immersion began with proper fitting of VR device after repositioning the patients on the procedure bed. Next, the patients were randomly assigned to a VR group or a control group (1:1), based on a group allocation number within an opaque envelope opened by a pain physician. The number in the envelope was matched to the group in a randomization table generated by an internet-based computer program (www.randomization.com), managed by a radio technician independent of the study. The patient was assisted with switching on the VR program in the test group or switching it off in the control group. A pain physician was available to support patients throughout the patient's stay in the OR.

Patients in the VR group experienced a 30-minute VR immersion (NUVO program by Oncomfort SA, Wavre, Belgium). The three-dimensional VR software consists of a seashore view with Korean language narrations designed to induce relaxation (Fig. 2). The program was developed initially as VR hypnosis to manage

anxiety and pain during anxiety-provoking moments of treatment with portable immersive 360° audio and video. During the VR immersion, the patient could feel relaxed, virtually sitting in front of the seashore. The patient could then move around and look at the scene from other views, enhancing physical and emotional comfort while listening to narrations designed to induce relaxation. The first author (EKK) corresponded with the program developers to translate the original English version into the Korean language. The VR experience started right after the group allocation, in order to create effective immersion in the hypnotic program.

Patients in the VR group were free to request discontinuation of the VR immersion at any time. In the control group, patients were asked to wear the VR head-mounted display and headphones, but the program was switched off while undergoing the procedure. During the procedure, the performing physician was blinded to which patients were in which group. The VR device was finally removed when the patient moved to the recovery room. Both groups could request removing their device at any time if they felt discomfort wearing the VR head-mount display and headphones.

Fig. 1. Photographs of a person wearing the virtual reality device in a prone position to undergo the lumbar sympathetic ganglion block.

Fig. 2. Images of NUVO program by Oncomfort SA, Wavre, Belgium.

2.3. Procedures

After entering the OR, patients were held in a prone position with a pillow under the lower abdomen, and draped in a sterile fashion. Other cushions were used to support the forehead and chest in patients wearing the VR head- mounted display in a prone position. All patients were administered an IV infusion of lactated Ringer's solution and monitored via pulse oximetry, electrocardiogram (EKG), and blood pressure measurements throughout the procedure. In addition, temperature probes were tightly attached to both soles using transparent patches (Tegaderm™, 3M Health Care, St. Paul, MN) before covering the patient's body to confirm the temperature increase in the ipsilateral lower extremity after the LSGB. After sterilizing the skin around the puncture sites, the body was covered by a sterile surgical drape. The procedure was performed under fluoroscopic guidance (OEC 9800 series; GE OEC Medical Systems, Salt Lake City, UT) by a single expert pain physician who had at least 10 years of experience to minimize inter-physician variation during the intervention. The pain physician was blinded to the patients' group allocation during the procedure and throughout the study. Skin infiltration with LA (2-3 mL of 1% lidocaine) was performed in

both groups. At least 3 minutes after skin infiltration, a 21-gauge 15 cm Chiba needle (Cook Inc., Bloomington, IN) was advanced at the L3 vertebral level under fluoroscopy-guided oblique projection. If a patient complained of moderate-to-severe procedure-related pain while advancing the needle, additional LA was injected via the Chiba needle. The total amount of LA was less than 5 mL, including skin infiltration, for procedural analgesia. When the needle reached the proper target site (anterolateral border of the L3 vertebral body), 1-2 mL of contrast agent was injected to confirm adequate spread around the target, followed by injection of 8 mL of 0.25% levobupivacaine. After removing the needle, temperature changes in the ipsilateral and contralateral soles were recorded for 20 minutes in the OR. The VR device was taken off and the patients were then transferred to the recovery room.

2.4. Data Collection

The primary outcome was the patient-reported procedural pain, which was measured using the 11-point numerical rating scale (NRS) on a scale of 0 (no pain) to 10 (the most severe pain imaginable). A research nurse recorded the pain scores

immediately after the patients arrived in the recovery room.

The secondary outcomes included patient-reported anxiety before and after the procedure and patient-reported satisfaction with procedural pain control. The patient-reported anxiety involving the procedure was assessed using the 5-point Likert scale (1, not at all anxious; 2, a little anxious; 3, moderately anxious; 4, very anxious; and 5, extremely anxious) [17]. It was based on two questions: 1) "How anxious do you feel about your upcoming procedure right now?", which was asked before entering the OR, and 2) "Please imagine that you are supposed to undergo the same procedure right now. How anxious would you feel about the procedure at this moment?", which was asked in the recovery room 30 minutes after the procedure. At the same time, patient-reported satisfaction with control of procedure-related pain was also evaluated using a 5-point Likert scale (1, dissatisfied; 2, less satisfied; 3, satisfied; 4, very satisfied; and 5, completely satisfied). The questionnaires for the patients are provided as Supplementary Data.

In the OR, the number of additive LA requirements (except for skin block) and any interruption of communication during the VR application were recorded. The total procedural time (min) was recorded, starting with the acquisition of the first radiographic

image to the removal of the Chiba needle. The total VR time (min) was recorded, specifically starting from putting on the VR device in the OR to its removal. In the recovery room, subjective perception of stay (min) was evaluated by asking: “How much time were you supposed to stay in the OR?” Also, the patients in the VR group were asked about their subjective feedback on VR use and whether they would prefer VR immersion in their next pain procedures.

Safety evaluation was conducted via regular monitoring of any adverse events throughout the procedure. Pre- and post-procedural hemodynamic variables were compared using an average of 3 repeated measurements before the skin infiltration and before wearing off the VR device. Additionally, the intraoperative hemodynamic parameters were measured at regular intervals in the presence of bradycardia (heart rate < 40 beats/min), hypotension (decrease in mean arterial pressure < 55 mmHg or up to a 30% decrement from baseline), oxygen desaturation (SpO2 < 90%), or provocation of arrhythmia on the EKG. Adverse effects due to VR immersion, such as dizziness, seizure, headache, or muscle twitching, were monitored until discharge.

Baseline demographic and clinical data included age, sex, body mass index, comorbidities (hypertension, diabetes mellitus, asthma, cardiovascular diseases, and cerebrovascular disease), comorbid

neuropsychiatric disorders (depression and anxiety), the presence of motion sickness, educational level (< high school, high school, > high school), duration of computer use (< 1 year, 1–5 years, > 5 years), diagnosis of pain, pain duration (month), baseline pain intensity (average level and the worst pain during the last week) based on an 11–point NRS pain score, and the use of strong opioids (morphine, oxycodone, hydromorphone, or fentanyl). Previous VR experience was evaluated dichotomously (yes or no). The patients' Hamilton Anxiety Rating (HAM–A) score was measured before the procedure. The HAM–A score is based on 14 individually rated items with the total score ranging from 0 to 54: a score of 14 or less indicates mild anxiety, a score ranging from 15 to 23 represents mild to moderate anxiety, and a score of 24 to 30 suggests moderate to severe anxiety [18].

2.5. Statistical analysis and sample size justification

In the absence of a preliminary study investigating the relevance of VR immersion to procedure–related pain scores in pain practice, we adopted a conventional strategy based on the differences in procedural pain between the two groups, suggested

by Dworkin et al. [19], which was assumed to represent a significant decrease in the 11-point NRS pain score of 2.0 under clinical settings. It was comparable to a previous VR study of pain control during dental procedures, which reported that the procedural pain was 1.8/10.0 for those using VR and 4.0/10.0 for the control group [20]. We determined that 17 patients per group were necessary, assuming a standard deviation (SD) of 2.1 based on a previous study involving LSGB [5], with a type 1 error of 0.05 and a type 2 error of 0.2. Allowing for 10% attrition, a total of 38 randomized patients were required for this study (G*Power 3.1.9.2).

All statistical analyses were performed using SPSS version 22.0 (IBM Co., Armonk, NY). The intention-to-treat approach was used for data analysis. To analyze continuous variables such as the primary endpoint (procedure-related NRS pain scores), the normality distribution was determined with the Kolmogorov–Smirnov test and an independent t-test was used to compare the normally distributed variables. The Mann–Whitney U-test was used to compare continuous variables without normal distribution. A chi-square test or Fisher's exact test was used to analyze all categorical data. Lastly, we calculated the Spearman correlation coefficients (ρ) to measure the correlation between the procedure-related NRS pain scores for the baseline and procedural variables.

Data were presented as the mean ± SD or the number (%). All P values are two-sided, and P values less than 0.05 were considered to indicate statistical significance.

Chapter 3. Results

3.1. Patient Demographics and Clinical Characteristics

A total of 45 patients were screened (Fig. 3). Two patients refused to participate and 5 patients had undergone LSGB or neurodestructive procedures within one year. The remaining 38 patients were randomized to the VR group (n = 19) and control group (n = 19). All of the participants complied with the study protocol and were included in the analysis without missing data. The patient demographics and clinical characteristics are shown in Table 1. The groups showed no statistically significant differences in any demographic variables or comorbidities, or in the level of education or duration of computer use. And the patients' pain, etiology, pain onset, the average and most severe NRS pain scores at baseline, and their current use of strong opioids were comparable. Patients' baseline anxiety levels based on the HAM-A scores did not differ between the groups, suggesting moderate anxiety levels. Five patients had experienced a VR application beforehand (n = 3 in the VR group and n = 2 in the control group); 1 in the VR group was familiar with VR technology.

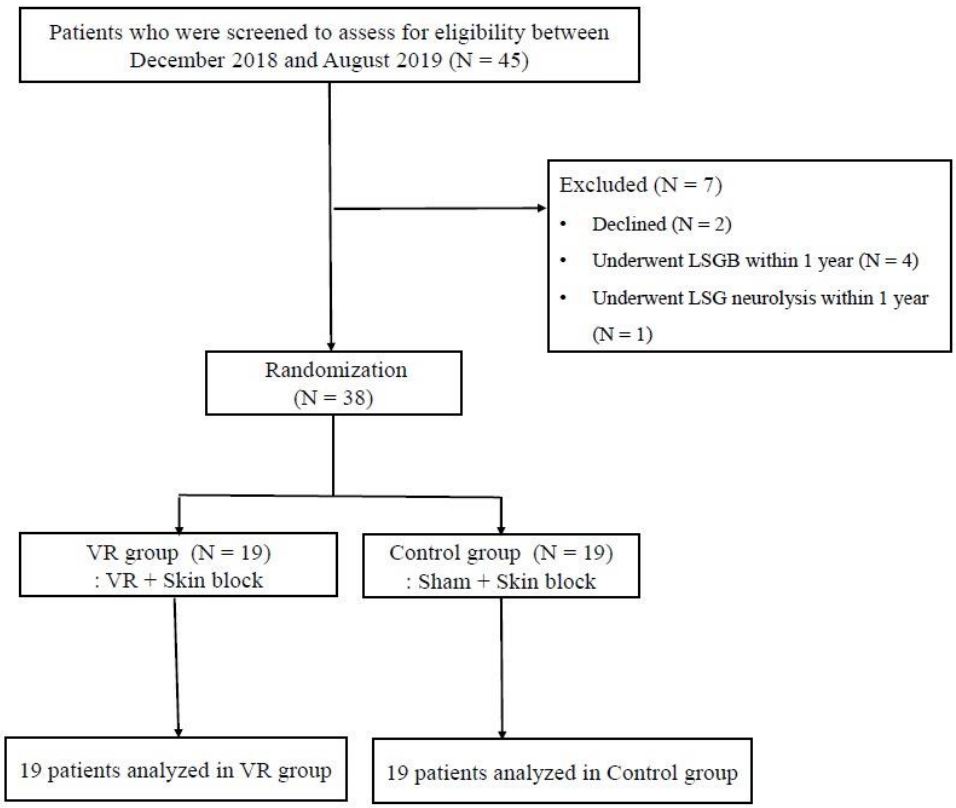

Fig. 3. Consolidated Standards of Reporting Trials (CONSORT) flow diagram. LSGB: lumbar sympathetic ganglion block, VR: virtual reality.

Table 1. Patient demographics and clinical characteristics

Variable	VR group (n = 19)	Control group (n = 19)	Total (n = 38)
Age (year)	60.1 ± 13.4	65.2 ± 12.9	62.6 ± 13.3
Body mass index (kg/m^2)	24.2 ± 4.1	23.2 ± 2.9	23.7 ± 3.5
Sex (N, %)			
Male	8 (42.1)	8 (42.1)	16 (42.1)
Female	11 (57.9)	11 (57.9)	22 (57.9)
Education level (N, %)			
< High school	8 (42.1)	5 (26.3)	13 (34.2)
High school	6 (31.6)	11 (57.9)	17 (44.7)
> High school	5 (26.3)	3 (15.8)	8 (21.1)
Duration of computer utilization (N, %)			
< 1 year	10 (52.6)	9 (47.4)	19 (50.0)
1–5 years	2 (10.5)	3 (15.8)	5 (13.2)
> 5 years	7 (36.8)	7 (36.8)	14 (36.8)
Previous VR experience (N, %)	4 (21.1)	2 (10.5)	6 (15.8)
Motion sickness (N, %)	7 (36.8)	9 (47.4)	16 (42.1)
Comorbidities (N, %)			
Hypertension	4 (21.1)	7 (36.8)	11 (28.9)
Diabetes mellitus	4 (21.1)	4 (21.1)	8 (21.1)
Asthma	1 (5.3)	1 (5.3)	2 (5.3)
Cardiovascular diseases	3 (15.8)	1 (5.3)	4 (10.5)
Cerebrovascular diseases	3 (15.8)	0 (0.0)	3 (7.9)
Neuropsychiatric disorders (N, %)			
Depression	6 (31.6)	4 (21.1)	10 (26.3)
Anxiety	3 (15.8)	5 (26.3)	8 (21.1)
Diagnosis (N, %)			
Complex regional pain syndrome	6 (31.6)	7 (36.8)	13 (34.2)

Failed back surgery syndrome	2 (10.5)	3 (15.8)	5 (13.2)
Postherpetic neuralgia	6 (31.6)	6 (31.6)	12 (31.6)
Others*	5 (26.3)	3 (15.8)	8 (21.1)
Pain duration (month)	22.8 ± 10.9	22.7 ± 24.2	22.7 ± 11.8
NRS average at baseline (0–10)	5.3 ± 1.9	5.3 ± 2.3	5.3 ± 2.1
NRS worst at baseline (0–10)	6.6 ± 1.6	6.7 ± 2.0	6.7 ± 1.8
Strong opioid use (N, %)	7 (36.8)	8 (42.1)	15 (39.5)
HAM-A score (0–54)	22.8 ± 10.9	23.6 ± 10.3	23.2 ± 10.4

Values are presented as mean ± standard deviation or number (%).

VR: virtual reality, NRS: numerical rating scale, HAM-A: Hamilton Anxiety Rating.

*Other diagnoses included painful peripheral diabetic polyneuropathy (n = 3 in the VR group and n = 2 in the control group) and chronic postoperative pain syndrome (n = 1 in each group).

3.2. Procedural variables

The primary endpoint of procedure-related NRS pain scores in the VR group were lower (3.7 ± 1.4) than in the control group (5.5 ± 1.7), which was statistically significant (P = 0.002) (Table 2). The 5-point patient-reported anxiety score involving the upcoming procedure did not differ between the groups before LSGB, suggesting moderate anxiety (P = 0.288); however, after the procedure, it was lower in the VR group (2.5 ± 0.8) than in the control group (3.2 ± 0.7) with statistical significance (P = 0.010). Patients in both groups reported "satisfied", or more, with pain control during the procedure, without a difference between the groups (P = 0.158). Seventeen patients (44.7%) requested additional analgesia during the LSGB, which was more prevalent in the control group (n = 13, 68.4% vs. n = 4, 21.1% in the VR group; P = 0.008). The total duration (min) of LSGB and wearing of the VR device were comparable between the groups. However, subjective perception of OR stay (min) was significantly shorter in the VR group (25.3 ± 4.8 vs. 20.9 ± 6.4, respectively; P = 0.022).

Significant correlations existed between the postprocedural NRS and the baseline average NRS pain scores (ρ = 0.32, P = 0.048); current strong opioid use (ρ = 0.32, P = 0.048); and

comorbid anxiety disorder (ρ = 0.49, P = 0.002) (Table 3). Subjective feedback on the use of VR immersion in the VR group revealed that 12 patients (63.2%) wanted to use VR immersion in their next pain procedure, 6 patients (31.6%) did not make the decision, and 1 patient (5.3%) declined due to unfamiliarity. The VR application was not interrupted by the physician or the patients in any instance.

Table 2. Procedure-related variables

Variable	VR (n = 19)	Control (n = 19)	P value
Procedure-related NRS pain score (0-10)	3.7 ± 1.4	5.5 ± 1.7	0.002
Procedure-related anxiety before intervention (1-5)	3.6 ± 0.6	3.4 ± 0.6	0.288
Procedure-related anxiety after intervention (1-5)	2.5 ± 0.8	3.2 ± 0.7	0.010
Difference between pre- and post-procedural anxiety (0-4)	-1.1 ± 0.8	-0.2 ± 0.6	0.001
Satisfaction on pain control for the procedure (1-5)	3.2 ± 0.8	3.6 ± 1.0	0.158
Patients reporting much and extremely satisfied scored 4 and 5 (%)	10 (52.6)	4 (21.1)	0.091
Patients who requested additive LA during the procedure (%)	4 (21.1)	13 (68.4)	0.008
Total procedure time (min)	6.2 ± 1.3	6.1 ± 1.2	0.765
Total stay at the operating room (min)	31.5 ± 2.7	30.0 ± 3.0	0.119
Patients' perception of the stay at the operating room (min)	20.9 ± 6.4	25.3 ± 4.8	0.022

Values are presented as mean ± standard deviation or number (%).

VR: virtual reality, NRS: numerical rating scale, LA: local anesthetics.

Table 3. Correlation of the procedure-related pain intensity and baseline variables

	Procedure-related NRS	Comorbid depression	Comorbid anxiety	Current use of the strong opioids	Average NRS pain score at baseline	The worst NRS pain score at baseline	HAM-A score at baseline
Procedure-related NRS	-	0.186	0.485**	0.322*	0.323*	0.263	0.104
Comorbid depression	0.186	-	0.424**	0.618**	0.517**	0.387*	0.049
Comorbid anxiety	0.485**	0.424**	-	0.639**	0.607**	0.568**	0.200
Current use of strong opioids	0.322*	0.618**	0.639**	-	0.603**	0.648**	0.152
Average NRS pain score at baseline	0.323*	0.517**	0.607**	0.603**	-	0.785**	0.080
The worst NRS pain score at baseline	0.263	0.387*	0.568**	0.648**	0.785**	-	0.222
HAM-A score at baseline	0.104	0.049	0.200	0.152	0.080	0.222	-

The values are the Spearman correlation coefficient (ρ).

NRS: numerical rating scale, HAM-A: Hamilton Anxiety Rating.

*P < 0.05. The correlation was measured using the Spearman correlation coefficient (ρ).

**P < 0.01. The correlation was measured using the Spearman correlation coefficient (ρ).

3.3. Comparison of Hemodynamic Variables and Adverse Reactions

Pre-procedural and post-procedural hemodynamic measurements did not differ between the groups (Table 4). In the VR group, 2 patients (10.5%) reported transient dizziness at some point during the procedure, but they refused to drop out, maintaining their VR immersion. Another 3 patients (1 in the VR and 2 in the control group) complained of discomfort wearing the VR headset in a prone position; however, it was bearable to continue. In the recovery room, 2 patients in the VR group (10.5%) and 3 patients in the control group (15.8%) reported transient dizziness along with mild nausea, which disappeared before discharge from the hospital. No other adverse events relating to the VR immersion were observed. No rescue medication was administered to either group during the study.

Table 4. Vital signs and adverse events

Variable	VR (n = 19)	Control (n = 19)	P value
Pre-systolic pressure (mmHg)	143.6 ± 26.8	142.7 ± 27.1	0.914
Post-systolic pressure (mmHg)	139.1 ± 24.9	139.2 ± 27.5	0.990
Pre-diastolic pressure (mmHg)	79.4 ± 13.2	73.1 ± 15.9	0.194
Post-diastolic pressure (mmHg)	78.5 ± 13.0	70.2 ± 15.3	0.079
Pre-mean pressure (mmHg)	100.8 ± 15.3	96.3 ± 17.9	0.411
Post-mean pressure (mmHg)	98.7 ± 13.9	93.2 ± 16.1	0.267
Pre-heart rate (beats/min)	76.4 ± 14.7	70.2 ± 13.9	0.197
Post-heart rate (beats/min)	72.7 ± 22.1	70.9 ± 13.4	0.775
Pre O_2 saturation (%)	98.2 ± 1.8	97.8 ± 2.4	0.595
Post-O_2 saturation (%)	98.1 ± 2.3	97.6 ± 2.3	0.577
Adverse events	3 (15.8)	3 (15.8)	> 0.999

Chapter 4. Discussion

We conducted an exploratory randomized controlled trial to evaluate the effectiveness of VR immersion combined with conventional skin infiltration compared to skin infiltration alone. To the best of our knowledge, this study was the first one to assess the feasibility of VR in patients in a prone position while performing a painful procedure. The procedure-related pain during LSGB was significantly lower in the VR group (3.7 ± 1.4 in the 11-pointed NRS score) than in the control group (5.5 ± 1.7 in the 11-point NRS score; P = 0.002), without any severe adverse events associated with the VR immersion during the procedure. Fewer patients required additive LA in the VR group. Although satisfaction with procedural pain control did not differ between the groups, post-procedural anxiety was lower, and patients' subjective perception of their stay in the OR was shorter in the VR group than in the control group. Almost two-thirds of patients (63.2%) wanted to undergo VR immersion again in their following pain procedure.

Despite their minimal invasiveness, pain interventions, including LSGB, are still painful and distressing for patients with chronic pain [5]. Pain physicians have attempted to alleviate procedure-related

pain and anxiety during their interventions. VR is one of the emerging options for rapid implementation in various clinical settings, ranging from managing acute procedure-related pain to rehabilitating chronic pain conditions [8,9]. It has been used in needle-related procedures, anesthesia administration, and other painful interventions, including dressing changes for burn wounds [10-16]. In recent studies, VR was suggested to positively modulate chronic intractable pain [21], and was self-administered at home to manage chronic low back pain during COVID-19 [22]. However, few studies have reported the use of VR in reducing acute procedure-related pain of the elderly in outpatient pain practice. Presumably, there have been several limitations in adopting VR in outpatient pain settings. First, most fluoroscopy-guided procedures in pain practice require patients to be in the prone position, which may hinder the comfortable use of the current VR device. Second, pain physicians may want to ensure instant patient response during the procedure. Accordingly, VR immersion may impede the interaction between patients and their physicians. Besides, many studies investigated the use of VR for procedural pain targets in pediatric cases, adolescents, or young adults rather than the elderly [9,23]; however, most of the subjects in pain practice are elderly, as in our study, which may discourage the

clinical application of VR in routine practice. Recently, Brown et al. [24] reported lower anxiety scores in patients with VR immersion than the controls at their outpatient spine center visits. However, in their study, patients experienced VR in a sitting position, but not in a prone position, ahead of the spine procedures [24]. Therefore, our study firstly showed the benefit of VR in procedure-related pain control for elderly patients undergoing minimally-invasive pain procedures in a prone position in outpatient pain practice. Although three patients in our study felt discomfort wearing the VR headset in a prone position, it was bearable. We suggest that lighter and more user-friendly VR hardware can extend the use of VR technology in various medical environments.

The types of VR for reducing procedural pain differ according to the subject's environment, ranging from non- immersive to fully-immersive approaches [9]. In previous studies, fully immersive VR distraction games were often used to relieve acute procedural pain, resulting in mostly successful outcomes [9]. Such VR distraction games might draw the patients' attention away from adverse stimuli by exposing them to rich sensory stimuli, creating a realistic experience [25,26]. Instead of VR distraction games, an immersive VR program commercially developed for medical hypnosis was used in our study, resulting in reduced procedural

pain and anxiety. VR hypnosis has rarely been studied in procedure-related pain control compared to VR distraction games [27]. Previously, Konstantatos et al. [28] used an 18-minute VR self-hypnosis program in burn patients undergoing awake dressings changes. However, their results showed increased pain after dressing in the VR hypnosis group, which suggested that a single session of VR hypnosis for burn patients undergoing an 18-minute dressing was not enough to reduce procedural pain. Although we used a VR hypnosis program, the pain-evoking procedure of LSGB lasted only about 6 minutes (shown in Table 2). Although our patients might not have been fully immersed in VR hypnosis during the first 6 minutes, they could experience it for the remaining 20 minutes without painful external stimuli, which probably contributed to differences between our study and Konstantatos' former study. Because there are numerous pain procedures with different durations and levels of invasiveness, further studies are necessary to identify the types of VR, which effectively attenuate procedural pain and anxiety in patients.

Although VR immersion reduced procedural pain with a statistical significance, the difference in the 11-point NRS pain scores between the VR and control groups was only 1.6 points, which did not meet our preset level that was a reduction of 2/10 or

more in the 11-point NRS pain score. Nonetheless, the IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) guideline stated that a smaller difference, of less than 2/10 between groups, might indicate a significant difference [19]. Besides the procedural pain reduction, VR immersion alleviated post-procedural anxiety in our study, similar to other VR studies [8,9]. In contrast to the former VR study [16], satisfaction with procedural pain control was not different between the VR and the control groups in the present study. We assume that this may be related to the interactive use of additive LA in conscious patients in both groups, responding to patients' requirements during the procedure. Moreover, our VR device allows screen transition only with pupil movement, not involving the head movement, provoking minimal dizziness during the procedure. Due to the reason, there was no significant difference of the incidence concerning dizziness between VR group and control, and no drop outs due to the adverse effect. VR technology is affordable, safer, and more user-friendly than IV sedation in busy outpatient pain settings. Therefore, there is no reason not to embrace this modality in pain practice.

Beyond the acute procedural pain control, VR technology is available for chronic pain management, such as phantom limb pain, complex regional pain syndrome, and fibromyalgia, suggesting its

potential neuromodulatory effect [8,27,29,30]. Although it was not shown in our results, when we compared the NRS pain scores in patients' follow-up visits, patients' average and worst pain intensity were not different between the groups at one month. We presume that a single session of VR intervention was not adequate to deduce the intensity of chronic pain, in contrast to previous studies that demonstrated the impact of multiple VR sessions [29-31]. The use of VR in conjunction with conventional chronic pain management warrants further investigation, incorporating different types of VR, interactivity, embodiment, and duration or frequencies of VR intervention according to the target goals of use in pain medicine.

The current study has several limitations. First, our study was a single-center trial with a small sample size, which might limit its external validity. The effect of VR intervention may differ in various clinical settings. Additional studies are needed to spread VR technology in other minimally invasive pain procedures, such as relatively simple (e.g., single epidural injection) or complex procedures (e.g., multi-level heat radiofrequency neurodestruction). Second, although we used sham intervention in the control group wearing the VR device, patients and physicians could not be blinded. Add-on design (VR + LA injection vs. LA

injection standalone) without blinding entails a placebo effect. To investigate that effect, it might be better to include a 3rd group not wearing the VR device, undergoing the procedure in the usual way in pain practice. Third, we measured patients' anxiety using the HAM-A score at baseline and a single 5-pointed Likert scale before and after the procedures. The Beck Anxiety Inventory may facilitate the evaluation of changes in procedure-related anxiety in detail [32]. Fourth, most of our patients were naïve to the VR application. The results could potentially differ if our participants were familiar with VR technology or the particular VR program. Fifth, our control group had put on the switched-off VR device during the procedure. The switched-off VR device may have induced another type of anxiety, such as claustrophobia, among the control group, affecting the patients' reported outcome. Finally, regarding the VR applications, we used the commercial VR hypnosis program rather than VR distraction games. Hypnosis would require some time of induction before the onset of the effect; however, we did not consider it in this study. Further, it is necessary to explore whether different VR programs work differently and investigate the types of VR that are the most effective to control procedural pain in the elderly during minimally invasive pain interventions.

In conclusion, the procedure-related pain during LSGB, and

anxiety after the procedure, were significantly lower in patients exposed to VR, along with skin infiltration, than in those with skin infiltration alone in outpatient pain practice. No severe adverse events were associated with the VR immersion during the procedure. Although patients' degree of satisfaction with their procedural pain control was similar, the additive requirements of LA during the procedure were fewer in patients exposed to VR immersion. This study suggests that VR immersion can be safely used as a novel adjunct to conventional skin block for managing procedural pain and anxiety in elderly patients undergoing fluoroscopy-guided spine procedures in a prone position.

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국문 초록

서론: 외래로 내원한 만성 통증 환자에서 복와위 자세로 C-arm 영상 유도 하 미세 침습 시술을 시행할 때, 가상현실 몰입을 국소마취와 함께 적용하는 경우 시술과 연관된 통증 및 불안감에 영향을 미치는 지 연구해 보고자 한다.

방법: 본 전향적 무작위 대조 연구는 외래에서 피부 국소 마취 하에 요부 교감신경총 차단술을 시행 받는 총 38명의 환자를 대상으로 진행하였다. 환자는 무작위로 가상현실 몰입군 또는 대조군으로 배정되었다. 가상현실 몰입군에서는 피부 국소 마취 실시 후 30분 가량의 가상 현실 프로그램을 시청하며 요부교감신경 차단술을 시행하였다. 대조군에서는 가상현실 체험 없이 국소 마취만을 시행한 뒤 가상현실 몰입 기기를 착용하되 프로그램은 켜지 않은 상태에서 시술을 진행하였다. 일차 평가변수는 시술 이후 회복실 직후 시술과 연관된 통증을 0-10점의 숫자통증 등급 점수로 수집하였다. 2차 평가 변수 및 안전성 평가를 위하여 통증 조절에 대한 환자 만족도, 시술 전과 후에 시술에 대한 불안 정도(0-5점 Likert scale), 시술 중 추가적으로 국소 마취제를 더 요구한 환자의 빈도, 그 외 혈액학적 안정 및 기타 부작용 등을 수집하여 비교 분석하였다.

결과: 시술 직후 회복실에서 측정한 시술 관련 통증은 가상 현실 몰입군(3.7 ± 1.4)에서 대조군과 비교하여(5.5 ± 1.7; P = 0.002) 유의하게 낮았다. 시술 전 측정한 시술관련 불안 점수는 두 군에서 차이가 없었으나(P = 0.288) 시술 이후 측정한 시술관련 불안 점수는 가상현실 몰입군(2.5 ± 0.8)에서 대조군에 비해 유의하게 낮았다(3.2 ± 0.7; P = 0.001). 시술 이후 두 군 간 사이 환자 만족도의 유의한 차이는 관찰되지 않았으나(P = 0.158), 시술 중 추가적인 국소마취제를 요구한 환자수는 가상 현실 몰입군보다 대조군에서 유의하게 많았다[4명(가상현실 몰입군) vs. 13명(대조군); P = 0.001). 안전성 평가에 있어 두 군 모두 시술 중과 회복실에서 중증 이상소견은 발견되지 않았다.

결론: 만성 통증 환자에게 외래에서 복와위 자세로 C-arm 영상 유도하 미세 침습 시술을 시행할 때 가상 현실 몰입을 국소마취와 함께 적용하여 시술과 연관된 통증 및 불안을 완화시킬 수 있다.

주요어: 가상 현실, 만성통증, 요부 교감신경 차단, 시술 관련 통증, 시술 관련 불안

Supplementary data. 연구대상자 설문지

No._____

연구에 참여해 주셔서 감사합니다. 깊이 있고 의미 있는 연구를 위해 연구대상자를 대상으로 설문을 진행합니다. 이곳에 기록하시는 모든 정보는 개인정보로서 철저히 관리되고 보안이 유지됨을 약속 드립니다. 솔직한 답변 부탁드립니다.

1. 다음 질문에 답변을 적어 주시거나 해당하는 항목에 표시를 부탁드립니다.

① 성별: 남 / 여

② 몸무게: _____ kg

③ 키: _____ cm

④ 학력: 초졸 / 중졸 / 고졸 / 대졸 / 대학원졸

⑤ 동반질환: 고혈압 / 당뇨병 / 천식 / 간염 / 심혈관질환 / 뇌혈관질환/ 안과질환 / 기타 _____

⑥ 다음은 귀하의 현재 겪고 있는 하지 통증에 대한 질문입니다.

⑥-1 귀하의 하지 통증은 언제부터 시작되었습니까? : __ 년__ 월 __일

⑥-2 하지통증에 대하여

현재 다리 통증의 정도를 0-10의 숫자로 표현해주세요.

(0:통증 없음, 2:약한 통증, 4:중증도 통증, 6:심한 통증, 8:극심한 통증,

10:최악의 통증)

0	1	2	3	4	5	6	7	8	9	10

지난 하루 동안 평균 다리 통증의 정도를 0-10의 숫자로 표현해주세요.

(0:통증 없음, 2:약한 통증, 4:중증도 통증, 6:심한 통증, 8:극심한 통증,

10:최악의 통증)

0	1	2	3	4	5	6	7	8	9	10

가장 아플 때 다리 통증의 정도를 0-10의 숫자로 표현해주세요.

(0:통증 없음, 2:약한 통증, 4:중증도 통증, 6:심한 통증, 8:극심한 통증,

10:최악의 통증)

0	1	2	3	4	5	6	7	8	9	10

⑦ 현재 귀하가 다른 병원에서 약물을 복용하고 있다면 말씀해 주세요.

그 약물은 무엇입니까?

_____

_____

⑧ 다음은 귀하의 정신건강에 대한 질문입니다.

⑧-1 정신건강의학과 진료 중 이십니까? 예 / 아니오

⑧-2 정신건강의학과 진료 중 이시라면 진단명은 무엇입니까?

기분장애(우울증 포함) / 불안장애 / 물질사용장애 (약물중독) / 외상후

스트레스장애 / 기타 _____

⑨ 귀하는 멀미를 경험한 과거력이 있습니까? : 예 / 아니오

⑩ 귀하는 기존에 가상현실체험에 어느 정도 익숙하십니까?

1 익숙하지 않음	2 보통	3 익숙함

⑪ 귀하는 머리에 외상을 입은 과거력이 있으십니까? 예 / 아니오

⑫ 귀하는 컴퓨터 사용에 익숙하십니까? 예 / 아니오.

컴퓨트를 사용해 온 기간은 얼마나 됩니까? (1년 미만 / 1년 – 5년 / 5년 초과)

⑬ 귀하는 술, 약물, 마약을 남용했던 과거력이 있으십니까? 예 / 아니오

⑭ 귀하는 평소 불면증이 있으십니까? 예 / 아니오

2. 불안감

(시술 전) 시술을 곧 받는다고 상상해 보십시오. 받게 되는 시술을 생각했을 때 귀하의 불안감을 1-5의 숫자로 표현해주세요.

1 전혀 불안하지 않음	2 조금 불안함	3 불안함	4 많이 불안함	5 극도로 불안함

3. 다음 질문은 시술 중 귀하의 불안 증상의 심각도를 측정하기 위한 설문입니다. 평가자와 함께 각 항목에 대한 심각도를 표시해주세요.

	질문사항	전혀 그렇지 않다	약간 그러한 편이다	중간 이다	꽤 그러한 편이다	매우 그렇다
1	불안한 기분	0	1	2	3	4
	걱정, 나빠질 것이라는 생각, 무서운 기대, 불안정함					
2	긴장	0	1	2	3	4
	긴장감, 피로, 놀람반응, 쉽게 눈물을 보임, 떨림, 차분하지 못함, 긴장을 풀지 못함					
3	공포	0	1	2	3	4
	어둠에 대한, 낯선 것에 대한, 혼자라는 것에 대한, 동물에 대한, 군중에 대한					
4	불면	0	1	2	3	4
	쉽게 잠들지 못함, 잠이 깸, 기상 시 피로감, 불충분한 수면, 꿈, 악몽, 야경증					
5	인지	0	1	2	3	4
	집중이 어려움, 기억력 감퇴					
6	우울한 기분	0	1	2	3	4
	흥미없음, 취미에 즐겁지 못함, 우울, 아침잠이 줄었다					
7	신체적 증상(근육)	0	1	2	3	4
	통증, 경련, 아픔, 뻣뻣함, 근간대성 경련, 이갈음, 불안정한 목소리, 근긴장도 증가					
8	신체적 증상(감각)	0	1	2	3	4
	이명, 시력저하, 일과성 열감, 일과성 한기, 힘없음, 욱신거림					
9	심혈관계 증상	0	1	2	3	4
	빈맥, 두근거림, 흉통, 혈관 박동, 실신할 것 같은 느낌, 부정맥					

10	호흡기계 증상	0	1	2	3	4
	흉부 압박감, 흉부 수축감, 목에 무엇인가 걸리는 느낌, 한숨, 호흡곤란					
11	소화기계 증상	0	1	2	3	4
	연하곤란, 복통, 작열감, 복부팽만, 오심, 구토, 복명, 설사, 체중감소, 변비					
12	비뇨기계 증상	0	1	2	3	4
	빈뇨, 절박뇨, 무월경증, 월경과다, 불감증, 조루, 성욕상실, 발기부전					
13	자율신경계 증상	0	1	2	3	4
	입마름, 홍조, 창백함, 진땀, 현기증, 긴장성 두통, 머리털이 곤두섬					
14	면담시 행동	0	1	2	3	4
	안절부절 못함, 서성거림, 손떨림, 긴장된 표정, 한숨, 빠른 호흡, 안면 창백, 침삼킴 등					

(14~17점: 가벼운 불안, 18~24점: 중등도 불안, 25~30점: 심한 불안)

연구대상자 설문지 (시술후 회복실)

4. (시술 직후 회복실) 시술 도중 귀하가 느꼈던 통증의 정도를 0-10의 숫자로 표현해주세요.

(0: 통증 없음, 2: 약한 통증, 4: 중증도 통증, 6: 심한 통증, 8: 극심한 통증, 10: 최악의 통증)

0	1	2	3	4	5	6	7	8	9	10

5. 불안감

(시술 직후 회복실) 시술을 곧 받는다고 상상해 보십시오. 받게 되는 시술을 생각했을 때 귀하의 불안감을 1-5의 숫자로 표현해주세요.

1 전혀 불안하지 않음	2 조금 불안함	3 불안함	4 많이 불안함	5 극도로 불안함

6. 시술시 마취 만족도

6-1) (시술 직후 회복실) 시술을 받을 때 시술로 인한 통증을 조절하는데 있어 귀하의 만족도를 알려주세요.

5 매우 만족	4 다소 만족	3 보통	2 다소 불만족	1 매우 불만족

6-2) 4-1의 답변에 대한 이유를 간단히 서술해주세요.

7. (시술 직후 회복실) 시술을 받을 때 시술로 인한 불편감이나 어지럼증, 그 외의 부작용이 있었다면 알려주세요.

8. 귀하가 시술장에서 시술을 받기 위해 머문 시간을 귀하가 느낀 대로 추정해서 써주세요. : 약 _____ 분