Research Square

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Immersive Virtual Reality Treatment Does Not Alleviate Maternal Anxiety During Spinal Anesthesia Procedure: A Randomized Controlled Trial

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Abstract

Background

Spinal anesthesia is the preferred technique for cesarean delivery, yet it can provoke anxiety and pain in parturients. Video-watching can alleviate these symptoms to some extent. However, whether immersive virtual reality (VR), as a novel distraction technique, is more effective remains inconclusive. We hypothesized that VR would provide superior relief for anxiety and pain during the procedure compared to video. This randomized controlled trial aimed to determine the superiority of immersive VR over video distraction in reducing maternal anxiety.

Methods

This randomized controlled trial allocated 146 parturients to receive either VR gaming or video-watching during spinal anesthesia puncture. The change in maternal anxiety scores (before vs. during the procedure) was the primary outcome. Secondary outcomes encompassed pain scores, satisfaction, distraction efficacy, and anesthesiologist - reported anxiety.

Results

There was no significant difference in the change in anxiety score ($P = 0.100$) between the two groups. However, compared with the iPad group, the VR group reported significantly less pain ($P = 0.011$), greater satisfaction ($P = 0.029$), and better distraction effects ($P = 0.003$). The anesthesiologist - reported maternal anxiety score was also significantly lower in the VR group ($P = 0.006$).

Conclusion

No significant difference in anxiety scores was observed between the VR and iPad groups during anesthetic puncture.

Trial registration:

ChiCTR2400081158, 24/2/2024

Introduction

Spinal anesthesia is the preferred anesthetic technique for cesarean delivery. However, many parturients anticipate more pain than they actually experience.[1, 2] This overestimation can provoke significant anxiety and fear,[1] potentially leading to adverse physiological responses,[3] increased risk of anesthetic

failure,[4] and even result in refusal of the procedure.[2] These concerns highlight the need for effective interventions to reduce maternal anxiety during spinal anesthesia.

Distraction, as a well-established non-pharmacological intervention, is widely applied in clinical settings such as venipuncture, dental care, and preoperative management. Its efficacy in alleviating anxiety and distress, reducing the need for sedatives, and promoting physiological stability has been consistently documented.[5, 6] Modalities include hypnotherapy, game-based interventions, music therapy,[7] video-based distraction,[8] among others. However, while some studies have reported that video distraction significantly reduces preoperative anxiety scores and even lowers blood pressure,[9] other have reported contradictory results.[10] Thus, identifying distraction methods that are effective, easy to implement, and low-cost remains a priority.

To overcome these challenges, immersive virtual reality (VR) has emerged as a promising alternative for anxiety reduction. VR generates simulated, interactive environments in real time, allowing users to engage through multiple sensory channels, including visual, auditory, and tactile stimuli.[11] Previous studies have demonstrated that VR technology can effectively reduce pain and anxiety during painful procedures.[12, 13] Moreover, VR treatment can also weaken expectant mothers' perception of pain by modulating the neurological conduction and processing of pain signals.[14]

To date, four case reports have observed that VR therapy can alleviate anxiety and pain in patients during lumbar punctures and epidural catheter placements.[15–18] A pilot study demonstrated that, under the condition where both groups received basic pharmacological sedation, VR intervention showed no significant advantage in reducing pain during lumbar punctures in adolescents with cancer.[19] Another randomized controlled study targeting patients requiring epidural steroid injections showed that the VR intervention group achieved equivalent effects to the pharmacologic sedation group in relieving pain and anxiety, and outperformed the control group.[20] Current evidence from randomized controlled trials supporting VR interventions during spinal puncture in the obstetric population remains limited.

Therefore, we designed a randomized controlled trial to investigate whether VR treatment is more effective than traditional distraction in reducing anxiety and pain during spinal anesthesia in parturients.

Methods

Study design

The study was a prospective, parallel, randomized controlled clinical trial. Ethical approval was obtained from the Ethics Committee of Shenzhen Maternity and Child Healthcare Hospital, Southern Medical University (SFYLS[2023]045). The trial was registered on February 24, 2024, at the Chinese Clinical Trial Registry (https://www.chictr.org.cn/showprojEN.html?proj=220085) with registration number ChiCTR2400081158, and the first participant was enrolled on March 1, 2024. This study followed the

Consolidated Standards for Reporting of Comprehensive Trials (CONSORT). All subjects provided written informed consent prior to participation.

Subjects

We included parturients who met the criteria for American Society of Anesthesiologists (ASA) physical status II, underwent elective cesarean section, and received spinal anesthesia. The exclusion criteria were as follows: severe motion sickness, mental illness, history of epilepsy, or audio-visual impairment.

Randomization and allocation

The participants were randomly assigned in a ratio of 1:1 to either the iPad or VR group. Randomization was performed by a researcher who was not involved in the data collection. Simple randomization was performed via Excel (Microsoft Inc., Redmond, WA, USA), and the randomized sequence for each subject was identified. These identifiers, which indicate the subject's serial number and grouping status (VR group or iPad group), were placed in sequentially coded, sealed, and opaque envelopes.

All eligible subjects were unaware of their grouping until informed consent and baseline assessment data were obtained. However, owing to the unique nature of the VR trial, it was not possible to blind the subjects to their study condition. Blinding was also not possible for the researchers who performed the intervention or the medical staff.

Intervention

iPad Group and Virtual Reality Group

In the VR group, the subjects played an eye-tracking cognitive assessment game (name redacted for blinding), which was a medical device approved by a national regulatory body (approval number redacted). The intervention was delivered using head-mounted VR displays (manufacturer and location redacted) with screen-casting capability to a tablet. The screen showed differently colored fireflies in a forest that could be caught by changes in the user's gaze (Fig. 1). Before the intervention, the researchers will briefly instruct the VR group participants on how to use the equipment. The formal game set to last 5 minutes. After the first game, the subjects were asked about their willingness to continue the intervention if necessary. If the subjects did not refuse, the game was restarted.

The participants in the iPad group received the traditional distraction intervention, consisting of watching a video. The video showed a forest in the rain, allowing participants to see and hear the rain through a window. Due to device limitations that precluded interactive gaming during the puncture, we chose nature landscapes with backgrounds and content similar to the VR group to maintain comparability. The video was 5 minutes long, and participants were permitted to rewatch it throughout the procedure or

stop at any time. The tablet was positioned on an adjustable bedside stand to facilitate viewing in the lateral position. A research assistant was present to ensure optimal viewing conditions and to provide assistance as needed.

The participants could call off the intervention at any time if they experienced any discomfort, such as dizziness or nausea. All equipment was wiped down with disinfectant wipes after each participant completed the intervention to avoid cross-contamination.

Intervention process

All participants received standard care, which included an explanation of the spinal anesthesia process, verbal reassurance, and assistance with position changes. Once inside the operating room, the participants were assisted in remaining in the right lateral position to undergo spinal anesthesia. At the same time, the participants received the intervention according to their group. The researcher assisted the participants in wearing the VR equipment or fixing the position of the tablet, and necessary adjustments were made to ensure that the instructions were clear and that participants were comfortable and safe. The participants could then play the eye-tracking game or watch the video until the end of spinal anesthesia. Once the anesthesia was completed, the intervention was terminated.

Outcomes

The change in anxiety score about puncture before and during spinal anesthesia was used as the primary outcome. The Visual Analog Scale (VAS) was used to assess the level of maternal self-reported anxiety and is represented as a horizontal line from 0 to 100, with 0 indicating no anxiety and 100 indicating extreme anxiety. The scale has demonstrated strong validity in prior research.[21]

Secondary outcomes included the maximum pain score during the spinal anesthesia, patient satisfaction score, degree of distraction caused by the intervention, and the anesthesiologist - reported maternal anxiety score. All these scores were assessed via VAS. We also marked the 100-point on the horizontal line as representing extreme pain, full satisfaction, total distraction, and very anxious. The reliability of these scales has been demonstrated in previous research.[21–24] Scoring of primary and other outcomes was performed within 15 minutes after completion of spinal anesthesia.

In addition, adverse effects experienced by subjects during the intervention were captured, including nausea, vomiting and dizziness. Specifically, for the subjects in the VR group, a feedback questionnaire was carried out, such as willingness to recommend the VR intervention to others, the degree of VR immersion, and other settings they would like to use VR treatment.The questionnaire used in this study was developed by the research team and is available as Additional file 1.

Statistical analysis

Sample size calculations were based on pilot research that included 30 subjects. By using PASS 2021 (PASS Inc., Lowa, IA, USA), we estimated that intergroup differences in the change of anxiety scores could be detected with 58 participants per group, with the mean difference of -12.333, a standard deviation (SD) of 23.354, and a power of 80% at the 5% significance level. Given the potential attrition rate of up to 20%, we aimed to recruit 146 subjects, with 73 in each group.

SPSS 26.0 (IBM Corp., Chicago, IL, USA) was used to analyze the data. The Shapiro–Wilk test was used to test the normality of continuous data. Normally distributed data were described as means and standard deviations (SDs), and non-normally distributed data were described as medians and interquartile ranges (IQRs). Categorical data are presented as percentages.

For continuous variables, the Shapiro-Wilk test is first used to assess the normality of the variable. For normally distributed data, continuous variables were subjected to independent t tests on the basis of the results of Levene's chi-square test. For non-normally distributed data, the Wilcoxon rank sum test was used to compare differences, and the Hodges-Lehmann estimate is applied to assess the median difference between the VR group and the iPad group. Categorical variables were analyzed via the χ^2 test. All tests were two-sided and considered statistically significant at $P < 0.05$. Given the non-normal distribution of both primary and secondary outcomes, data were summarized using the median with interquartile range (IQR), and group comparisons were performed via the Wilcoxon rank-sum test.

Results

Baseline data and patient characteristics

A total of 160 eligible parturients who were enrolled in elective cesarean sections between March 1 and June 30, 2024, were recruited, of which 14 were excluded. A total of 146 mothers were randomly divided into the treatment or control group (73 per group). Figure 2 depicted the flow chart of the study implementation. There were no statistically significant differences between the two groups in terms of demographic factors such as age, BMI, gestational days, fetal number, childbirth history, cesarean history, or spinal anesthesia history (Table 1).

All participants received spinal anesthesia with only one subject received combined spinal epidural anesthesia for consideration of the long duration of the surgery. This subject was allocated to the VR group and received the VR treatment according to the trial process. We statistically analyzed all data from this subject using the original grouping.

Table 1
Maternity demographic and clinical characteristics

Demographic	**VR Group(n = 73)**	**iPad Group(n = 73)**
Age, yr	33.4 ± 3.9	32.9 ± 4.4
BMI, (kg/m^2)	25.8(24.1 to 28.4)	26.7(25 to 29.2)
Days of pregnancy	273(271 to 277)	272(268 to 276)
Number of fetuses		
Singleton, *n(%)*	73(100)	70(95.9)
Twin pregnancy, *n(%)*	0(0)	3(4.1)
History of childbirth, *n(%)*		
0	54(74.0)	45(61.6)
1	16(21.9)	25(34.3)
2	3(4.1)	3(4.1)
History of cesarean section, *n(%)*		
0	57(78.1)	49(67.1)
1	13(17.8)	22(30.1)
2	3(4.1)	2(2.7)
History of spinal anesthesia, *n(%)*		
0	56(76.7)	49(67.1)
1	14(19.2)	20(27.4)
2	3(4.1)	4(5.5)
First puncture site, *n(%)*		
L2-3	71(97.3)	71(97.3)
L3-4	2(2.7)	2(2.7)
Combined obstetric diseases[a], *n(%)*	35(48)	42(57.5)
Combined chronic diseases[b], *n(%)*	13(17.8)	15(20.6)
Puncture Duration[c], min	6(4 to 10)	7(5.5 to 10)
Duration of intervention[d], min	6(4 to 9)	7(5.5 to 9.5)
Pre-puncture anxiety score	50(35 to 75)	70(50 to 80)

Continuous variables are presented as mean ± standard deviation (SD) or median (interquartile range). Categorical variables are presented as frequency(%).

BMI, body mass index; VR, virtual reality.

[a] Defined as conditions that occur during pregnancy, including: gestational hypertension, gestational diabetes mellitus, hypothyroidism, etc.

[b] Defined as a pre-existing condition prior to pregnancy, including: hyperthyroidism, hypothyroidism, hepatitis B, etc.

[c] Defined as the difference between the end time and the start time of the puncture.

[d] Defined as the difference between the end time and the start time of the intervention.

Primary outcome

The change in anxiety score (pre-puncture anxiety score minus intra-puncture anxiety score) is presented in Table 2. We found that there was no significant difference in score changes between the iPad and VR group [0 (-10 to 10) vs. 0 (-20 to 5), *P* = 0.100].

Table 2
Primary and secondary outcomes

Variables	**VR group (n = 73)**	**iPad group (n = 73)**	**Hodges-Lehmann estimate (95% CI)**	***P* value**
Change in anxiety score[a]	0(-10 to 10)	0(-20 to 5)	5(0 to 10)	0.100
Pain score	30(20 to 50)	50(30 to 70)	-10(-20 to 0)	0.011
Patient satisfaction score	90(70 to 90)	80(50 to 90)	10(0 to 15)	0.029
distraction score	60(50 to 75)	50(30 to 70)	10(5 to 20)	0.003
Anesthesiologist-reported maternal anxiety score	35(20 to 60)	50(32.5 to 65)	-10(-20 to 0)	0.006

Data are expressed as median (interquartile range).

VR: virtual reality.

[a] Change in anxiety score = pre-puncture anxiety score − intra-puncture anxiety score.

Secondary outcomes

Compared with the iPad group, the VR group demonstrated significantly less pain [30 (20 to 50) vs. 50 (30 to 70), *P* = 0.011], greater satisfaction [90 (70 to 90) vs. 80 (50 to 90), *P* = 0.029] (Fig. 3), and a deeper degree of distraction [60 (50 to 75) vs. 50 (30 to 70), *P* = 0.029] during spinal anesthesia. Moreover, the results revealed that anesthesiologist - reported maternal anxiety scores were significantly lower in the VR group than in the iPad group [35 (20 to 60) vs. 50 (32.5 to 65), *P* = 0.006] (Table 2).

Only 1 participant (1.37%) in the VR group reported mild dizziness during the intervention, which quickly disappeared after removal of the VR device. Other participants experienced no adverse effects during the intervention.

In the VR group, the median and the third quartile (P75) of maternal satisfaction scores are identical, causing the median and upper quartile markers in the box plot to overlap, making them indistinct.

Discussion

The results revealed that the VR group did not significantly differ in regard to anxiety scores before and during the spinal anesthesia compared to the iPad group. However, this trial also revealed that VR treatment via an active distraction approach significantly decreased pain, increased patient satisfaction, diverted more attention and reduced anesthesiologist - reported anxiety among parturients receiving spinal anesthesia.

A study on VR intervention applied to epidural steroid injections demonstrated that virtual reality more effectively reduced patient anxiety compared to the blank control group, while showing comparable efficacy to the pharmacological sedation group.[20] However, our research revealed that the VR group failed to alleviate maternal anxiety during spinal anesthesia when compared with the iPad group. This discrepancy may be explained by the calming effects produced by the iPad group's soothing music and imagery, which also effectively reduced anxiety. Yet previous studies have suggested that VR content designed for users of specific ages might improve users’ experience when receiving painful stimuli.[25] The lack of alignment between VR content and participant age in this trial may be one of the reasons why the VR treatment did not significantly alleviate maternal anxiety. Future studies should be designed to involve parturients of different age groups in VR content development to better align with their needs.

Our study revealed that VR treatment was effective in reducing pain and increasing patient satisfaction among participants receiving spinal anesthesia. A systematic review of 18 studies demonstrated the efficacy of VR interventions in alleviating acute pain in adults, showing benefits during wound dressing changes as well as for reducing anxiety and pain in the first stage of labor. This highlights the potential of VR treatment in managing brief yet painful medical procedures.[26] Similarly, another randomized controlled trial demonstrated that using a domed ceiling screen to watch VR animations significantly alleviated pain perception in children during intravenous placement.[27] Our findings are supported by a case report on VR-assisted epidural catheter placement in parturients, which described comparable analgesic effects.[18]

In addition, this trial demonstrated that, compared with the iPad treatment, VR treatment increased the extent to which maternal attention was diverted and reduced anesthesiologist - reported maternal anxiety during anesthesia operation. While the active-passive categorization of distraction interventions is well-established,[28] few studies have directly compared their efficacy, with one notable exception being a randomized trial in a pediatric burn care setting.[29] The advantages of VR treatment to divert attention, improve users' compliance and increase satisfaction via greater engagement had been documented in previous research.[25] Thus, the significant difference between these two interventions may be attributed to the active distraction intervention provided by the virtual reality device in this study. VR eye-tracking games may distract users' attention more easily and enhance interaction, which reduces attention to pain related to medical operations and the environment.

The generalizability of our findings is subject to certain limitations. This study has some limitations. First, selection bias may have been introduced by the refusal of several parturients with extreme pre-anesthesia anxiety to enroll, a subgroup that may include individuals with heightened vigilance and sensitivity. The non-inclusion of this population may be one of the confounding factors that lead to no difference in the primary outcome. Second, the intervention content was different between the two groups. However, VR intervention is characterized by an immersive experience, so eye-tracking games cannot be implemented in the iPad group. Third, in this trial, we assessed anxiety using the Visual Analog Scale (VAS-A) rather than a self-rating scale such as the Spielberger State-Trait Anxiety Inventory (STAI). Because it is maternity woman friendly and easier to implement, among other things, VAS-A has been validated and widely used.[30] Fourth, we were unable to blind participants or researchers due to the obviousness of the VR intervention. Finally, some maternity women reported that the VR content was not interesting enough. The lack of parturient involvement in VR content development at the study design phase could be a plausible factor influencing such perceptions among the maternal population.

Conclusion

This clinical trial revealed that VR treatment did not significantly reduce maternal anxiety during spinal anesthesia compared to the iPad group. However, this intervention could reduce pain, divert more attention, increase satisfaction, and reduce anesthesiologist - reported anxiety to a greater extent than the iPad group. In the future, personalized VR content is expected to become the trend in order to optimize the effects of VR interventions.

Abbreviations

virtual reality, VR

Consolidated Standards for Reporting of Comprehensive Trials, CONSORT

American Society of Anesthesiologists, ASA

Visual Analog Scale, VAS

standard deviation, SD

interquartile range, IQR

Spielberger State-Trait Anxiety Inventory, STAI

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Shenzhen Maternity and Child Healthcare Hospital, Southern Medical University (SFYLS[2023]045). All subjects gave informed consent to participate in the study before taking part. All methods were performed in accordance with the relevant guidelines and regulations, including the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing Interests

The authors declare no conflicts of interest.

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Author Contribution

Yemiao Hu and Yang Xu wrote the main manuscript text. Yemiao Hu, Yang Xu, Yunfeng Shou, Caiping Xu, Jiayi Shen, Chu Xiao, Yuting Hu, and Yuantao Li contributed to methodology, formal analysis, investigation, data curation, and conceptualization. Yunfeng Shou, Caiping Xu, and Yuantao Li supervised the study. Yuantao Li contributed to project administration, resources, and writing—review and editing. Chu Xiao prepared figures. All authors reviewed the manuscript.

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Data Availability

The datasets generated and/or analysed during the current study are not publicly available due to participant privacy and the sensitive nature of the clinical data. However, de-identified data are available from the corresponding author on reasonable request.

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Figures

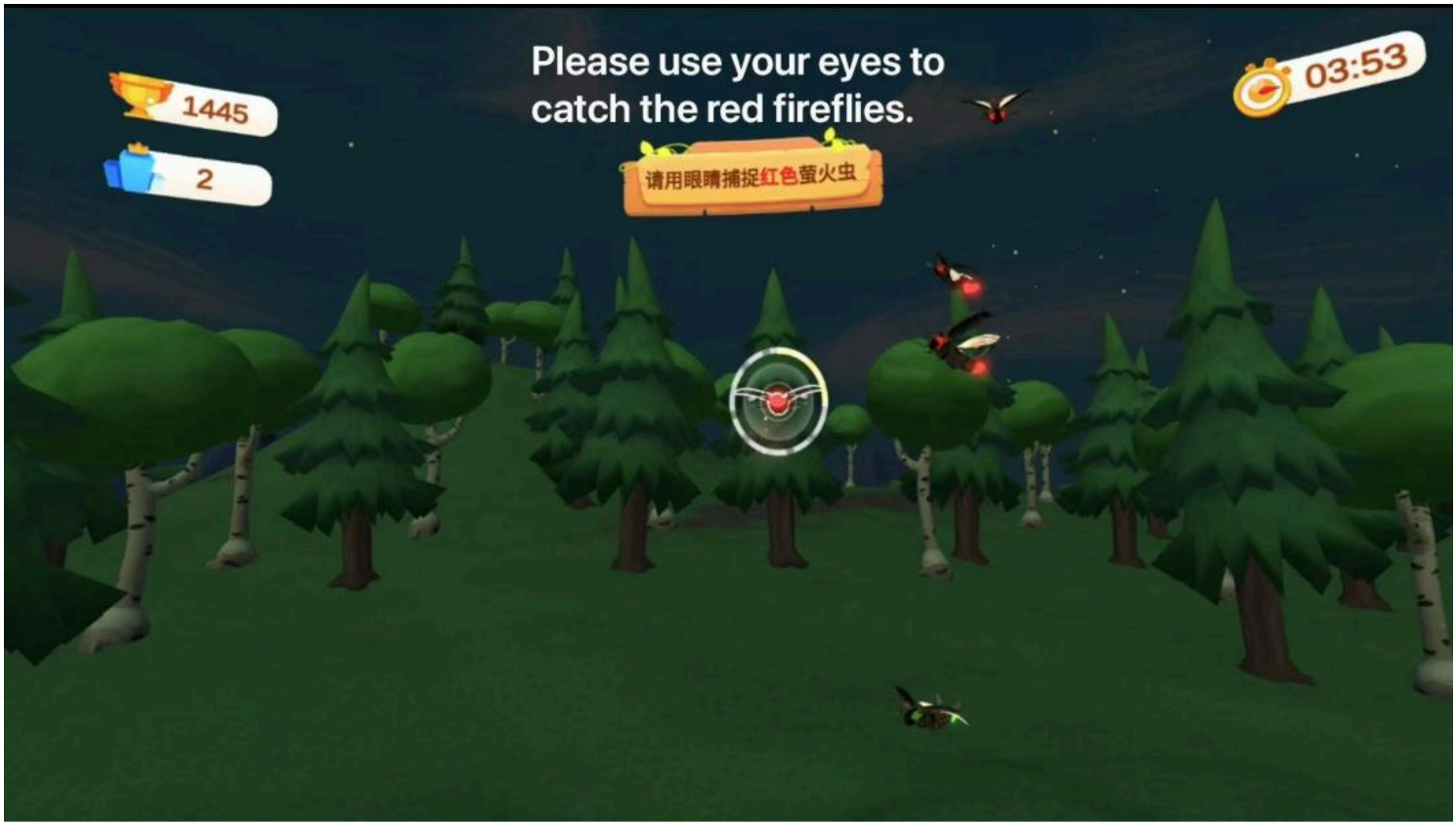


Figure 1

VR game scene display

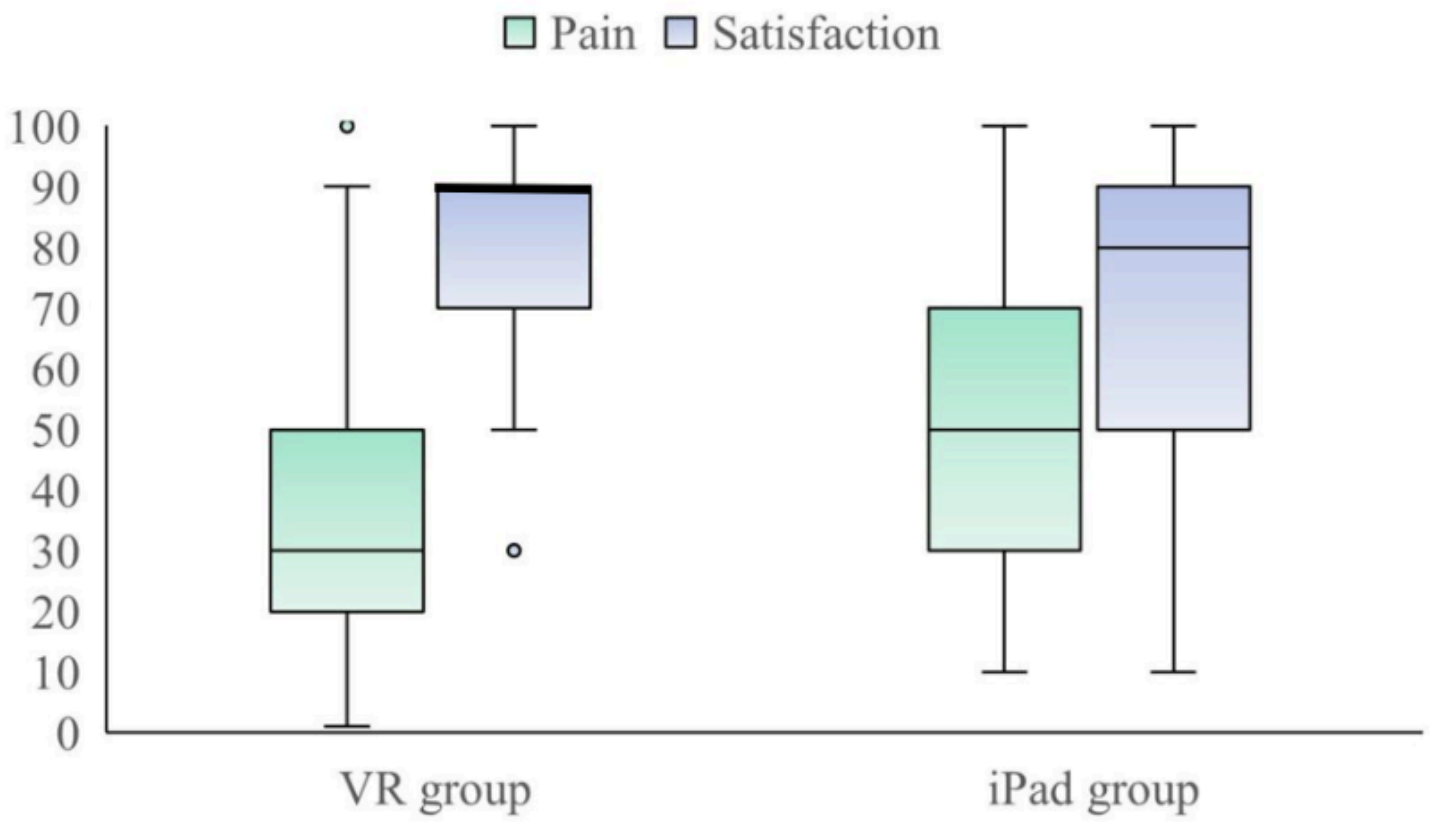


Figure 3

Comparison of puncture pain and satisfaction scores

Supplementary Files

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