Multicenter, randomized, controlled comparative-effectiveness study comparing virtual reality to sedation and standard local anesthetic for pain and anxiety during epidural steroid injections

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Summary

Background The use of sedation during interventional procedures has continued to rise resulting in increased costs, complications and reduced validity during diagnostic injections, prompting a search for alternatives. Virtual reality (VR) has been shown to reduce pain and anxiety during painful procedures, but no studies have compared it to a control and active comparator for a pain-alleviating procedure. The main objective of this study was to determine whether VR reduces procedure-related pain and other outcomes for epidural steroid injections (ESI).

Methods A randomized controlled trial was conducted in 146 patients undergoing an ESI at 6 hospitals in Thailand and the United States. Patients were allocated to receive immersive VR with local anesthetic, sedation with midazolam and fentanyl plus local anesthetic, or local anesthetic alone. The primary outcome was procedure-related pain recorded on a 0-10 scale. Other immediate-term outcome measures were pain from a standardized subcutaneous skin wheal, procedure-related anxiety, ability to communicate, satisfaction, and time to discharge. Intermediate-term outcome measures at 4 weeks included back and leg pain scores, function, and success defined as a ≥2-point decrease in average leg pain coupled with a score ≥5/7 on a Patient Global Impression of Change scale.

Findings Procedure-related pain scores with both VR (mean 3.7 (SD 2.5)) and sedation (mean 3.2 (SD 3.0)) were lower compared to control (mean 5.2 (SD 3.1); mean differences –1.5 (–2.7, –0.4) and –2.1 (–3.3, –0.9), respectively), but VR and sedation scores did not significantly differ (mean difference 0.5 (–0.6, 1.7)). Among secondary outcomes, communication was decreased in the sedation group (mean 3.7 (SD 0.9)) compared to the VR group (mean 4.1 (SD 0.5); mean difference 0.4 (0.1, 0.6)), but neither VR nor sedation was different than control. The trends favoring sedation and VR over control for procedure-related anxiety and satisfaction were not statistically significant. Post-procedural recovery time was longer for the sedation group compared to both VR and control groups. There were no meaningful intermediate-term differences between groups except that medication reduction was lowest in the control group.

The Lancet Regional Health - Southeast Asia 2024;27: 100437

Published Online xxx
https://doi.org/10.1016/j.lansea.2024.100437

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Interpretation VR provides comparable benefit to sedation for procedure-related pain, anxiety and satisfaction, but with fewer side effects, superior communication and a shorter recovery period.

Funding Funded in part by grants from MIRROR, Uniformed Services University of the Health Sciences, U.S. Dept. of Defense, grant # HU00011920011. Equipment was provided by Harvard MedTech, Las Vegas, NV.

Keywords: Virtual reality; Distraction; Epidural steroid injection; Sciatica; Radiculopathy

Research in context

Evidence before this study

Virtual reality (VR) has been shown to reduce pain and anxiety during procedures, but there are no studies comparing it to sedation and a control group for pain interventions.

Added value of this study

This study establishes non-inferiority to sedation for pain and anxiety, but VR was superior for communication, length of recovery and was associated with a lower incidence of side effects.

Implications of all the available evidence

Virtual reality appears to provide comparable benefit to sedation, which is overused in clinical practice and associated with significant risks and costs. More research is needed to determine the ideal programs and patients, and whether virtual reality provides objective (biomarkers) and subjective long-term benefits for pain and anxiety.

Introduction

Epidural steroid injections (ESI) are perhaps the most commonly performed interventional pain procedures in the world, but have been plagued by questions concerning overutilization, cost-effectiveness, and mixed results.[1,2]

One reason for the increased scrutiny is reimbursement, with high costs negatively altering the cost-effectiveness and risk-benefit ratios, as increased payments inevitably lead to increased utilization.[3] As third-party payer reimbursement rates have leveled off, there has been a concomitant surge in utilization of sedation and anesthesia services with professional fees for the latter often exceeding that for the injection. Sedation is routinely used for lumbar ESI by over 40% of practitioners, and articles continue to be published advocating routine sedation during ESI.[4–6] This is despite guidelines by the American Society of Anesthesiologists and other organizations asserting that sedation should not be routinely administered for ESI, studies finding that deep sedation significantly increases the risk of complications and does not improve satisfaction rate, and for diagnostic procedures such as selective nerve root blocks, that sedation increases the false-positive rate.[7–9] In 2017, the Centers for Medicare and Medicaid Services declared that sedation was rarely necessary for ESI, and would not be reimbursed without documentation of medical necessity.[10] Yet, the use of inappropriate sedation persists.

The most common reasons cited for sedation during pain management procedures include the alleviation of anxiety, reducing procedure-related pain, and preventing unnecessary movement, which can lead to complications and increased technical difficulties.[11] In a randomized, crossover trial, the use of sedation was found to decrease procedure-related pain but increase the false-positive rate of diagnostic pain injections, while having no effect on satisfaction or intermediate-term outcomes.[9] In an observational study (n = 301) by Kim et al. evaluating the need for sedation during lumbar ESI and facet blocks, 44% chose not to be sedated, 4% received oral diazepam and 52% requested intravenous sedation with diazepam, with those requesting sedation reporting higher anxiety levels.[12] In an earlier study by the same group, the use of intravenous diazepam was paradoxically associated with higher procedure-related pain, though selection bias likely contributed to those results.[13]

Virtual reality (VR) has been touted as a safe and effective option for acute pain. In a systematic review evaluating the effect of VR on acute and chronic pain in 20 studies, Mallari et al. found strong evidence for an effect on acute pain, weak evidence for an immediate effect on chronic pain, and a lack of evidence on the long-term alleviation of chronic pain.[14] In the qualitative analysis, 4 studies compared VR to a no-VR group for procedure-related pain, but none used an active comparator, none evaluated its utility for a chronic pain intervention, and none evaluated its effect on intermediate-term outcomes.

The issue regarding cost, necessity and safety of sedation is not limited to pain management but is also salient for specialties such as gastroenterology, interventional radiology and dentistry.[15,16] To address gaps in the literature, we performed a randomized study

comparing VR to sedation and a control group that received only local anesthesia. The objectives of our study were: 1) To determine the relative effectiveness of VR to reduce procedure-related pain and other outcomes for ESI compared to sedation and a control group; 2) Determine whether the short-term use of VR during the ESI has an effect on intermediate-term outcomes; and 3) Identify demographic and clinical characteristics that might predict response.

Methods

This randomized 3-arm parallel group study compared VR to light sedation (both with local anesthetic) to a local anesthetic only during lumbosacral ESI. Approval to conduct this study was granted by the institutional review boards at Johns Hopkins Medical Institutions, New York University School of Medicine, and the Central Research Ethics Committee of the National Research Council of Thailand which served as the central institutional review board for Ramathibodi Hospital, Siriraj Hospital (both affiliated with Mahidol University), King Chulalongkorn Memorial Hospital (Chulalongkorn University) and the Phramongkutklao College of Medicine in Bangkok. All subjects enrolled provided written consent and were treated between March 28, 2022 (December 1, 2022 in Thailand) and August 7, 2023. The trial was registered on ClinicalTrials.gov on May 14, 2021, NCT04887285.

Participants and settings

All patients were enrolled by physician investigators or research personnel. The sites included two teaching hospitals in Eastern U.S. cities and the 4 largest University hospitals in Bangkok, Thailand including the Phramongkutklao Royal Thai Army Hospital. Inclusion criteria were age ≥18 years, average leg pain score ≥4 on a 0–10 numerical rating scale (NRS), duration of pain >6 weeks, willingness to undergo an ESI using any of the studied modalities, and a diagnosis of lumbosacral radicular pain caused by herniated disc, central or foraminal spinal stenosis or degenerative disc disease. Exclusion criteria were untreated coagulopathy or being unable to stop anticoagulants, prior spine surgery at the affected level, body mass index >40, lumbar ESI within 6 months, allergy to contrast or another injectate, pregnancy, serious medical or psychiatric conditions that could interfere with participation or affect outcomes, and if available, discordant radiological imaging.[17]

Randomization and allocation

146 patients were randomized in a 1:1:1 ratio into two treatment and one control group by site-specific computer-generated randomization tables at the time they were scheduled for treatment. A research coordinator stratified participants by site in blocks ranging between 9 and 27, with assignments concealed from physicians. Subgroup allocation was based on ESI approach (e.g., interlaminar or transforaminal) given the differences in the procedures (i.e., more procedure-related pain during transforaminal procedures).

Treatment groups

Sedation group

Patients randomized to sedation received either minimal (awake but relaxed) or moderate sedation (depressed consciousness but responsive to verbal stimuli or light touch) based on the judgment of the pain physician and anesthesia provider. Analgesia and anxiolysis were achieved by the use of fentanyl and midazolam. Sedative medications were titrated to effect by a board-certified anesthesiologist. In addition to the intravenous sedation, patients also received lidocaine 1% using a 1.25-inch 25-gauge needle that extended from a standardized skin wheal down through the soft tissues as needed, with deeper pain treated with local anesthetic administered through the epidural needle at the discretion of the physician.

Virtual reality group

To accommodate the device, patients were positioned prone with either their slightly flexed head resting on the platform, with the top of their head off the platform, or with 1 or 2 pillows under their chest to accommodate a head-elevated position, depending on preference. The VR hardware is a PICO headset filled with proprietary software designed by Harvard MedTech (Las Vegas, NV), herein referred to as the Vx Platform. It is a visually-activated apparatus in which patients at all sites preselected one of 33 programs divided into pain-based knowledge, meditation, distraction and escape platforms. Participants were instructed how to activate the programs, could test-run different programs before the procedure and switch from one program to another (including if the procedure was still going on when a program ended); the program lengths varied between just under 4–20 min. Each program provides a head- and earphone-facilitated immersive experience through visual and auditory stimuli in a non-internet-connected environment. The content is curated to minimize vertigo, but patients could remove the Vx Platform should side effects ensue.

Control group

Patients randomized to the control group received a 1 mL skin wheal using lidocaine 1% administered through a 25-gauge gauge needle, with additional local anesthetic given as deemed necessary by the physician overseeing the injection through the 25-gauge or epidural needle depending on the depth where the pain was experienced.

Epidural steroid injections

ESI were performed by or under the supervision of a board-certified pain medicine physician using

fluoroscopic guidance in accordance with standard practices. The spinal level for the injection was based on presentation and radiological findings. With rare exceptions (n = 2 bilateral transforaminal ESI done in patients with spondylolisthesis), interlaminar injections were done for bilateral symptoms while transforaminal injections were done in those with predominantly (≥80%) unilateral symptoms. For interlaminar ESI, a 20-gauge Tuohy needle was inserted midline or parasagittally towards the more painful side and advanced into the epidural space with image guidance in multiple views using loss of resistance. For transforaminal ESI, a 22-gauge spinal needle(s) was inserted co-axially into the anterior-superior part of the targeted foramen with the image intensifier ipsilaterally obliqued approximately 35°. Correct placement was confirmed by real-time injection of contrast after which a 3 mL solution containing 1 mL of 40 mg/mL of depo-methylprednisolone, 1 mL of normal saline and 1 mL of 0.25% bupivacaine was injected. In the 33 patients who underwent bilateral or 2-level TFESI, the same solution was injected at both levels. For participants who received an interlaminar ESI, a 4 mL injectate consisting of 1 mL of 40 mg/mL of depo-methylprednisolone, 2 mL of normal saline and 1 mL of 0.25% bupivacaine was administered. In 10 patients deemed to have challenging anatomy with bilateral symptoms, or bilateral symptoms involving S2, single-shot caudal ESI were performed. Given the longer distance from the sacral hiatus to spinal pathology, a 10 mL solution consisting of 80 mg of depo-methylprednisolone, 2 mL of 0.25% bupivacaine and 6 mL of saline was injected in these patients.

Outcome measures

Between the ESI and the 4-week primary endpoint, no new co-interventions besides exercise were permitted, though patients could remain on their stable (>2 weeks without change) baseline analgesics. For acute procedure-related pain, a non-steroidal anti-inflammatory drug, acetaminophen or in those with contraindications, a short course of tramadol could be prescribed. Four-week outcome data was recorded by a disinterested evaluator blinded to allocation.

Baseline recorded data included age, ethnicity, duration, inciting event, type(s) and level(s) of pathology, type and level of ESI, co-prevalent psychiatric and pain conditions, average and worst leg and back pain score over the past week, Oswestry Disability Index version 2.1a score (0–100% in which higher scores indicate greater back pain-related disability); Hospital Anxiety and Depression Scale (HADS) in which subscales range between 0 and 21 points, with scores ≥8 and 11 being borderline abnormal and abnormal, respectively; and Somatic Symptom Scale (SSS-8), with scores ≥12 indicative of a high somatic symptom burden.[18–20]

The primary outcome measure was patient-reported procedure-related pain on a 0–10 verbal pain scale, recorded within 5 min of procedure completion. Secondary outcomes were the contemporaneous verbal pain score on a 0–10 scale following the standardized skin wheal[21]; the patient's perceived ability to communicate on a 1–5 Likert scale (1 = unresponsive, 2 = marked decreased ability to communicate, 3 = slightly decreased ability, 4 = no change in communication and 5 = improved ability to communicate, compared to a face-to-face discussion without sedation); procedure satisfaction on a 1–5 Likert scale (1 = very unsatisfied, 2 = unsatisfied, 3 = neither unsatisfied nor satisfied, 4 = satisfied, 5 = very satisfied); anxiety on a 1–5 Likert scale (1 = extreme anxiety, 2 = high anxiety, 3 = average or expected anxiety, 4 = minimal or mild anxiety, 5 = no anxiety); volume of local anesthetic and the amount of midazolam and fentanyl used; time to discharge from post-anesthesia care unit (PACU); and side effects recorded during the PACU stay and a telephone follow-up the next day.

The sole follow-up visit was 4 weeks post-procedure. A positive categorical outcome was defined as a 2-point or greater reduction in the average leg pain score over the past week coupled with a score of ≥5/7 on a Patient Global Impression of Change (PGIC) scale where 1 = no change or worse, 2 = almost the same, 3 = a little better, 4 = somewhat better, 5 = moderately better, 6 = better, and 7 = a great deal better.[22] Other intermediate-term outcomes included average and worst leg pain over the past week, ODI score, HADS scores, and medication reduction, defined as either cessation of a non-opioid analgesic or >20% decrease in opioid dose.[17,21]

Power calculation and sample size

Sample size requirements were calculated based on 95% power to detect a 2-point difference in procedure-related pain between the 2 treatment groups and the control group at a significance level of 0.05. Calculations assumed three equally-sized groups, mean procedure-related pain score of 5.5 (SD 2.5) in the control group, and mean procedure-related pain scores of 3.5 (SD 2.5) in the treatment groups. With these assumptions, 38 patients would need to be enrolled in each group. To account for a 10% dropout rate, we planned to enroll at least 42 patients in each group.

Statistical analysis

All analyses were performed using an intention-to-treat approach. Group means and standard deviations are reported for continuous outcomes, with analysis of variance (ANOVA) used to compare groups. Percentages are reported for categorical outcomes, with chi-square tests used to compare groups.

For analysis of the primary outcome, the three groups were compared with linear regression. Secondary outcome measures were also compared with linear or logistic regression models as appropriate for the outcome. To assess factors contributing to outcomes,

univariate and multivariate regression models were constructed for the primary outcome, as well as the main secondary outcomes. Linear regression models were used for the continuous outcomes of procedure-related pain and average leg pain score, while logistic regression models were used for categorical procedural success. Multivariate regression models were constructed from covariates using a backward stepwise approach, with variable removal criteria of $p = 0.05$. Covariates were selected based on factors known and hypothesized to be associated with pain outcomes, including treatment, age, sex, pain duration, opioid use, disability, obesity, smoking, presence of a psychiatric disorder, and baseline average leg pain, back pain, ODI, HADS anxiety and depression, and SSS-8 scores. Data are presented per intention-to-treat analysis, with the few (0.75%) missing datapoints dropped from analysis. There were two patients who did not receive treatment in their assigned group; all others completed the procedure in their assigned group per study protocol above, and were included in a per-protocol sensitivity analysis. Statistical analyses were performed using Stata/IC 16 (StataCorp, College Station, TX, USA). All hypothesis tests were two-sided, with an alpha of 0.05 considered statistically significant.

Role of funding sources

The funding sources played no role in study design, acquisition of data, statistical analysis or interpretation of the results, or manuscript preparation.

Results

361 patients were screened, with 146 patients meeting selection criteria (Fig. 1). Forty-eight were randomized to VR, 50 to sedation, and 48 to the control group. The mean age of participants was 57 years (SD 14), with 65% being female. Disease burden was moderate, with the average leg pain score being 6.3 (SD 2.0), the mean duration of pain being 3.8 years (SD 4.4), the cohort having a mean ODI score of 42% (SD 15%) and 16% being on disability or Worker's compensation. 52% had a co-existing psychiatric disorder, 16% were receiving opioids, and 45% had a herniated disc as their primary pathology.

All patients except 2 who were missing subcutaneous skin wheal and procedure-related anxiety scores had complete baseline and procedure-related data. Two patients in the sedation group and three in the control group were lost to follow-up and did not have 4-week outcomes. The mean doses of midazolam and fentanyl

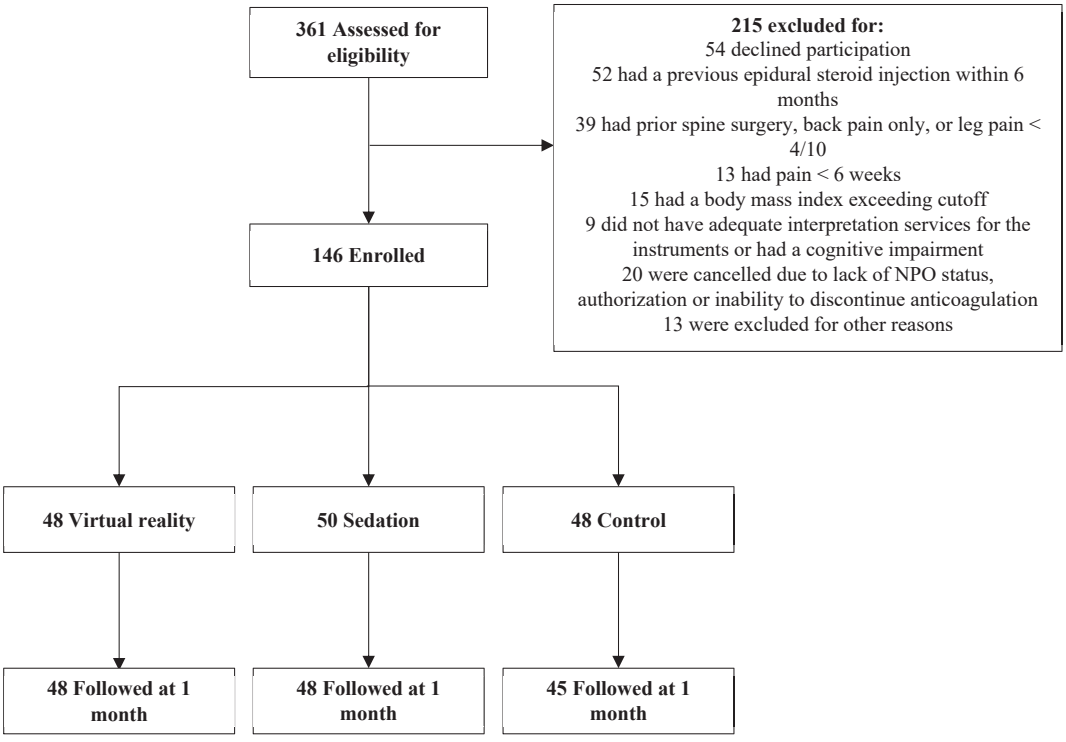

Fig. 1: Study flow chart. Footnotes: 1. Enrollment numbers: King Chulalongkorn Memorial Hospital (N = 26), Siriraj Hospital (N = 3), Phramongkutklao Royal Thai Army Hospital (N = 19), Ramathibodi Hospital (N = 25), New York University Langone Medical Center (N = 2), Johns Hopkins Hospital (N = 71). 2. Reasons for "other" exclusions were overextended clinic visits and/or research assistant unavailable (n = 9), perceived inability to adequately follow-up (n = 3), and secondary gain (n = 1).

in the sedation group were 1.4 (0.8) mg and 51.8 (34.0) mcg, respectively. Two patients were randomized to VR but declined to wear them during the procedure; all other patients completed the procedure according to their assignments. All patients except 2 who were missing subcutaneous skin wheal and procedure-related anxiety scores had complete baseline and procedure-related data. Outcomes were not significantly different with the per-protocol sensitivity analysis (Table 1).

Primary and immediate-term outcome measures

For the primary outcome, procedure-related pain scores differed significantly among groups (p = 0.001). Whereas procedure-related pain scores with both VR and sedation were lower compared to control (VR vs. control: 3.7 (2.5) vs. 5.2 (3.1), mean difference –1.5 (–2.7, –0.4) and sedation vs. control: 3.2 (3.0) vs. 5.2 (3.1), mean difference –2.1 (–3.3, –0.9) respectively), VR and sedation pain scores did not significantly differ. In the Thai cohort (n = 73), VR was not significantly different from control (VR vs. control: 4.2 (2.3) vs. 5.4 (3.0), mean difference –1.2 (–2.7, 0.3)), but sedation was associated with a significant decrease in pain score compared to control (sedation vs. control: 2.5 (2.5) vs. 5.4 (3.0), mean difference –2.8 (–4.4, –1.4) and VR (sedation vs. VR; 2.5 (2.5) vs. 4.2 (2.3), mean difference –1.7 (–3.1, –0.2)), respectively. In the non-Thai cohort, there were no significant differences among all or between any two groups. There were no significant differences in any outcome when stratified by prior ESI (n = 18, mean difference –0.5 (95% CI: –1.9, 0.9) for prior ESI vs. no prior ESI).

Among secondary outcomes, procedure-related communication was significantly decreased in the sedation group compared to the VR group (VR vs. sedation: 4.1 (0.5) vs. 3.7 (0.9), mean difference 0.4 (0.1, 0.7)), but neither VR nor sedation was different than control (VR vs. control: 4.1 (0.5) vs. 4.0 (0.4), mean difference 0.1 (–0.2, 0.4) and sedation vs. control; 3.7 (0.9) vs. 4.0 (0.4), mean difference –0.3 (–0.6, 0)). Post-procedural recovery time (minutes) was longer for the sedation group compared to both VR and control groups (sedation vs. VR: 38.8 (14.5) vs. 27 (20.7), mean difference 11.7 (2.2, 21.4) and sedation vs. control; 38.8 (14.5) vs. 24.4 (24), mean difference 14.4 (4.8, 24)), but was not significantly different between VR and control (VR vs. control: 27 (20.7) vs. 24.4 (24), mean difference 2.6 (–7.1, 12.3)). All other immediate-term outcomes were statistically comparable across groups, including for the standardized subcutaneous skin wheal.

Results were similar in the as-treated sensitivity analysis, re-categorizing to the control group the two patients assigned to VR who chose not to use the headset during the procedure. All outcomes with significant differences remained statistically significant, and all outcomes without significant differences remained insignificant except procedure-related satisfaction. This was not significantly different in the intention-to-treat analysis but was different in the as-treated analysis (omnibus ANOVA, p = 0.018). In pairwise comparisons, the as-treated control group was associated with a 0.4-point decrease in procedure-related satisfaction on a 5-point Likert scale compared to the as-treated VR group (95% CI: 0.07, 0.72); insert Table 2).

Adverse events

Adverse effects were similar across groups, with no adverse events reported in 43 out of 48 (90%) VR participants, 40 out of 50 (80%) sedation participants, and 44 out of 48 (92%) control participants (p = 0.19). The most common adverse effect in the VR group was nausea in 2 participants (4%, 1 with vomiting), compared to 1 (2%, with vomiting) in the sedation group and none in the control group. In the sedation group, respiratory depression occurred in 4 participants (8%), which was significantly higher compared to no cases in the VR and control groups (sedation vs. control/VR: 8% vs. 0%, mean difference –8% (95% CI: –15%, 0.4%). Dizziness occurred in 3 patients in the sedation group and one each in the VR and control groups. The other 2 adverse events in the sedation group were severe pain and a wet tap. Nearly all adverse events were self-limited, and only three warranted additional treatment (e.g., rescue medication): one VR and one sedation case with nausea, and one sedation case with respiratory depression that required additional oxygen and physical stimulation. Side effects in the control group included two cases of hypertension or tachycardia (>20% above baseline) that did not require treatment and one case of diaphoresis. One patient in the VR group experienced both excessive post-procedure pain and a rash within 4 weeks that was diagnosed as acute herpes zoster, deemed possibly related to steroids while another VR patient had excessive pain during the procedure with local swelling that persisted for several days.

Intermediate-term outcomes

Four weeks post-procedure, there were no significant differences among groups except for medication reduction. In the control group, only 18% of patients taking daily pain medications were able to reduce them compared to 43% in the sedation group (mean difference 25% (95% CI: 7.5%, 42.5%)). Other outcomes were not significantly different among groups.

Predictors of outcome

Of the covariates examined, only assignment to the control group, increased age, having a co-morbid psychiatric disorder, and baseline average back pain score were significantly associated with increased procedure-related pain. In the multivariate model, assignment to the control group was associated with a 1.39-point

Characteristic	Virtual reality (N = 48)	Sedation (N = 50)	Control (N = 48)	Total (N = 146)
Age, years (mean ± SD)	57 ± 13	58 ± 13	56 ± 16	57 ± 14
Female (n, %)	31 (65%)	37 (74%)	27 (56%)	95 (65%)
Race (n, %)				
Asian	26 (54%)	22 (44%)	25 (52%)	73 (50%)
Black	9 (19%)	17 (34%)	13 (27%)	39 (27%)
Hispanic	1 (2%)	0	1 (2%)	2 (1%)
White	12 (25%)	7 (14%)	8 (17%)	27 (19%)
Other (mixed or declined to answer)	0	4 (8%)	1 (2%)	5 (3%)
Duration of pain, years (mean ± SD)	4.7 ± 5.0	3.3 ± 3.0	3.5 ± 4.9	3.8 ± 4.4
Type of epidural steroid injection (n, %)				
Interlaminar	11 (23%)	19 (38%)	12 (25%)	42 (29%)
Transforaminal	32 (67%)	30 (60%)	32 (67%)	94 (64%)
Caudal	5 (10%)	1 (2%)	4 (8%)	10 (7%)
Pathology[a]				
Herniated disc	24 (50%)	22 (44%)	20 (42%)	66 (45%)
Central spinal stenosis	15 (31%)	15 (30%)	15 (31%)	45 (31%)
Foraminal stenosis	10 (21%)	16 (32%)	13 (27%)	39 (27%)
Noncompressive spondylosis	0	3 (6%)	2 (4%)	5 (3%)
Opioid use (n, %)	7 (15%)	11 (22%)	5 (10%)	23 (16%)
Disability or worker's compensation (n, %)	10 (21%)	6 (12%)	7 (15%)	23 (16%)
Obesity (n, %)[b]	11 (23%)	14 (28%)	19 (40%)	44 (30%)
Smoking (n, %)	6 (13%)	7 (14%)	10 (21%)	23 (16%)
Inciting event (n, %)				
Fall	8 (17%)	5 (10%)	7 (15%)	20 (14%)
Motor vehicle collision	1 (2%)	2 (4%)	1 (2%)	4 (3%)
Lifting	4 (8%)	4 (8%)	3 (6%)	11 (8%)
Work-related	4 (8%)	4 (8%)	2 (4%)	10 (7%)
Sports	2 (4%)	0	0	2 (1%)
Other	2 (4%)	1 (2%)	5 (10%)	8 (6%)
None	28 (58%)	34 (68%)	30 (63%)	92 (63%)
Co-existing psychiatric condition (n, %)[c]				
Depression	11 (23%)	11 (22%)	12 (25%)	34 (23%)
Anxiety	10 (21%)	17 (35%)	5 (10%)	32 (22%)
Posttraumatic stress disorder	2 (4%)	0	1 (2%)	3 (2%)
Substance misuse	5 (10%)	2 (4%)	1 (2%)	8 (6%)
Multiple psychiatric disorders	7 (15%)	6 (12%)	4 (8%)	17 (12%)
None	24 (50%)	22 (44%)	24 (50%)	70 (48%)
Average leg pain (mean ± SD)	5.7 ± 2.0	6.5 ± 1.9	6.6 ± 1.9	6.3 ± 2.0
Worst leg pain (mean ± SD)	7.9 ± 2.0	8.7 ± 1.7	8.4 ± 2.0	8.4 ± 1.9
Average back pain (mean ± SD)	5.3 ± 2.0	6.2 ± 2.1	6.3 ± 2.4	5.9 ± 2.2
Worst back pain (mean ± SD)	8.0 ± 1.9	8.6 ± 1.8	8.3 ± 1.8	8.3 ± 1.8
Oswestry Disability Index (%, mean ± SD)	42 ± 16	41 ± 16	42 ± 14	42 ± 15
Hospital Anxiety & Depression Scale (mean ± SD)				
Anxiety subscale	6 ± 4	6 ± 4	6 ± 3	6 ± 4
Depression subscale	5 ± 4	5 ± 4	5 ± 4	5 ± 4
Somatic symptom scale-8	10 ± 5	11 ± 6	10 ± 4	10 ± 5

[a]Denotes primary pathology. Multiple etiologies counted in multiple subcategories. [b]Body mass index ≥30. [c]Denotes active condition (including controlled under treatment); substance misuse includes patients in remission.

Table 1: **Baseline demographic and clinical characteristics of study subjects.**

increase in procedure-related pain score (95% CI: 0.30, 2.49). The presence of a co-morbid psychiatric disorder was significantly associated with a 1.19-point increase in procedure-related pain score (95% CI: 0.29, 2.09), each 1-year increase in age was associated with a 0.05-point increase (95% CI: 0.02, 0.08), and each 1-point increase in baseline back pain was associated with a 0.21-point increase (95% CI: 0.01, 0.42).

Outcome variable	Virtual reality (N = 48)	Sedation (N = 50)	Control (N = 48)	Mean difference/Coefficient (95% CI)[f]		
				VR-control	Sedation-control	VR-sedation
Immediate-term outcome measures						
Procedure-related pain score: mean (SD)[a]	3.7 (2.5)	3.2 (3.0)	5.2 (3.1)	−1.5 (−2.7, −0.4)	−2.1 (−3.3, −0.9)	0.5 (−0.6, 1.7)
Skin wheal pain score: mean (SD)[a]	4.0 (2.4)	3.8 (2.8)	4.5 (2.8)	−0.4 (−1.5, 0.7)	−0.7 (−1.7, 0.4)	0.2 (−0.9, 1.3)
Volume of lidocaine, mL: mean (SD)	5.6 (2.5)	5.4 (2.6)	6.3 (2.9)	−0.7 (−1.8, 0.4)	−0.9 (−2.0, 0.2)	0.2 (−0.9, 1.3)
Procedure-related anxiety score: mean (SD)[b]	4.0 (1.3)	4.2 (1.1)	3.8 (1.1)	0.2 (−0.3, 0.6)	0.4 (−0.0, 0.9)	−0.3 (−0.7, 0.2)
Procedure-related satisfaction score: mean (SD)[b]	4.7 (0.6)	4.6 (0.8)	4.5 (0.7)	0.3 (−0.0, 0.5)	0.2 (−0.1, 0.4)	0.1 (−0.2, 0.4)
Procedure-related communication score: mean (SD)[b]	4.1 (0.5)	3.7 (0.9)	4.0 (0.4)	0.1 (−0.1, 0.4)	−0.3 (−0.5, −0.0)	0.4 (0.1, 0.6)
Time in post-procedural recovery, minutes (mean, 95% CI) [log transformation]	27.0 (21.0, 33.0) 1.3 (1.2, 1.4)	38.8 (34.7, 42.9) 1.6 (1.5, 1.6)	24.4 (17.4, 31.4) 1.3 (1.2, 1.4)	0.0 (−0.1, 0.2)	0.3 (0.2, 0.4)	−0.6 (−0.9, −0.3)
Complications (n, %) (95% CI)	5 (10%) (4.1%, 21.3%)	10 (20%) (10.8%–32.6%)	4 (8%) (2.9%–18.6%)	2.1% (−9.6, 13.9)	11.7% (1.9, 25.2)	−9.6% (−23.7, 4.5)
4-Week outcomes						
Average leg pain mean (SD)	3.0 (2.4)	3.1 (2.8)	3.8 (2.7)	−0.8 (−1.8, 0.3)	−0.7 (−1.8, 0.4)	−0.1 (−1.2, 0.9)
Worst leg pain mean (SD)	4.9 (3.3)	4.8 (3.4)	5.8 (2.9)	−0.7 (−1.9, 0.6)	−1.1 (−2.4, 0.2)	0.1 (−1,3, 1.4)
Average back pain mean (SD)	3.1 (2.3)	3.5 (2.6)	3.6 (2.7)	−0.5 (−1.5, 0.6)	−0.1 (−1.1, 0.9)	−0.3 (−1.3, 0.7)
Worst back pain mean (SD)	5.1 (3.5)	5.5 (3.3)	5.5 (3.1)	−0.3 (−1.6, 1.1)	−0.1 (−1.5, 1.2)	−0.3 (−1.7, 1.1)
Oswestry disability index: %, mean (SD)	32 (17)	36 (17)	34 (15)	−2.0 (−7.5 to 3.4)	3.2 (−2.3, 8.6)	−5.2 (−10.6, 0.1)
Hospital anxiety & Depression scale mean (SD)						
Anxiety subscale	4.9 (4.0)	5.1 (4.5	4.3 (3.0)	0.6 (−0.8, 2.1)	0.9 (−0.7, 2.4)	−0.2 (−1.9, 1.5)
Depression subscale	4.0 (3.9)	4.5 (3.9)	3.8 (3.5)	0.1 (−1.4, 1.7)	0.7 (−0.8, 2.3)	−0.6 (−2.2, 1.0)
Patient Global Impression of Change Scale mean (SD)[c]	4.7 (1.8)	4.5 (2.0)	4.6 (1.9)	0.1 (−0.6, 0.9)	−0.1 (−0.8, 0.7)	0.2 (−0.6, 1.0)
Medication reduction (n, %)[d]	16/46 (35%)	19/44 (43%)	7/40 (18%)	1.99 (0.82, 4.83)	2.47 (1.04, 5.87)	0.81 (0.41, 1.57)
Positive outcome (n, %)[e]	25 (52%)	25 (52%)	24 (53%)	0.98 (0.56, 1.71)	0.98 (0.56, 1.71)	1.0 (0.57, 1.74)

[a]Recorded on 0–10 verbal rating scale. [b]Based on 1–5 Likert Scale with 5 denoting no anxiety, very satisfied with procedure or improved ability to communicate. [c]Based on 1–7 Likert Scale with higher scores denoting greater improvement (1 = no change or worse, 3 = a little better, 5 = moderately better and 7 = a great deal better). [d]Categorically defined as cessation of a non-opioid analgesic or >20% decrease in opioid dose. Excludes subjects not taking daily medication for pain. [e]Defined as a 2-point or greater reduction in the average leg pain score over the past week coupled with a score of ≥5/7 on a Patient Global Impression of Change (PGIC) scale. [f]Mean differences are presented in terms of the outcome measure scale (e.g., pain score on 0–10 scales, in points on outcomes measured with Likert scales (e.g., anxiety, communication score). For variables expressed in percentages (medication reduction, positive outcome), mean difference represents the incidence rate ratio. The mean difference for the log transformation of post-procedural recovery time is unitless.

Table 2: **Immediate and intermediate-term clinical outcomes for epidural steroid injections stratified by treatment group.**

For 4-week outcomes, group assignment was not associated with categorical outcome. Only decreased baseline ODI was associated with 3% increased odds of a positive outcome (95% CI: 1%, 6%). Increased average leg pain, presence of disability or a workers' compensation claim, and increased baseline ODI were significantly associated with increased average leg pain score at 4 weeks. A 1-point increase in baseline average leg pain score was associated with a 0.34-point increase in pain at 4 weeks (95% CI: 0.13, 0.56), a 1 percentage point increase in baseline ODI was associated with a 0.03-point increase in pain at 4 weeks (95% CI: 0.01, 0.06), and disability/worker's compensation was associated with a 1.93-point increase in leg pain 4-weeks post-procedure (95% CI: 0.79, 3.08, Table 3).

Discussion

The main findings in this study are that VR was equivalent to sedation and superior to local anesthetic only for the primary outcome measure, but for the principal secondary outcome measure, pain after a standardized skin wheal, the differences between the control group and the two treatment groups were not statistically significant. Compared to sedation, VR was associated with a shorter PACU stay and improved communication. Although our sub-analysis in the Thai cohort indicates that Southeast Asians may possibly experience fewer benefits with VR relative to sedation, these results should be viewed with caution and need to be confirmed in studies adequately powered to detect ethnic differences. Reasons for this possibility include lower body weights, and differences in metabolism of opioids and sedatives.[23,24] In one mini-meta-analysis, Black participants experienced less cybersickness than White patients, suggesting that racial and ethnic differences in treatment response may exist for VR, possibly due to genetics, cultural expectations, and exposure.[25,26]

Several randomized trials have shown some benefit for add-on VR compared to other forms of anesthesia. Huang et al. found that although VR was well-tolerated as an adjunct to spinal anesthesia for joint replacement, it was not associated with reduced anesthetic

Primary outcome: procedure-related pain			
Variable	**Unadjusted coefficient (95% CI)**	**Full model**	**Backward stepwise regression**
		Adjusted coefficient (95% CI)	Adjusted coefficient (95% CI)
VR group	−1.54 (−6.13, 3.05)	−1.67 (−2.84, −0.49)	−1.39 (−2.49, −0.30)
Sedation group	−2.06 (−11.80, 7.68)	−2.25 (−3.41, −1.09)	−2.21 (−3.28, −1.15)
Age	0.04 (0.01, 0.08)	0.050 (0.02, 0.08)	0.050 (0.02, 0.08)
Sex	0.65 (−0.36 to 1.66)	0.63 (−0.41 to 1.67)	
Pain duration	0.06 (−0.01, 0.13)	0.03 (−0.09, 0.14)	
Opioid use	0.07 (−3.20, 3.34)	−0.17 (−1.61, 1.26)	
Disability	1.00 (−4.80, 6.80)	0.85 (−0.60, 2.29)	
Obesity	0.25 (−6.01, 6.51)	−0.39 (−1.45, 0.68)	
Smoking	0.63 (−4.78, 6.03)	−0.04 (−1.52, 1.44)	
Co-morbid psychiatric disorder[a]	1.18 (−0.73, 3.09)	1.06 (0.08, 2.04)	1.19 (0.29, 2.09)
Baseline average leg pain	0.14 (−1.57, 1.85)	−0.12 (−0.42, 0.19)	
Baseline average back pain	0.29 (−0.32, 0.90)	0.25 (−0.04, 0.54)	0.21 (0.01, 0.42)
ODI	0.04 (0.03, 0.05)	0.02 (−0.02, 0.05)	
HADS-Anxiety	0.08 (−0.27, 0.43)	0.01 (−0.16, 0.17)	
HADS-Depression	0.06 (−0.81, 0.92)	−0.02 (−0.20, 0.16)	
SSS-8	0.04 (−0.03, 0.10)	−0.03 (−0.17, 0.11)	
Secondary outcome measure: 4-week average leg pain			
VR group	−0.80 (−5.69, 4.09)	−0.52 (−1.56, 0.52)	
Sedation group	−0.70 (−7.15, 5.75)	−0.54 (−1.58, 0.50)	
Age	0.00 (−0.25, 0.26)	0.01 (−0.02, 0.04)	
Sex	−0.31 (−1.24 to 0.63)	−0.33 (−1.25 to 0.60)	
Pain duration	0.06 (−0.52, 0.63)	0.02 (−0.08, 0.12)	
Opioid use	1.22 (−8.61, 11.04)	0.00 (−1.29, 1.29)	
Disability	2.75 (0.75, 4.76)	1.89 (0.56, 3.22)	1.93 (0.79, 3.08)
Obesity	0.71 (−2.39, 3.82)	0.32 (−0.62, 1.26)	
Smoking	2.45 (1.94, 2.95)	1.14 (−0.16, 2.44)	
Co-morbid psychiatric disorder[a]	0.89 (−6.64, 8.41)	0.40 (−0.47, 1.27)	
Baseline average leg pain	0.53 (−0.09, 1.14)	0.24 (−0.03, 0.51)	0.34 (0.13, 0.56)
Baseline average back pain	0.40 (−1.35, 2.14)	0.08 (−0.17, 0.33)	
ODI	0.06 (−0.01, 0.12)	0.03 (−0.002, 0.06)	0.03 (0.01, 0.06)
HADS-Anxiety	0.09 (−0.37, 0.55)	−0.14 (−0.28, 0.01)	
HADS-Depression	0.15 (−0.20, 0.50)	−0.01 (−0.16, 0.16)	
SSS-8	0.14 (−0.12, 0.39)	0.03 (−0.09, 0.15)	
Secondary outcome measure: positive 4-week categorical outcome[b]			**Adjusted odd ratio (95% CI)**
VR group	0.95 (0.63, 1.43)	1.19 (0.47, 3.04)	
Sedation group	0.95 (0.53, 1.72)	0.99 (0.39, 2.51)	
Age	0.10 (0.99, 1.00)	1.00 (0.97, 1.02)	
Sex	1.17 (0.59, 2.33)	1.11 (0.49, 2.53)	
Pain duration	1.01 (0.93, 1.09)	1.01 (0.93, 1.10)	
Opioid use	0.50 (0.32, 0.78)	0.62 (0.19, 2.05)	
Disability	0.40 (0.36, 0.44)	0.34 (0.10, 1.19)	
Obesity	1.63 (1.35, 1.96)	1.78 (0.75, 4.23)	
Smoking	0.46 (0.38, 0.55)	0.70 (0.22, 2.25)	
Co-morbid psychiatric disorder[a]	0.72 (0.36, 1.47)	0.10 (0.46, 2.16)	
Baseline average leg pain	0.95 (0.90, 1.00)	1.09 (0.86, 1.38)	
Baseline average back pain	0.94 (0.81, 1.08)	0.99 (0.79, 1.24)	
ODI	0.97 (0.95, 0.98)	0.96 (0.94, 0.99)	0.97 (0.94, 0.99)
HADS-Anxiety	0.98 (0.95, 1.01)	1.07 (0.93, 1.22)	
HADS-Depression	0.95 (0.79, 1.15)	1.00 (0.86, 1.15)	
SSS-8	0.97 (0.91, 1.02)	1.01 (0.90, 1.12)	

[a]Includes depression, anxiety, substance misuse, and post-traumatic stress disorder. [b]Defined as a 2-point or greater reduction in the average leg pain score over the past week coupled with a score of ≥5/7 on a Patient Global Impression of Change (PGIC) scale.

Table 3: **Multivariable analysis of primary and main secondary outcome measures.**

requirements or satisfaction.[27] Mott and colleagues found that VR reduced pain scores compared to intravenous opioids and sedatives in children with burn injuries undergoing dressing changes.[28] A study evaluating add-on VR in patients undergoing lithotripsy with topical local anesthetic and a non-steroidal anti-inflammatory drug reported lower pain scores, but no difference in comfort levels.[29] Virtual reality has also been shown to be superior to receiving no anxiolytic or analgesic for pain, anxiety and satisfaction, in patients undergoing colonoscopy and lipoma excision,[30,31] and superior for post-procedure anxiety but not for pre-procedure anxiety or post-procedure pain in patients undergoing transcatheter aortic valve replacement.[32] In a study performed in a similar setting, Joo et al. found a VR-hypnosis program in addition to local anesthetic resulted in less procedure-related pain than local anesthetic alone during lumbar sympathetic block.[33]

For clinically-relevant comparative-effectiveness studies, a small randomized trial (n = 37) comparing VR to midazolam sedation during urologic surgery performed under spinal anesthesia reported higher patient and anesthesiologist satisfaction rates, better operative conditions, and fewer side effects in the VR group.[34] However, a 4-arm study performed in 120 patients undergoing colonoscopy found music therapy was superior to audiovisual VR for the procedure- and post-procedure related pain, which in turn was more effective than stress ball therapy and a control group that received no intervention. For anxiety, no differences were observed.[35] Similar to our study, these studies utilized audiovisual immersive VR, with all but one study[28] evaluating its effectiveness for procedures of longer duration. Although no study evaluated patients' ability to communicate during procedures, which is particularly relevant for ESI and other nerve blocks,[36] a randomized trial comparing music therapy to midazolam during regional anesthesia nerve blocks found music therapy was associated with lower patient satisfaction scores and poorer physician- and patient-rated communication, with no differences observed in procedure anxiety.[37]

Similar to other studies, we generally found non-inferiority for VR compared to sedation for procedure-related pain, trends towards superiority compared to no adjunct on measures such as anxiety and satisfaction but with fewer side effects, and a greater ability to communicate. In terms of the comparability to sedation for acute pain, one reason for VR to reduce the perception of pain is via distraction, which may also be useful at alleviating breakthrough episodes of chronic pain.[14] Another possible mechanism for analgesia and anxiolysis is the modulation of painful stimuli as evidenced by changes in brain metabolism and decreased activity in areas involved in nociception and anxiety on fMRI in acute pain models.[38] In this study performed in 9 volunteers, both VR and opioid therapy were more effective at reducing pain and pain-related unpleasantness, a surrogate for the affective component of pain, with the combination being more effective than either therapy alone. Although these changes may endure after cessation of therapy, we did not find differences in intermediate-term pain outcomes. Besides treatment allocation, the only clinical factors associated with outcomes were age, the presence of psychiatric morbidity, secondary gain and disease burden, which have previously been shown to predict outcome for ESI and other pain procedures.[39] Whereas VR can be associated with side effects such as increased anxiety and motion sickness, most side effects are less prominent than with intravenous sedation and none of our participants experienced either of these.[40] Whereas the recovery period for VR is also shorter than with opioids, part of the difference in PACU stays may be attributable to protocols requiring a certain period of observation (e.g., 30 min at participating U.S. hospitals, 60 min in Thailand) following procedural sedation. Last, patients randomized to either sedation or VR may also have had a stronger placebo effect than those in the control group.

The results of this study suggest that VR may be an alternative to sedation or no treatment for a variety of painful and anxiety-provoking procedures performed in interventional radiology, internal medicine clinics (endoscopy, bronchoscopy), surgical clinics (e.g., dressing changes) and emergency departments. In pain clinics, the use of deep sedation increases the incidence of complications for ESI while for diagnostic procedures such as facet blocks and sacroiliac joint injections, it increases the false-positive rate.[9,36] The costs for moderate sedation for a 20-min procedure vary in the U.S. from about $64 to $140 in 2022 dollars for federal payers depending on whether or not the proceduralist (vs. a different provider) is overseeing the sedation, to $30–$100 in Thailand; for private payers, rates are generally more than double. When anesthesiologists provide sedation, private payer reimbursement may be over $400. In addition to the increased costs for administering sedation, recovery room costs also significantly increase with sedation, wherein guidelines generally specify a minimum of 30 min to recover a person who receives sedation. These costs and risks have led to multiple guidelines recommending against the routine use of sedation, and payors refusing to authorize it for simple procedures without a psychological indication.[7,9,10,36,41]

There are several avenues future researchers should pursue. One major area of exploration pertains to the use of biomarkers both to identify potential candidates for VR and as an objective surrogate for subjective outcomes such as pain and anxiety. Other areas ripe for study include determining whether certain VR programs are better than others for different patients and procedures, comparing VR to other non-pharmacological relaxation techniques, determining its effectiveness in longer-lasting procedures, and figuring

out whether enhanced validity during diagnostic injections translates to better outcomes.

There are limitations to this study that warrant consideration. As noted above, the open-label format without a placebo arm may have amplified differences between the treatment and control groups. Second, ESI are not meant to be diagnostic, so whether VR can increase the validity of diagnostic injections or improve definitive treatment outcomes after prognostic procedures (e.g., facet radiofrequency ablation or joint replacement) compared to sedation is unknown. Third, what constitutes a statistically significant difference in pain trials is not always clinically meaningful for an individual. Fourth, the different startup times between the U.S. and Thai sites might have introduced an undetected form of bias, though this is unlikely given that the manner in which ESI are performed or patients are sedated has not significantly changed in decades. Finally, we did not evaluate biomarkers (e.g., inflammatory cytokines) such that our main outcome measures were all subjective.

In summary, we found that VR was non-inferior to sedation for procedure-related pain, anxiety and satisfaction during ESI, superior to sedation for communication, and better than no adjunctive therapy for some immediate-term outcomes, but not intermediate-term ones. Future research is necessary to determine whether these findings translate to longer-lasting and non-pain management procedures, refine patient and program selection, and determine whether there are circumstances during which VR therapy can translate into longer-term benefit.

Contributors

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Lead Thai Investigator & Essential Intellectual Contributor (validating Thai questionnaires and involving in study design): NT.

Manuscript preparation, 1st draft (SPC, TD, NT). Critical review and revisions: All Authors.

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IRB and administrative work: SPC, SM, PC, PP, CQ, KN, PE, NT.

Recruitment and Enrollment: All authors.

Data sharing statement

The protocol, consent form and de-identified data will be available upon request to the corresponding author.

Declaration of interests

SPC is a consultant for Avanos, SPR Therapeutics, Persica, Scilex and SWORD, and has previously served as a consultant for Relieviate and Clearing in the past 3 years.

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Acknowledgements

The authors would like to acknowledge Mike Burda, Craig Segasser and the staff from Harvard MedTech for providing the equipment for this study.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lansea.2024.100437.

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