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Percutaneous auricular neuromodulation (nerve stimulation) for the treatment of pain following cholecystectomy and hernia repair: a randomized, double-masked, sham-controlled pilot study

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Received 5 January 2024
Accepted 22 January 2024

To cite: Ilfeld BM, Abramson WB, Alexander B, *et al*. *Reg Anesth Pain Med* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/rapm-2024-105283

ABSTRACT

Background Percutaneous auricular nerve stimulation (neuromodulation) involves implanting electrodes around the ear and administering an electric current. A device is currently available within the USA cleared to treat symptoms from opioid withdrawal, and multiple reports suggest a possible postoperative analgesic effect. The current randomized controlled pilot study was undertaken to (1) determine the feasibility and optimize the protocol for a subsequent definitive clinical trial; and (2) estimate the treatment effect of auricular neuromodulation on postoperative pain and opioid consumption following two ambulatory surgical procedures.

Methods Within the recovery room following cholecystectomy or hernia repair, an auricular neuromodulation device (NSS-2 Bridge, Masimo, Irvine, California, USA) was applied. Participants were randomized to 5 days of either electrical stimulation or sham in a double-blinded fashion.

Results In the first 5 days, the median (IQR) pain level for active stimulation (n=15) was 0.6 (0.3–2.4) vs 2.6 (1.1–3.7) for the sham group (n=15) (p=0.041). Concurrently, the median oxycodone use for the active stimulation group was 0 mg (0–1), compared with 0 mg (0–3) for the sham group (p=0.524). Regarding the highest pain level experienced over the entire 8-day study period, only one participant (7%) who received active stimulation experienced severe pain, versus seven (47%) in those given sham (p=0.031).

Conclusions Percutaneous auricular neuromodulation reduced pain scores but not opioid requirements during the initial week after cholecystectomy and hernia repair. Given the ease of application as well as a lack of systemic side effects and reported complications, a definitive clinical trial appears warranted.

Trial registration number NCT05521516.

INTRODUCTION

Managing pain after ambulatory surgical procedures is often challenging, with patients having laparoscopic cholecystectomy reporting severe pain for 26% of their waking hours when queried on postoperative day 1.[1] One possible analgesic alternative is percutaneous auricular nerve stimulation (neuromodulation) that involves implanting electrodes around the ear and administering an electric current using an external pulse generator.[2] Although its mechanism of action is complex and still under study, it involves the modulation of various neurotransmitter pathways which leads to the release of norepinephrine, serotonin, and endogenous opioids like beta-endorphins.[3 4] This form of neuromodulation also affects pain perception, anxiety, and depression.[3]

An auricular neuromodulation device is cleared by the US Food and Drug Administration to alleviate opioid withdrawal symptoms (NSS-2 Bridge, Masimo, Irvine, California, USA; figure 1).[5] This device has several advantages: it is relatively simple to apply, requires no specialized training or additional equipment, and has few contraindications. Unlike opioids, it has no systemic side effects and no risk of misuse, dependency, overdose, or diversion.

Additionally, it is more cost-effective compared with ultrasound-guided neuromodulation devices and can address pain from multiple peripheral nerves concurrently with a single device.

There is evidence that it may also be effective for postoperative analgesia: one pilot study found lower pain scores and opioid sparing after knee arthroplasty.[6] In contrast, two other investigations involving cesarean and colorectal surgery were negative for their primary and most secondary outcomes.[7 8]

Consequently, we conducted a randomized, double-blinded, sham-controlled pilot study to investigate the use of auricular neuromodulation for pain following hernia repair and cholecystectomy. We aimed to better inform the planning of a subsequent definitive trial by (1) determining the feasibility of and optimizing a study protocol; and (2) estimating the treatment effect.

METHODS

This study followed Good Clinical Practice and was conducted within the ethical guidelines outlined in the Declaration of Helsinki. The study was approved by the University of California San Diego Institutional Review Board (IRB Protocol #802775). The Institutional Review Board determined that the auricular stimulator is a non-significant risk device per the criteria outlined in 21 CFR 812.3(m), and

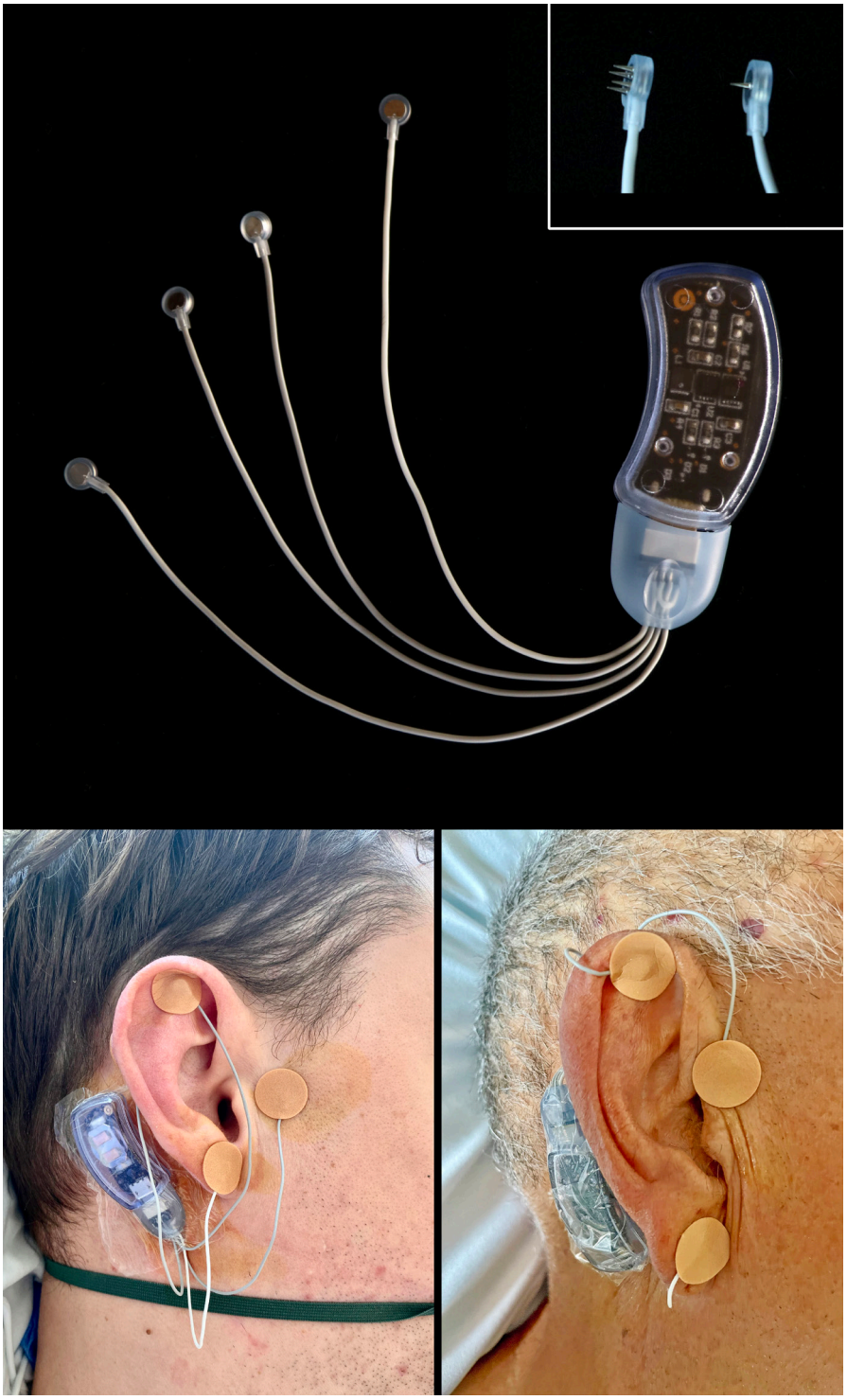

Figure 1 A percutaneous auricular nerve stimulation system (NSS-2 Bridge, Masimo, Irvine, California, USA). Each of the three electrodes has a 2-millimeter-long integrated needle/lead (inset) and the ground electrode has four 2-millimeter-long integrated needles/leads (inset). Used with permission from Brian M Ilfeld.

therefore approved the off-label use of this device to investigate its potential to provide postoperative analgesia. Written, informed consent was obtained from all participants.

Participants

Enrollment was offered to adult patients at least 18 years of age scheduled for primary laparoscopic cholecystectomy or laparoscopic/open unilateral/bilateral/ventral hernia repair. Although initially intended to include ventral hernia repair, it was discovered after study completion that this type of repair had been inadvertently excluded from the Institutional Review Board (IRB) protocol and registry. These cases were subsequently reported to the IRB of record as protocol deviations. Patients were excluded for (1) chronic opioids and/or tramadol use (daily use within the 2 weeks prior to surgery and duration of use >4 weeks); (2) neuromuscular

Table 1 Population and procedural information

	Active (n=15)	Sham (placebo) (n=15)
Age (years)	51 (20)	51 (17)
Female (%)	27% (4)	33% (5)
Height (cm)	173 (13)	173 (9)
Weight (kg)	82 (18)	82 (14)
Body mass index (kg/m^2)	27 (5)	27 (4)
Device laterality: left ear	40% (6)	60% (9)
Device and unilateral procedure same side	27% (4)	27% (4)
Device electrode repositioned	13% (2)	7% (1)
Surgery duration (min)	55 (45)	67 (45)
Unanticipated hospital admission	0% (0)	7% (1)
Peripheral nerve block*		
Transversus abdominis plane block	13% (2)	20% (3)
Rectus sheath block	13% (2)	13% (2)
No peripheral nerve block	73% (11)	67% (10)
Laparoscopic surgical procedure	47% (7)	47% (7)
Cholecystectomy	20% (3)	6% (1)
Unilateral inguinal hernia	6% (1)	20% (3)
Bilateral inguinal hernia	13% (2)	0% (0)
Ventral hernia	6% (1)	20% (3)
Open surgical procedure	53% (8)	53% (8)
Unilateral inguinal hernia	13% (2)	13% (2)
Ventral hernia	40% (6)	40% (6)

Values are reported as mean (SD) or percentage (number of subjects).
*Totals not equal to 100% due to rounding error.
†Totals not equal to 47% due to rounding error.

deficit of the surgical area; (3) history of opioid misuse or dependence; (4) concurrent use of another electric stimulator (eg, cardiac pacemaker); (5) history of bleeding disorder; (6) anticoagulation condition and/or therapy; (7) skin abnormality at the treatment site; (8) psoriasis vulgaris; (9) incarceration; (10) pregnancy; or (11) inability to contact the investigators during the treatment period.

Intervention

Ultrasound-guided single-injection peripheral nerve blocks were administered using ropivacaine 0.5% with epinephrine. Participants who underwent the anticipated surgical procedure were randomized within the recovery room and continued within the study. An investigational pharmacist (University of California San Diego, San Diego, California, USA) created the randomization list in blocks of 2 and a 1:1 allocation into active and sham treatment groups. Active and sham devices appear identical and were provided directly to the investigational pharmacist from the manufacturer. The investigational pharmacist labeled each device with the appropriate randomization number, and no investigator, clinical staff member, or participant was aware of the treatment group assignment until study completion.

The study device was affixed to the ear and activated prior to discharge from the recovery room. There is currently no consensus regarding the placement on the ipsilateral or contralateral ear relative to unilateral surgical procedures. Therefore, the device was placed on the side that the participant sleeps on least. The external pulse generator was placed posterior or inferior to the ear using benzoin, the included adhesive pad, and an occlusive dressing (figure 1). The wire harness was inserted into the external pulse generator which initiated the passage of electrical current (for participants allocated to the active treatment group). The four electrode locations were cleaned with an alcohol pad and then a skin protectant wipe applied (Sureprep, Medline, Northfield, Illinois, USA). A medical light was used to transilluminate the antihelix and the two electrodes on the cephalad half of the ear were placed 1–3 mm from a neurovascular bundle and never immediately opposite each other.

The first lead was placed at the most cephalad portion of the antihelix by simply pressing the electrode directly into the skin similar to a thumbtack (figure 1). The second electrode was inserted immediately cephaloanterior to the incisura and either anterior or posterior to the superficial temporal arterial pulse. The third electrode was inserted on the posterior ear opposite the antihelix at the level of the incisura. The ground electrode with four 2-millimeter-long integrated needles was inserted on the anterior side of the lobule. No local anesthetic was administered. Benzoin and small round bandages were used to secure the electrodes. If there was discomfort from any of the electrodes, that specific electrode was repositioned.

Postoperatively, patients received acetaminophen 975 mg three times a day, a non-steroidal anti-inflammatory drug, and, if needed, the synthetic oral opioid oxycodone (5 mg tablets). Patients were instructed to keep the pulse generators and electrodes dry with the use of a shower cap when bathing. Participants were discharged home with their electrodes in situ.

The pulse generators automatically ceased functioning after 120 hours (5 days) and patients or their caretakers then removed the leads and device, after which the single-use, disposable device was discarded. Following study completion, the results were provided to all participants using non-technical language.

Outcome measures

Participants were contacted by telephone for endpoint collection daily for the first 8 postoperative days. The dual primary outcome measures were the (1) cumulative oral opioid consumption (in oxycodone equivalents); and (2) mean value of the 'average' daily pain scores measured on the 0–10 Numeric Rating Scale (NRS) within the initial 5 postoperative days.

Secondary outcome measures

The primary instrument was the Brief Pain Inventory (short form) which assesses pain and its interference with physical and emotional functioning.[9] The instrument includes three domains: (1) *pain,* with four questions using an NRS to evaluate four pain levels: 'current', 'least', 'worst', and 'average' (collected postoperative days 1–8); (2) percentage of *relief* provided by pain treatments with one question (not used for this study); and (3) *interference* with physical and emotional functioning using a 0–10 scale (0=no interference; 10=complete interference) (collected postoperative days 2, 4, 6, and 8). The seven interference questions involve general activity, mood, walking ability, normal work activities (both inside and outside of the home), relationships, sleep, and enjoyment of life.[9] These seven functioning questions can be combined to produce an interference subscale (0–70). Opioid consumption and awakenings due to pain were also recorded during each phone contact.

Statistical analysis

This investigation was designated a priori as a pilot study to assist in planning a subsequent definitive trial and we

therefore used a convenience sample of 30 participants undergoing cholecystectomy and hernia repair. While there were two primary outcomes specified prior to enrollment, there was no specific data analysis plan defined prospectively. Comparisons of independent samples were performed using a two-tailed Mann-Whitney U test. The Fisher's exact test was used for differences in proportions. $P<0.05$ was considered statistically significant for the primary outcomes. Adjustments were not made for multiple comparisons. Prism V.10.0.2 (GraphPad, Boston, Massachusetts, USA) was used for all analyses.

RESULTS

Between November 2022 and October 2023, a total of 30 participants were enrolled (table 1 and figure 2).

Primary outcomes

In the first 5 days, the median pain level for those receiving active stimulation (n=15) was 0.6 (IQR 0.3–2.4) vs 2.6 (IQR 1.1–3.7) for the sham group (n=15) (p=0.041). Concurrently, the median oxycodone use for the active stimulation group was 0 mg (IQR 0–1), compared with 0 mg (IQR 0–3) for the sham group (p=0.524).

Secondary outcomes

Daily least, average, and worst pain between days 2 and 7 were lower in the active treatment than sham group (figure 3). Ten (67%) participants in both treatment groups avoided opioids for the entire study period. Regarding the highest pain level experienced over the entire 8-day study period, only one participant (7%) who received active stimulation experienced severe pain, versus seven (47%) in those given sham (p=0.031, figure 4). Participants who received active treatment had less physical and emotional interference due to pain during portions of both the treatment (postoperative day 4) and post-treatment (day 6) phases (figure 3). Pain did not interfere to any degree with physical or emotional functioning during the entire 8-day study period in seven participants (47%) who received active stimulation, versus only one (7%) in those given sham (p=0.031). Awakening due to pain over all eight postoperative nights in participants given active stimulation was a median (IQR) of 0 (0–1) vs 0 (0–5) in those given sham (p=0.485).

Adverse events and protocol deviations

No device-related localized cutaneous irritation, systemic side effects, or other adverse events were identified. A total of three participants removed their devices early due to discomfort at one or more of the electrode sites: postoperative day 1 (both active and sham groups) and day 4 (sham group). Two participants from each treatment group had an electrode dislodge during the treatment period, and one in the sham group pushed the lead back into the skin. Lastly, a participant who had an uneventful open ventral hernia repair and sham neuromodulation reported severe pain uncontrolled with oral and intravenous opioids and was subsequently provided with a low thoracic epidural infusion for approximately 48 hours within the hospital.

DISCUSSION

This randomized, double-blinded, sham-controlled pilot study suggests that percutaneous auricular nerve stimulation improves analgesia and reduces pain's interference with physical and emotional functioning during the first week following cholecystectomy and hernia repair. However, while the pilot study results appear promising, definitive conclusions require a subsequent, adequately powered clinical trial.

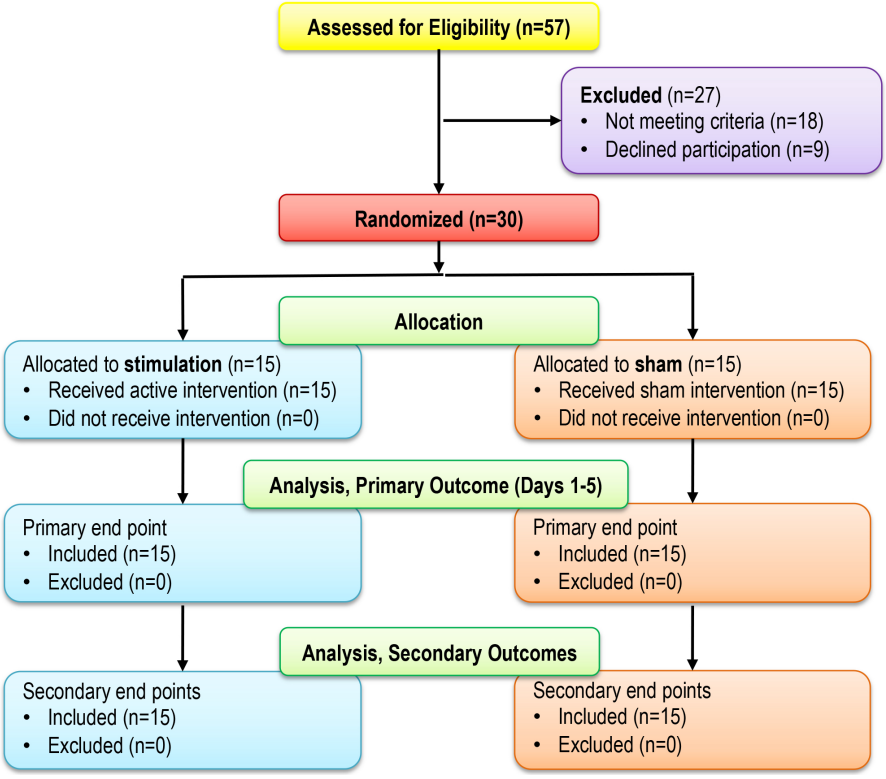

Figure 2 Consolidated Standards of Reporting Trials diagram.

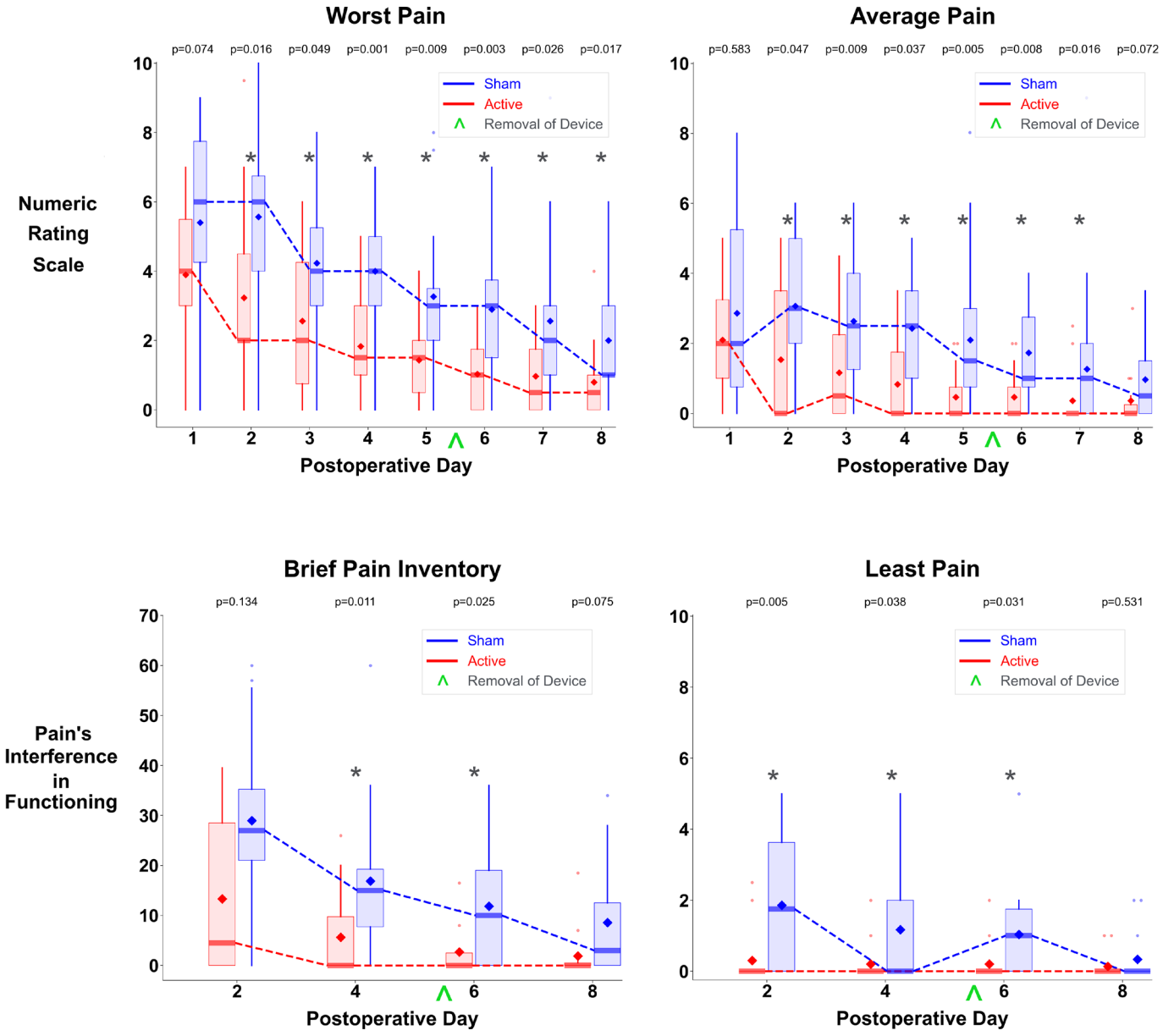

Figure 3 Effects of 5 days of percutaneous auricular nerve stimulation on daily worst, average, and least pain as well as the Brief Pain Inventory (interference domain) following cholecystectomy and hernia repair. Pain severity was measured using a Numeric Rating Scale with 0 equal to no pain and 10 being the worst imaginable pain. Regarding the Brief Pain Inventory, pain interference indicated using a Numeric Rating Scale of 0–70, with 0 and 70 equivalent to no and maximum interference, respectively. Data expressed as median (dark horizontal bars) with 25th–75th (box), 10th–90th (whiskers), mean (diamonds), and outliers (circles). Asterisks denote p<0.05.

Worthy of comment is that the 'average' daily pain scores recorded on day 1—from the time of discharge from the recovery room until the first data collection point—showed no statistically significant difference between the treatment groups (figure 3). This outcome is likely attributable to the administration of bupivacaine hydrochloride both infiltrated directly into the surgical site and as a peripheral nerve block in many participants. In the subsequent 24 hours, there was a statistically significant reduction in pain scores (figure 3). The study did not apply statistical correction for multiple comparisons due to the specific characteristics and limited power of this pilot investigation. Notably, this trend of improvement persisted over the 2 days following the removal of the auricular stimulator on the fifth postoperative day. This observation aligns with expectations set by previously published reports,[10] which prompted the continuation of data collection for an additional 3 days following device removal. A future definitive trial should extend the duration of data collection to capture possible analgesic improvements even greater than 3 days following stimulation cessation.

The reduced pain scores using auricular neuromodulation did not lead to decreased opioid use between the two treatment groups. This is most likely due to the relatively low consumption of opioids following cholecystectomy and hernia repair: the majority of participants receiving sham (67%) did not consume any opioids following recovery room discharge, so there was little room for improvement with auricular neuromodulation.[11] However, the low opioid consumption in the sham group did not reflect a lack of pain: nearly half the participants receiving placebo reported experiencing severe pain during the 8-day study period, vs only 7% in the active treatment group

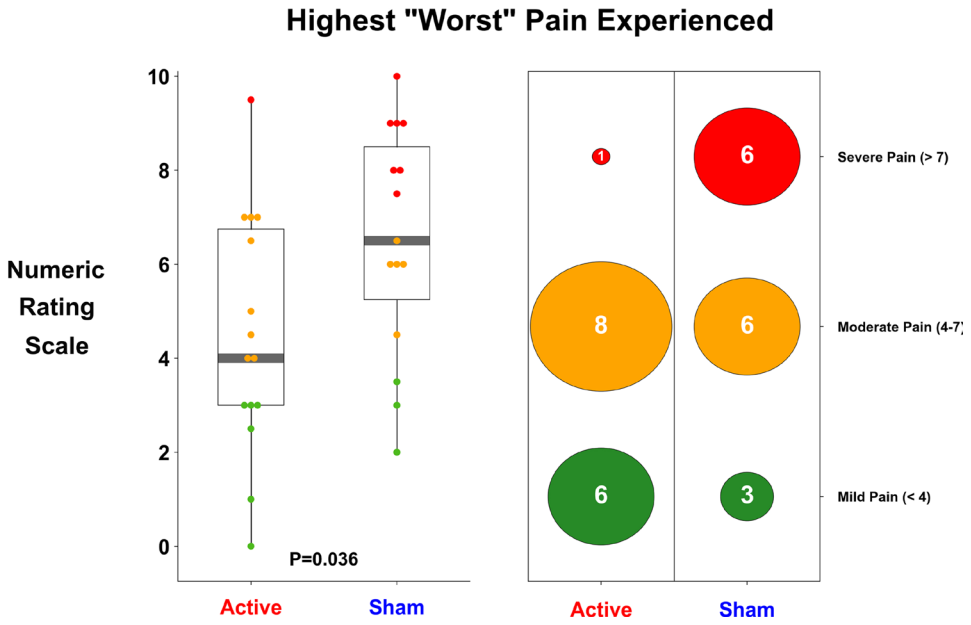

Figure 4 Effects of percutaneous auricular nerve stimulation on the highest 'worst' (maximum) pain level experienced following cholecystectomy and hernia repair. Pain severity was measured using a Numeric Rating Scale with 0 equivalent to no pain and 10 being the worst imaginable pain. Data expressed as median (dark horizontal bars) with 25th–75th (box), 10th–90th (whiskers), mean (diamonds), and outliers (circles).

(p=0.031, figure 4). Additionally, auricular neuromodulation decreased pain's interference with physical and emotional functioning evident both during and after active treatment as quantified with the Brief Pain Inventory (figure 3).

Percutaneous auricular nerve stimulation has been used previously to treat chronic and acute pain, with both success and failure (and in one case worsening pain).[8 12–14] Unfortunately, results from these studies are difficult to apply to the neuromodulation device used in the current study since each device exhibits substantial variability in key parameters such as amplitude, pulse duration, frequency, number of electrodes, duty cycle, and anatomic electrode location; and these factors determine the electric field characteristics. This built-in variability greatly constrains the extent to which results from a single clinical trial can be applied to other devices, possibly explaining the diverse outcomes seen across studies.[8 12–14] The pulse generator used in this study comes with a built-in 3-volt battery and is compatible with load impedances between 1 k and 10 k Ω, offering a peak output of 3.2 volts. It functions on a biphasic, symmetrical stimulation cycle at a 0.125 Hz frequency, punctuated by occasional non-stimulating periods of rest.

A major objective of the current pilot study was to prepare for a larger definitive clinical trial. Towards that end, there are three product modifications that may improve the magnitude of treatment response. The first is allowing patients to self-adjust the pulse generator parameters—such as amplitude, frequency, duty cycle, and pulse duration—which are all currently fixed. The importance of enabling patients to titrate the degree of stimulation to their constantly changing analgesic requirements and toleration of electrical current has been demonstrated for both vagal nerve stimulation[15] and ultrasound-guided percutaneous peripheral nerve stimulation.[16] Second, sleeping on the side with the applied device is reportedly uncomfortable—if not impossible—due to the rigid, angular device positioned behind the ear. This issue has not been reported for a different auricular neuromodulation device with a considerably slimmer and more rounded design.[13 14 17–20]

The most significant limitations of this pilot study include a small sample size and the absence of a pre-established plan for data analysis. However, the positive outcomes for not only the primary analgesic outcome measure but nearly every daily least, average, and worst pain score decrease the probability of a false positive (type 1 error). Nonetheless, these results certainly require confirmation with a larger, definitive clinical trial. Additionally, we could not confirm whether the electrodes remained properly inserted, or if the devices functioned continuously during the entire 5-day treatment phase, as the current version of the neuromodulation device lacks any indicator light or other signs to confirm active electrical operation. Adding a light-emitting diode would offer real-time operational administration verification.

In conclusion, this randomized controlled pilot study provides evidence that percutaneous auricular neuromodulation is feasible for ambulatory surgical procedures and may be an effective analgesic following discharge. Considering its few contraindications, ease of application, applicability to multiple surgical procedures, absence of systemic side effects or serious complications, low patient and healthcare provider burden, and lack of misuse, dependence, and diversion potential, further study with a larger, definitive trial appears warranted.

Acknowledgements The authors appreciate the donation of active and sham auricular neuromodulation devices from the manufacturer (Masimo, Irvine, California, USA).

Contributors BMI helped conceive the study, write the protocol, acquire the required study devices, implement the investigation, oversee data collection, interpret the results, and write the initial draft of the manuscript. WBA, BSA, JFS, ETS, and JJF contributed to protocol development, trial implementation, intervention management, participant care and safety oversight, data interpretation, and manuscript revision. RCB, BJS, JJD, and LMA contributed to protocol development, data interpretation, and manuscript revision. BA contributed to protocol implementation, data collection and management, and manuscript revision. BJC contributed to data management, manuscript preparation, and manuscript revision.

Funding Funding for this project was provided by the University California San Diego Department of Anesthesiology (San Diego, California, USA). The manufacturer

of the auricular neuromodulation devices (Masimo, Irvine, California, USA) donated the units to the university for use in this research.

Disclaimer Project conception, design, and implementation were exclusively by the authors. The first author retained complete control of the study protocol; data collection, analysis, and interpretation; and the resulting manuscript. Masimo was provided with preliminary results—but not the manuscript—and had no influence over data interpretation or reporting. The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the funding entities. None of the authors has a personal financial interest in this research.

Competing interests BMI, WBA, BA, JFS, ETS, BA, and JJF—the University of California San Diego has received funding and/or product from the following companies for other research studies of these authors: Epimed International (Dallas, Texas, USA), SPR Therapeutics (Cleveland, Ohio, USA), Infutronix (Natick, Massachusetts, USA), Avanos Medical (Irvine, California, USA), Masimo (Irvine, CA, USA), and Varian Medical Systems (Palo Alto, California, USA). Th remaining authors have no conflicts to disclose.

Patient consent for publication Not required.

Ethics approval The study was approved by the University of California San Diego Institutional Review Board (IRB Protocol #802775).

Provenance and peer review Not commissioned; externally peer reviewed.

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