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Original Article

A physiological assessment of patient pain during surgery with wide-awake local anesthesia

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ABSTRACT

Purpose: Patients receiving surgery with wide-awake local anesthesia typically report little or no intraoperative pain. However, self-report assessments of pain are susceptible to bias. In the present study, patient self-report ratings were supplemented with objective physiological measures of electrodermal activity.
Methods: Fifteen patients receiving forefoot surgery using wide-awake local anesthesia were recruited. Pain ratings and skin conductance responses were acquired during the initial anesthetic injection (into unanesthetized tissue), during a follow-up anesthetic injection (into anesthetized tissue), and during five intraoperative procedures.
Results: The highest ratings of self-reported pain coincided with the initial anesthetic injection, and pain ratings were similarly low at all remaining measurement points. Fourteen patients reported no pain beyond the initial injection, whereas one patient reported minimal pain during two intraoperative procedures. Skin conductance data were consistent with pain ratings such that responses to the initial injection were significantly larger than responses at any subsequent measurement point.
Conclusion: These results provide further evidence that patients experience little or no pain during surgery with wide-awake local anesthesia.

1. Introduction

Wide-awake local anesthesia is an alternative to traditional forms of anesthesia that is widely used in hand surgery[1–5] and has recently been adapted for foot and ankle surgery.[6,7] It is characterized by a preoperative injection of local anesthetic and epinephrine into the operative site. The local anesthetic provides anesthesia and pain control, whereas the epinephrine triggers vasoconstriction and reduces blood flow to the operative field.[8–12] Surgery with wide-awake local anesthesia is performed without general anesthesia or sedation, and so it avoids the risks and side effects that are associated with the use of those techniques. Furthermore, no tourniquet is needed for surgery due to the presence of the epinephrine, meaning that tourniquet pain and discomfort are not a concern. This form of anesthesia can be safely administered by the surgeon and requires no anesthesia staff or equipment for medication delivery or patient monitoring. Consequently, surgery tends to have a relatively low cost.[13–15]

The patient experience during surgery with wide-awake local anesthesia is an important issue. Patients receiving hand surgery or foot and ankle surgery with this anesthesia tend to report little or no intraoperative pain.[6,7,16–18] However, self-report measures of pain are susceptible to bias. For instance, patients may provide a positive assessment of their surgical experience to portray themselves in a positive light ("the good patient") or to avoid angering or disappointing their surgeon. Ideally, objective physiological measures of pain should be used to supplement and validate patients' self-report ratings.

Researchers have found that traditional vital measures such as blood pressure and respiration are poor indices of pain in both medical and non-medical settings.[19–25] Electrodermal activity is an alternate pain index that has shown greater promise in the literature.[21–27] Briefly, painful stimuli trigger a sympathetic response that manifests in increased sweating and skin hydration on the palm of the hand. This activity can be assessed by passing a small electrical current through the skin to measure skin conductance, with the results depicted graphically as a horizontal waveform.[21,28,29] Increases in the amplitude of the skin conductance waveform are indicative of greater skin hydration and a pain response.

Electrodermal activity provides an objective means for determining whether patients undergoing surgery with wide-awake local anesthesia are experiencing intraoperative pain. If the surgical experience is relatively pain-free, as past studies have indicated, then skin conductance

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responses and self-reported pain ratings should be lower during surgery than when patients are exposed to a known (and relatively mild) pain stimulus, such as the initial injection of the anesthetic solution.[30–32] The current study assessed this possibility in a sample of patients receiving forefoot surgery with wide-awake local anesthesia. Supplementary information on patients' anxiety levels and operative satisfaction was also collected to gain additional insight into the patient experience.

2. Methods

2.1. Patient selection

Ethics approval for this study was obtained from the relevant institutional review boards. A power analysis conducted using G*Power version 3.1.9.2 (Heinrich-Heine-Universität, Düsseldorf, Germany; 2014) indicated that 15 participants would be required to detect large effects with .80 power and an alpha level of .05. Large effects were expected based on the results of similar analyses from past research.[6,7] Consistent with the power analysis, 15 patients requiring a first metatarsophalangeal (MTP) joint fusion were recruited for the study (11 females, four males; *M* age = 63.73 years, *SD* = 7.85; 100% White/Caucasian). All patients were under the care of the same orthopedic surgeon (the second author). Informed consent was obtained from patients during a preoperative appointment with the surgeon. Individuals were excluded from the study if they were incapable of providing consent (e.g., patients with dementia); if they experienced peripheral neuropathy in the lower limbs; or if they were taking anticholinergic drugs, which tend to reduce levels of sweating.[33]

2.2. Apparatus

Self-reported pain was measured using an 11-point numerical rating scale, with ratings ranging from 0 (*no pain*) to 10 (*worst possible pain*). Self-reported anxiety was also measured using an 11-point numerical rating scale, with ratings ranging from 0 (*relaxed, not anxious*) to 10 (*very anxious*). Patient satisfaction was assessed using three categorical questions that covered (1) preferred anesthesia for future surgeries (*general anesthesia*, *local anesthesia plus sedation*, or *wide-awake local anesthesia*), (2) whether the patient would recommend wide-awake local anesthesia to someone who required surgery (*yes*, *no*, or *not sure*), and (3) how the surgery compared to preoperative expectations (*better than expected*, *similar to expected*, or *worse than expected*). These latter questions were adapted from past assessments of the patient experience with wide-awake local anesthesia.[6,7,18,34] Skin conductance was recorded with a DataPac_EDA™ constant voltage (0.5 V) system from Limestone Technologies (Odessa, ON, Canada) using disposable Ag/Ag–Cl wet gel electrodes. The DataPac_EDA™ is built to IEC-60601-01 medical specifications and meets the requirements for IEC-61000-4-2 electrostatic discharge protection.

2.3. Injection technique

The anesthetic injections were performed by the surgeon in a designated side room approximately 25 min prior to the planned start time of surgery. The anesthetic solution consisted of 15 mL of 1% lidocaine with 1:100,000 epinephrine, 5 mL of 0.25% bupivacaine, and 3 mL of sodium bicarbonate (8.4%), all of which was mixed in a 100 mL bag of saline. Lidocaine was used for its quick onset of action, whereas bupivacaine was used for its long duration of action.[35,36] The epinephrine was used to reduce blood flow in place of a tourniquet. The sodium bicarbonate was used as a buffer to counter the acidity of the local anesthetic.[37]

The anesthetic solution was drawn from the saline bag using 10 mL syringes. Afterward, the filling needle was replaced with a 30-gauge needle for the initial anesthetic injection. The needle was inserted perpendicular to the dorsal tissue of the first toe and 1–2 mLs of anesthetic were injected. Once the patient had good anesthetic effect around the injection site, additional anesthetic was injected into the surrounding area using a 25-gauge needle. To limit patient pain, subsequent injections stayed about 1 cm within the blanched tissue produced by the injected epinephrine. After the dorsal aspect of the foot was anesthetized, anesthetic was injected into the plantar aspect of the foot in the middle intermetatarsal space up to the level of the midshaft of the metatarsal. Among other injections, anesthetic was injected underneath the first metatarsal deep through the abductor hallucis fascia. Surrounding areas were also injected to ensure recurrent or abnormal branches of the plantar nerve, if present, were anesthetized. The entirety of the anesthetic solution (i.e., the full bag) was used over the series of injections. By the end of the injections, the operative area had a tumescent appearance and good anesthetic effect. Note that patients did not receive any other preoperative anesthetic or analgesic drugs.

2.4. Study procedure

Prior to the anesthetic injections, patients filled out a demographic questionnaire that included questions on gender, age, race or ethnicity, and pre-existing medical conditions. Once the questionnaire was complete, patients reclined supine on the hospital bed with their non-dominant hand visible. The palm of the non-dominant hand was cleaned with lukewarm water.[33] Wet-gel electrodermal electrodes were fixed to the thenar and hypothenar eminences of the palm a minimum of 10 min before the injections to allow sufficient moisturizing of the skin.

Measurements were recorded at seven time points. The first measurement point, in which a pain response was expected, occurred during the initial injection of the anesthetic solution. Subsequent measurement points, in which no pain response was expected, occurred (1) during a follow-up injection of the anesthetic solution (i.e., into anesthetized tissue); (2) during the initial surgical incision; (3) during joint preparation (e.g., rongeur); (4) during drilling into the bone; (5) during insertion of a compression screw; and (6) during closure of the operative site. At each measurement point, skin conductance responses and pain ratings were recorded, as were anxiety ratings. Once the surgery was complete and the patient had been taken to the recovery area, he or she was given a postoperative questionnaire that contained the three patient satisfaction questions.

2.5. Electrodermal scoring

All electrodermal data were stored in the DataPac_EDA™ program until statistical analysis was ready to begin. At each measurement point, skin conductance was assessed for the 4 s following stimulus onset.[33] Amplitude of the skin conductance response (in microsiemens, μS) was the primary outcome variable.

2.6. Statistical analysis

Data were entered into SPSS version 24.0 (IBM Corp., Armonk, NY, USA; 2016) for statistical analysis. Skin conductance responses, pain ratings, and anxiety ratings were each analyzed using a repeated measures analysis of variance (ANOVA). Greenhouse-Geisser corrections were applied to account for violations of sphericity. Significant results were followed up with Least Significant Difference (LSD) tests. Responses to each of the three patient satisfaction questions were analyzed with a chi-square goodness-of-fit test. The significance level was set at $p < .05$ for each analysis.

3. Results

Patients were at the hospital for approximately 3.25 h (*SD* = 0.62) on the day of the surgery. Surgery lasted an average of 35.27 min (*SD* = 8.38) from initial incision to closure, with the bulk of the remaining time attributed to waiting in the preoperative holding area, administration of the anesthetic solution, preoperative prepping and draping for the procedure, and postoperative bandaging of the wound.

Patients generally left the hospital 20–30 min after exiting the operating room.

There was a significant difference in patients' pain ratings over the various measurement points, $F(1.14, 15.96) = 31.24$, $p < .001$, $\eta_p^2 = 0.69$. Follow-up tests indicated that ratings were higher during the initial anesthetic injection than they were during a follow-up injection ($p < .001$), the initial surgical incision ($p < .001$), joint preparation ($p < .001$), drilling ($p < .001$), screw insertion ($p < .001$), and closure of the operative site ($p < .001$). All other pairwise comparisons were non-significant (all p values $> .05$). Note that pain during the initial anesthetic injection was generally mild. Fourteen patients reported no pain at any subsequent measurement point, whereas one patient reported minimal pain (a score of 1 out of 10) to two of the five intraoperative procedures. See Table 1 for means and standard deviations.

Skin conductance responses also differed over the various measurement points, $F(1.08, 15.16) = 20.80$, $p < .001$, $\eta_p^2 = 0.60$. Follow-up tests indicated that responses were larger during the initial anesthetic injection than they were during a follow-up injection ($p = .001$), the initial surgical incision ($p < .001$), joint preparation ($p < .001$), drilling ($p < .001$), screw insertion ($p < .001$), and closure of the operative site ($p < .001$). All other pairwise comparisons were non-significant (all p values $> .05$). Note that a typical skin conductance response to a non-painful stimulus generally ranges from 0.10 to 1.00 μS.[29] In the current study, the mean skin conductance response to the initial injection far surpassed this range, whereas the mean responses to the follow-up injection and the intraoperative stimuli were at the low end of this range, as one might expect given the self-reported pain ratings.

Anxiety ratings declined steadily over the assessment period, $F(2.06, 28.81) = 4.24$, $p = .024$, $\eta_p^2 = 0.23$. Follow-up tests indicated that ratings were lower during closure than they were during the initial anesthetic injection ($p = .014$), a follow-up anesthetic injection ($p = .032$), the initial surgical incision ($p = .046$), and joint preparation ($p = .038$). In addition, ratings were lower during screw insertion than they were during the initial anesthetic injection ($p = .029$). All other pairwise comparisons were non-significant (all p values $> .05$). Note that the mean anxiety rating for the initial measurement point was mild to moderate in intensity, whereas the mean rating by the final measurement point was minimal.

When asked about their preferred anesthesia for future surgeries, all patients indicated that they would prefer wide-awake local anesthesia, whereas no patients would prefer general anesthesia or local anesthesia plus sedation, $\chi^2 (2, N = 15) = 30.00, p < .001, w = 1.41$. Regarding their endorsement of wide-awake local anesthesia, all patients indicated that they would recommend this form of anesthesia, whereas no patients were against recommending the anesthesia or unsure about recommending the anesthesia, $\chi^2 (2, N = 15) = 30.00$, $p < .001$, $w = 1.41$. Regarding their expectations, most patients reported that the surgery was better than expected ($N = 9$) or similar to what they expected ($N = 6$), whereas no patients said that it was worse than expected, $\chi^2 (2, N = 15) = 8.40$, $p = .015$, $w = 0.75$.

4. Discussion

Past research on wide-awake local anesthesia relied on self-report measures to determine whether patients experienced intraoperative pain. In the present study, patient self-report ratings were supplemented with an objective physiological index: electrodermal activity. Ultimately, results confirmed pre-test expectations. Patients reported mild pain during the initial anesthetic injection and little or no pain during either a follow-up injection or exposure to various surgical stimuli. These ratings were substantiated by the skin conductance data, in which responses to the initial injection were significantly larger than responses at any subsequent measurement point. As mentioned in the Results section, responses to the initial injection were quite large, whereas responses to the subsequent stimuli were minimal. One might wonder why these latter responses were not even lower (i.e., non-existent) given that patients were anesthetized at the time of measurement. Patients often noted that they could feel pressure or movement in the operative area, and attending to these sensations likely caused slight orienting responses.[29] However, these responses were small and easily distinguishable from the larger response to the painful injection. The correspondence between self-report and electrodermal results suggests that self-report measures of pain were not affected by a reporting bias.

Consistent with past research in this area, patient anxiety was generally low and declined steadily over the duration of the perioperative period.[6,7,18,34] In addition, patients reported high levels of satisfaction with their respective surgeries, as indicated by their future anesthesia preferences and their endorsement of surgery with wide-awake local anesthesia. In terms of their expectations, a similar number of patients indicated that the surgery was either better than expected or similar to their expectations. The latter category was inflated by two patients who previously had surgery using this method and were knowledgeable about the surgical experience. Notably, no patients reported that surgery was worse than their preoperative expectations. These findings mirror results from past studies in which patients indicated high satisfaction with their surgical experience.[6,7,17,18,34]

The results of this study are limited by the fact that testing was confined to patients receiving one specific (albeit common) procedure: first MTP fusions. It is possible that individuals receiving other procedures would have experienced higher levels of intraoperative pain or anxiety than those tested in this study. However, it should be noted that the current findings are consistent with past research incorporating a much wider range of procedures.[6,7,16–18,34,38] Another limitation with this study is the fact that there was no control or comparison group. Intraoperative comparisons with patients receiving general anesthesia or sedation would be problematic for obvious reasons. However, patients receiving wide-awake local anesthesia could be compared to those receiving local anesthesia with a tourniquet (and no sedation) to see how the intraoperative experience of these patients differs. Some studies from the hand surgery literature indicate that patients have a more positive intraoperative experience with wide-awake local anesthesia,[12,39,40] and this outcome would likely translate to a foot and ankle setting.

The relatively benign nature of surgery with wide-awake local anesthesia has now been demonstrated across a variety of operative procedures and using a number of different methods and techniques. As a result, future studies should shift the research emphasis away from issues of intraoperative pain and toward other aspects of the patient experience. Anecdotally, some patients receiving surgery with wide-awake local anesthesia report intraoperative sensations (e.g., pressure or movement) that are not adequately captured by rating scales of pain. A qualitative study might provide a more nuanced view of the patient

Table 1
Skin conductance responses, pain ratings, and anxiety ratings.

	Initial Injection *M* (*SD*)	Follow-up Inject. *M* (*SD*)	Initial Incision *M* (*SD*)	Joint Prep. *M* (*SD*)	Drilling (Bone) *M* (*SD*)	Screw Insertion *M* (*SD*)	Closure *M* (*SD*)
Skin Conductance Responses	2.23 (1.76)	0.18 (0.18)	0.17 (0.27)	0.08 (0.09)	0.09 (0.13)	0.09 (0.09)	0.07 (0.15)
Pain Ratings	1.77 (1.15)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.07 (0.26)	0.07 (0.26)	0.00 (0.00)
Anxiety Ratings	3.37 (3.57)	2.83 (3.29)	2.83 (3.62)	2.40 (3.19)	2.13 (2.99)	1.90 (2.69)	1.43 (1.73)

Note: Skin conductance responses (SCRs) are presented in microsiemens (μS). Pain and anxiety ratings range from 0 to 10.

experience. Moreover, future studies should assess the care team to determine how these surgeries compare to more conventional surgeries from their perspective. The presence of a conscious and conversant patient results in a unique experience for the care team, although potential advantages and disadvantages have not been studied empirically.

Author contribution

The first author contributed to study design, data collection, data analysis, and manuscript writing and revision. The second author contributed to study design and manuscript writing and revision.

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Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jor.2019.11.046.

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