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A prospective comparison of wide-awake local anesthesia and general anesthesia for forefoot surgery

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ABSTRACT

Background: A recent case series suggested that surgery with wide-awake local anesthesia is tolerated well by most foot and ankle patients. However, patients were assessed retrospectively and there was no comparison group to show the relative efficacy of this approach. The present study was conducted to address these concerns.
Methods: Perioperative pain and anxiety were assessed in 40 patients receiving forefoot surgery using either wide-awake local anesthesia or general anesthesia. Ratings were collected on the day of surgery using 11-point (0–10) numerical rating scales.
Results: Patients in the two anesthesia groups reported no differences in preoperative pain ($p = 0.500$) or anxiety ($p = 0.820$). Patients who received wide-awake local anesthesia reported lower levels of postoperative pain ($p < 0.001$) and anxiety ($p < 0.001$) than patients who received general anesthesia. They also reported little pain ($M = 0.17$, $SD = 0.32$) or anxiety ($M = 1.33$, $SD = 1.74$) during the operation.
Conclusions: Results indicate that surgery with wide-awake local anesthesia is tolerated well by most patients, and that it may have some benefit compared to surgery with general anesthesia.
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1. Introduction

Orthopaedic foot and ankle surgery is typically performed while the patient is under general or regional anesthesia. These anesthetic techniques have inherent risks and costs associated with them [1], and alternate approaches should be considered if they have the potential to improve on these methods. Developed for use in hand surgery [2–7], wide-awake local anesthesia is one such alternative that has been used successfully in a foot and ankle setting [8]. Wide-awake local anesthesia is characterized by a surgeon-administered mixture of local anesthetic (e.g., lidocaine) for pain control and epinephrine for hemostasis and improved anesthetic effect. No tourniquet, sedation, or general anesthesia are used for the surgery, and the patient remains fully awake for the duration of the procedure.

The benefits of this approach are evident [9–13]. Wide-awake local anesthesia has few risks for the patient and can be used in situations where other types of anesthesia, particularly general anesthesia, are contraindicated. Moreover, patients rarely require preoperative testing, and anesthesia can be delivered without the need of anesthesia staff or equipment. Consequently, wide-awake local anesthesia has the potential to increase patient access to foot and ankle care while providing this care at a much reduced cost.

The patient experience during these surgeries is an important consideration. A recent retrospective survey of foot and ankle patients indicated that surgery with wide-awake local anesthesia is tolerated well by most individuals [8]. Patients in this study reported low levels of anxiety that declined steadily over the perioperative period. Intraoperative pain was negligible, with a mean rating of 0.75 on a 0–10 numerical rating scale. Most patients indicated that they would choose wide-awake local anesthesia for a future procedure (87%), that they would recommend this type of surgery to a friend (88%), and that the surgery was better than expected (83%).

While the results from this study were favorable, they are subject to certain limitations. To begin with, the retrospective patient reports were collected an average of 6.5 months after surgery. Given the length of this delay, patients' recall of their perioperative pain and anxiety may have been inaccurate. An additional limitation was the absence of a proper comparison group. Though patients receiving wide-awake local anesthesia reported a positive perioperative experience, it is unclear how this experience compares to that of patients receiving surgery

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with a more conventional form of anesthesia, such as general anesthesia.

The current study was conducted to address these limitations. Patients undergoing forefoot surgery using wide-awake local anesthesia were assessed on the day of their procedure, and their results were compared to those of similar patients undergoing surgery with general anesthesia. Based on previous research, it was expected that patients receiving wide-awake local anesthesia would report decreases in anxiety and pain over the perioperative period, and that their intraoperative ratings would be relatively low. Comparisons between the two anesthesia groups were novel. Although no differences in their preoperative anxiety or pain were expected, the size and direction of postoperative differences (if any) were uncertain.

2. Methods

Ethics approval for this study was obtained from the local research ethics board. Forty patients (31 females, 9 males; *M* age = 59.48 years, *SD* = 11.92) receiving forefoot surgery from the senior investigator (author DJM) consented to participate in the study. Twenty of these patients were scheduled to receive surgery with wide-awake local anesthesia, whereas the remaining 20 were scheduled to receive surgery with general anesthesia. The frequency of specific procedures was similar between the two groups (see Appendix A in Supplementary material for a complete list of the performed procedures). Patients under the age of 19 or those with severe comorbidities (e.g., diabetes, peripheral neuropathy) were excluded from participation.

On the day of surgery, one group of patients received general anesthesia using standard techniques. The second group of patients received wide-awake local anesthesia in the following manner. The surgeon determined the size of the anticipated operative field and then mixed local anesthetic with epinephrine and sodium bicarbonate according to guidelines from MacNeill and Mayich [8]. Consistent with safe anesthetic practices, all local anesthetic dosages were below 7 mg/kg (3.5 mg/lb) and a total dose of 300 mg was never exceeded. Patients were injected in a designated side room prior to surgery. The surgeon used a filling needle with 10 cc and 20 cc syringes to draw mixed local anesthetic from the saline bag, and the filling needle was replaced with a 30 gauge needle for the initial injection. This initial injection proceeded slowly using technical pearls from Strazar et al. [14]. After the initial anesthetic had been insufflated within a reasonable area, the 30 gauge needle was exchanged for a 25 gauge needle for the remainder of the injection. Additional injections using different approaches were often required to ensure that the entire operative field was anesthetized. To minimize patient pain during these follow-up injections, the needle was only introduced to previously anesthetized tissue, which was easily identified by the pale appearance of the adrenalized skin. Patients were taken to the operating room directly after the anesthetic injections.

At the conclusion of the procedure, patients in both anesthesia groups received a dose of local anesthetic to assist with postoperative pain control. Each dose consisted of 20 mL of 0.25% bupivacaine mixed with 10 mL of sterile injectable saline, which was insufflated throughout the surgical field. When necessary, patients with vascular conditions who were given wide-awake local anesthesia also received phentolamine rescue following the completion of the procedure to counteract the effects of the epinephrine. This technique involved an injection of 1 mg of phentolamine diluted in 5 mL of sterile injectable saline in each area where reversal was required.

Ratings of anxiety and pain were acquired from patients throughout the perioperative period using 11-point (0–10) numerical rating scales. Low scores indicated low levels of anxiety or pain, whereas high scores indicated high levels of anxiety or pain. Preoperative ratings were collected from both anesthesia groups prior to delivery of the anesthesia. Intraoperative ratings were collected from patients who received wide-awake local anesthesia every 15 min from the initial incision, and these ratings were subsequently averaged to create single intraoperative measures of anxiety and pain. Ratings of pain were also collected from these patients during the initial anesthesia injection. Postoperative ratings of anxiety and pain were collected from both anesthesia groups, although at slightly different time points. Patients who received wide-awake local anesthesia were assessed prior to leaving the hospital, approximately 15 min after the surgery. Patients who received general anesthesia were assessed when they regained consciousness, approximately 30 min after the surgery.

Patients were contacted six weeks after the surgery for a follow-up assessment. They provided a final rating of pain using the same numerical rating scale described above. They were also administered a patient questionnaire that was adapted from past research on the patient experience with wide-awake local anesthesia [8,15,16]. This questionnaire asked patients to report the approximate duration of their hospital visit and whether they experienced feelings of postoperative nausea and vomiting (PONV). It also evaluated patient satisfaction using two categorical questions. The first question asked patients to report their preferred anesthesia for future surgeries (general anesthesia, local anesthesia plus sedation, or wide-awake local anesthesia). The second question asked patients how the surgery compared to their preoperative expectations (better than expected, similar to expected, or worse than expected).

Data were entered into SPSS version 24.0 (IBM Corp., Armonk, N.Y., USA) for statistical analysis. Perioperative changes in anxiety and pain among patients who received wide-awake local anesthesia were assessed using repeated measures ANOVAs. Significant results were followed up with dependent *t*-tests. Injection pain and intraoperative pain were also compared using a dependent *t*-test. Group differences in pre- and postoperative ratings of anxiety and pain were analyzed using mixed ANOVAs, with anesthesia group as the between-subjects factor and time point as the within-subjects factor. Significant results were followed-up with dependent and independent *t*-tests. Group comparisons of six-week pain and hospital visit duration were also carried out using independent *t*-tests. All categorical data were analyzed using chi-square goodness-of-fit tests or chi-square independence tests, as necessary. The significance level was set at $p < 0.05$ for each analysis. Note that observed power for all of the significant main analyses was high (0.89–1.00).[1]

3. Results

Patients who received wide-awake local anesthesia reported a significant change in anxiety over the perioperative period, $F(2, 38) = 17.49$, $p < 0.001$, $\eta_p^2 = 0.48$. Anxiety decreased from the preoperative to the intraoperative period, $t(19) = 3.73$, $p = 0.001$, $d = 0.76$, and there was a further decrease from the intraoperative to the postoperative period, $t(19) = 3.33$, $p = 0.004$, $d = 1.00$. See Table 1 for means and standard deviations. These patients also reported a significant change in pain over the perioperative period, $F(2, 38) = 6.71$, $p = 0.003$, $\eta_p^2 = 0.26$. Pain decreased from the preoperative to the intraoperative period, $t(19) = 3.36$, $p = 0.003$, $d = 1.04$, but intraoperative and postoperative pain did not differ,

[1] One patient did not indicate a preferred anesthesia for future surgeries, and the same patient did not report time spent at the hospital on the day of surgery. The sample size was $N = 39$ for each of these analyses.

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Table 1
Patient anxiety and pain ratings (0–10 scale).

	Anxiety		Pain	
	General anesthesia *M* (*SD*)	Wide-awake local anesthesia *M* (*SD*)	General anesthesia *M* (*SD*)	Wide-awake local anesthesia *M* (*SD*)
Preoperative	2.98 (3.21)	3.20 (3.02)	1.25 (1.71)	1.65 (1.99)
Intraoperative	NA	1.33 (1.74)	NA	0.17 (0.32)
Postoperative	2.75 (3.08)	0.08 (0.34)	5.38 (3.13)	0.45 (1.10)

$t(19) = 1.06$, $p = 0.303$, $d = 0.35$. Also note that patients' intraoperative pain was significantly less than the mild pain reported during their initial anesthesia injections ($M = 1.52$, $SD = 2.10$), $t(19) = 3.04$, $p = 0.007$, $d = 0.90$.

There was a significant interaction between anesthesia group and time point in terms of anxiety ratings, $F(1, 38) = 42.05$, $p = 0.008$, $\eta_p^2 = 0.17$. Patients who received wide-awake local anesthesia reported a decrease in anxiety from the preoperative to the postoperative period, $t(19) = 4.63$, $p < 0.001$, $d = 1.46$. Patients who received general anesthesia reported no changes in anxiety over the same timeframe, $t(19) = 0.28$, $p = 0.779$, $d = 0.07$. While the two anesthesia groups did not differ in terms of their preoperative anxiety, $t(38) = 0.23$, $p = 0.820$, $d = 0.07$, wide-awake patients reported lower levels of postoperative anxiety than general anesthesia patients, $t(38) = 3.87$, $p < 0.001$, $d = 1.22$.

There was a similar interaction between anesthesia group and time point in terms of pain ratings, $F(1, 38) = 37.86$, $p < 0.001$, $\eta_p^2 = 0.50$. Patients who received wide-awake local anesthesia reported a decrease in pain from the preoperative to the postoperative period, $t(19) = 2.23$, $p = 0.038$, $d = 0.75$. Patients who received general anesthesia reported an increase in pain over the same timeframe, $t(19) = 6.08$, $p < 0.001$, $d = 1.63$. While the two anesthesia groups did not differ in terms of their preoperative pain, $t(38) = 0.68$, $p = 0.500$, $d = 0.22$, wide-awake patients reported lower levels of postoperative pain than general anesthesia patients, $t(38) = 6.63$, $p < 0.001$, $d = 2.10$.

Patients who received wide-awake local anesthesia reported a lower incidence of PONV than patients who received general anesthesia (5% versus 40%), χ^2 (1, $N = 40$) = 4.33, $p = 0.037$, $\varphi = 0.33$. In addition, they spent less time at the hospital on the day of the surgery than general anesthesia patients ($M = 3.60$ h, $SD = 1.23$ versus $M = 5.26$ h, $SD = 1.52$), $t(37) = 3.76$, $p = 0.001$, $d = 1.20$. By the sixth week after surgery, there were no significant differences in pain between patients who received wide-awake local anesthesia ($M = 0.80$, $SD = 1.62$) and those who received general anesthesia ($M = 1.22$, $SD = 2.60$), $t(38) = 0.62$, $p = 0.538$, $d = 0.20$.

The two anesthesia groups reported differences in terms of their future anesthesia preferences, χ^2 (2, $N = 39$) = 19.12, $p < 0.001$, $V = 0.70$. Most patients who received wide-awake local anesthesia (85%) would prefer the same anesthesia for a future procedure instead of general anesthesia (10%) or local anesthesia plus sedation (5%). Most patients who received general anesthesia (74%) would prefer the same anesthesia for a future procedure instead of wide-awake local anesthesia (16%) or local anesthesia plus sedation (11%). The anesthesia groups also tended to show variations in terms of how their surgeries compared to preoperative expectations, although these differences failed to reach significance, χ^2 (2, $N = 40$) = 2.83, $p = 0.243$, $V = 0.27$. A majority of wide-awake patients (70%) said that surgery was better than expected, versus similar to expected (15%) or worse than expected (15%). By comparison, a minority of general anesthesia patients (45%) said that surgery was better than expected, versus similar to expected (35%) or worse than expected (20%).

4. Discussion

Consistent with a past retrospective study [8], patients who received wide-awake local anesthesia reported little intraoperative pain or anxiety and high levels of satisfaction with their operative experience. They also reported a significantly better postoperative experience than patients who received general anesthesia. The lower levels of anxiety among these patients can likely be attributed to a number of factors, such as their low incidence of PONV and their negligible postoperative pain. The group differences in postoperative pain are more difficult to account for, although these results might be explained, at least in part, by sensitization processes. Trauma incurred during surgery can modify the nervous system, causing a heightened state of neural reactivity and an increased sensitivity to pain [17–20]. A preoperative dose of local anesthetic prevents this sensitization by blocking the transmission of pain signals during surgery. By comparison, general anesthesia renders the patient unconscious but does not block the synaptic transmission that leads to sensitization. Therefore, patients who receive general anesthesia tend to experience heightened postoperative pain and an increased requirement for analgesics following their surgeries [17]. It is likely that these anesthetic differences influenced postoperative pain outcomes in the current study.

It should be noted that this study was a cohort study that compared two nonrandomized treatment groups. A common criticism of cohort studies is that they are susceptible to a self-selection bias, whereby patient characteristics that influence their group selection may have a similar impact on the study's outcomes. Most patients in this study ($N = 35$) did not express an anesthesia preference and were assigned to their anesthesia group based on their availability and the availability of a surgery date. Moreover, removing the five patients with a specific anesthesia preference from the analysis had no influence on the study's results. Thus, the likelihood of a self-selection bias in the present study is minimal. Regardless, patients were not randomly assigned to their treatment groups and so confounding influences cannot be ruled out. If nothing else, these results suggest that a randomized control trial can be safely and feasibly conducted within this patient population for more definitive conclusions.

Future studies may wish to compare wide-awake local anesthesia to a more conventional peripheral block using local anesthesia. While these two approaches are similar in some respects, peripheral blocks are often used in conjunction with a painful or uncomfortable tourniquet, and patients may require some form of sedation to deal with this discomfort. Therefore, differences in the patient experience are likely. In addition, future studies on wide-awake local anesthesia should consider the experiences of the surgeon and the operating room staff. During these operations, the surgical team needs to be aware of the patient and mindful of his or her wellbeing, something that requires a certain amount of interaction with the patient. This interaction can be useful for providing the patient with additional insight into the procedure and the recovery process. However, it might also add to the stress and difficulty of the case, particularly if the procedure is

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complex and demands the undivided attention of the surgical team. A future study should assess levels of stress in the surgeon and the operating room staff to gain a better understanding of how these surgeries compare to more conventional surgeries from the perspective of the care team.

5. Conclusion

The results of this study indicate that surgery with wide-awake local anesthesia is tolerated well by most patients, and that it likely has some benefit compared to surgery with general anesthesia. However, we should note that it may not be ideal for all patients. Standard doses of local anesthetic appear to be less effective for chronic opioid users [21], and so these patients should be treated using more a more conventional anesthetic technique. In addition, those with uncommonly high levels of anxiety may wish to undergo surgery using sedation or general anesthesia so that their awareness of the procedure is limited. Doctors can screen for these patients using a common clinical tool, such as the Generalized Anxiety Disorder Scale [22]. A surgeon who is not comfortable performing surgeries on conscious patients may exacerbate the situation by triggering anxiety in his or her patient. Therefore, surgeons should adhere to their desired working environment, and those who choose to perform wide-awake surgeries should receive appropriate guidance or training. Provided these issues are adequately managed, we suggest that this approach presents a viable alternative to conventional anesthetic techniques for many common procedures.

Declaration of conflicting interests

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.fas.2017.10.015.

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