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Replacing the Basal Infusion with Automated Boluses and a Delayed Start Timer for "Continuous" Sciatic Nerve Blocks

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Introduction

Ambulatory continuous popliteal-sciatic nerve blocks provide analgesia at home following foot and ankle surgery. (1) Until recently, there were two primary local anesthetic delivery modalities: a continuous basal infusion and patient-controlled bolus doses. However, some ambulatory infusion devices are now capable of delivering bolus doses automatically at a programmed interval. (2) Most comparisons of continuous infusion to automated boluses have failed to demonstrate significant benefit of one technique over another. (3) Although, continuous infusions of local anesthetic often result in exhaustion of the reservoir prior to resolution of the surgical pain, and automated boluses may decrease the rate of consumption of local anesthetic. (2,4) Thus, if automated boluses allow for a decrease in hourly anesthetic consumption while providing at least non-inferior analgesia, this dosing strategy could prolong anesthetic administration and analgesia.

Some new ambulatory infusion pumps feature an integrated start-delay timer, which delays local anesthetic administration for a programmed number of hours to conserve of the local anesthetic reservoir. (5) Start-delay timers have not been studied for continuous peripheral nerve blocks, but this technology may also help match the duration of a single injection nerve block combined with local anesthetic infusion to the length of time patients experience pain following orthopedic surgery. (5) The present study sought to improve and prolong analgesia following outpatient foot and ankle orthopedic surgery by 1) delaying initiation using an integrated pump timer and 2) delivering a lower hourly volume of local anesthetic as automated boluses.

Materials and Methods

This study adhered to Good Clinical Practice standards and ethical guidelines defined by the Declaration of Helsinki. Study protocol approval and oversight were conducted by the UC San Diego Institutional Review Board (IRB #200247; San Diego, California). Written consent was obtained from all participants. The trial was prospectively registered at clinicaltrials.gov (NCT 04458467, date of registration: July 7, 2020). Enrollment was offered to adults undergoing unilateral ambulatory foot and/or ankle surgery with a planned popliteal-sciatic catheter. Exclusion criteria were: 1) neuropathy of the ipsilateral sciatic nerve; 2) current daily opioid use; 3) morbid obesity; 4) surgery outside of ipsilateral sciatic and saphenous nerve distributions; 5) pregnancy; and 6) incarceration.

Prior to surgery, a linear array ultrasound transducer was used to visualize the sciatic nerve proximal to the bifurcation in short-axis, and a 17-guage Tuohy needle (FlexTip Plus; Teleflex Medical, Research Triangle Park, NC) was inserted. A 19-gauge flexible, single-orifice perineural catheter was inserted under ultrasound guidance 2-3 cm beyond the needle tip. Ropivacaine 0.5% with 5-10 µg/mL epinephrine (20 mL) was injected in divided doses through the catheter under ultrasound visualization. The catheter was then secured with clear, occlusive dressings.

Participants were randomized using a computer-generated list in opaque, sealed security envelopes to one of two treatments groups (1:1 ratio) in blocks of 4: 1) automated bolus (8 mL bolus every 120 minutes with 4 mL patient-controlled bolus, 30-minute lockout) with a 5-hour delayed start or 2) continuous infusion (6 mL/h basal infusion, 4 mL patient-controlled bolus, 30-minute lockout) with an immediate start. Following completion of the surgical procedure, an electronic infusion pump (Nimbus™ II PainPRO, InfuTronix, Natick, MA) with a 500 mL reservoir of 0.2% ropivacaine was attached to the perineural catheter. The pump was programed based on randomization group by a provider not involved in data collection or analysis.

Participants were discharged with a prescription for oxycodone (5 mg tablets) for supplementary analgesia and contacted daily for 6 days following surgery to collect study outcome measures. These were: 1) worst, average, least, and current surgical pain measured using the Numeric Rating Scale; 2) daily opioid consumption 3) number of sleep disturbances due to pain 4) degree of sensory block measured on a 0-10 scale, and 5) satisfaction with postoperative analgesia also measured on a 0-10 scale.

Results/Case Report

Seventy-one participants were enrolled over 8 months and all but one participant had a successful sciatic nerve block. The remaining seventy participants were randomized, equally divided between the treatment groups, and all randomized participants were included in analyses. All demographic factors were balanced between the groups except for body mass index (BMI), with a higher BMI in the continuous infusion group (Absolute Standardized Difference 0.693). Thus, the analysis was adjusted for BMI and it was found that larger BMI was associated with shorter infusion duration (-1.13 hours per BMI, 95% CI -1.96 to -0.299, p=0.008).

The day following surgery, participants with automated boluses had a median [IQR] pain score of 0.0 [0.0 to 3.0] vs. 3.0 [1.75 to 4.75] for the continuous infusion group: unadjusted 95% CI: -2.00 to <-0.001, P=0.007 (Figure 1a). Local anesthetic reservoir exhaustion in patients with automated boluses occurred after a median [IQR] of 119 h [109, 125] vs. 74 h [57, 80] for the continuous infusion group: 95% CI: 42 to 53, P<0.001 (Figures 1b and 1c).

Daily average and worst pain scores were lower for the bolus versus basal groups at nearly all time points through postoperative day 5 (Figure 2). Automated boluses reduced the median cumulative opioid consumption by 83%, (p<0.001, Figure 2) and cumulative sleep disturbances by 75%, (p<0.001, Figure 2). Participants receiving automated boluses experienced more numbness at all time points, although local anesthetic leakage did not differ between treatments and satisfaction with analgesia differed only on postoperative days 1 and 4 (Figure 2).

No falls, catheter-related infections, nerve injuries, or other complications were observed in either group.

Discussion

Compared with a continuous basal infusion initiated prior to discharge, perineural local anesthetic administered with automated bolus doses at a lower volume/dose and a 5-hour delay following discharge resulted in 1) superior analgesia during the period that both modalities were functioning; and 2) a longer duration of anesthetic administration. Significant benefits were identified for pain scores, opioid consumption, and sleep quality for nearly all of the first five postoperative days—while both techniques were administering local anesthetic as well as following the reservoir exhaustion of the basal infusion participants.

References

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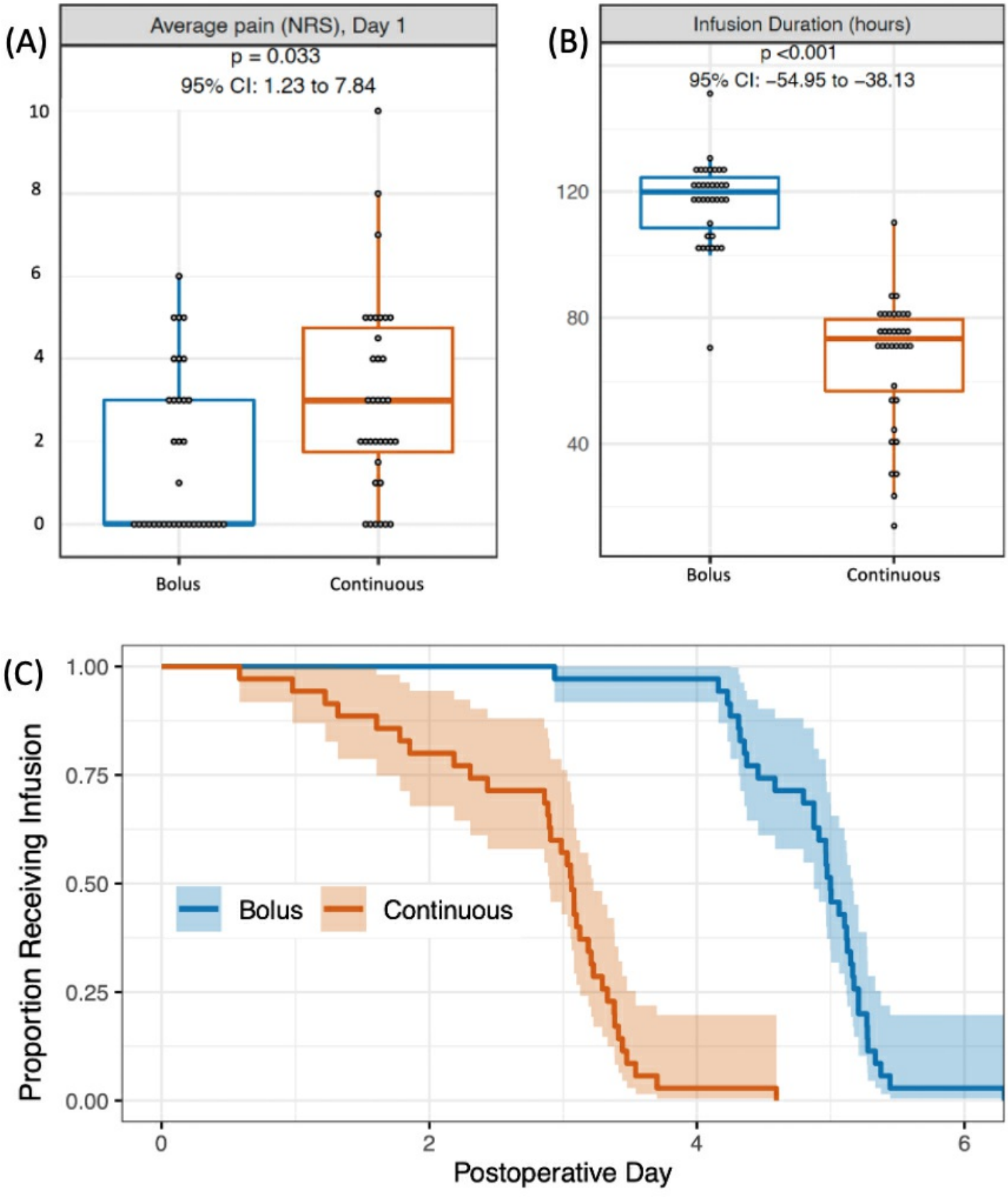
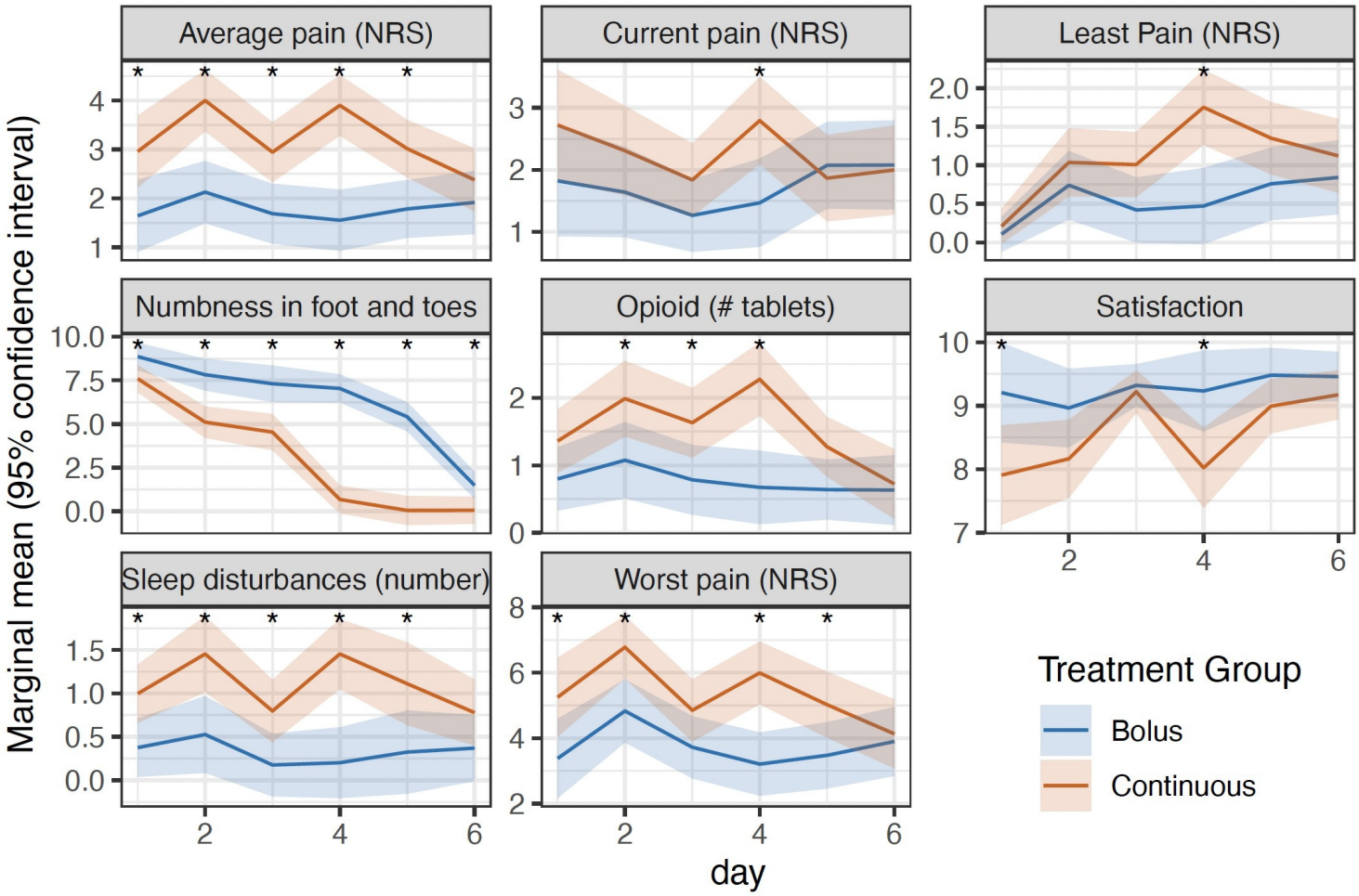
Disclosures

Yes

Tables / Images


(A)
Average pain (NRS), Day 1
p = 0.033
95% CI: 1.23 to 7.84
10
8
6
4
2
0
Bolus
Continuous
(B)
Infusion Duration (hours)
p <0.001
95% CI: −54.95 to −38.13
120
80
40
Bolus
Continuous
(C)
Proportion Receiving Infusion
1.00
0.75
0.50
0.25
0.00
Bolus
Continuous
0
2
4
6
Postoperative Day


Average pain (NRS)
Current pain (NRS)
Least Pain (NRS)
Numbness in foot and toes
Opioid (# tablets)
Satisfaction
Sleep disturbances (number)
Worst pain (NRS)
Marginal mean (95% confidence interval)
day
Treatment Group
Bolus
Continuous