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Authors

Khatibi, Bahareh

Said, Engy T

Sztain, Jacklynn F

et al.

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Continuous Transversus Abdominis Plane Nerve Blocks: Does Varying Local Anesthetic Delivery Method—Automatic Repeated Bolus Versus Continuous Basal Infusion—Influence the Extent of Sensation to Cold?: A Randomized, Triple-Masked, Crossover Study in Volunteers

Bahareh Khatibi, MD,* Engy T. Said, MD,* Jacklynn F. Sztain, MD,* Amanda M. Monahan, MD,* Rodney A. Gabriel, MD,* Timothy J. Furnish, MD,* Johnathan T. Tran, BS,† Michael C. Donohue, PhD,‡ and Brian M. Ilfeld, MD, MS*§

BACKGROUND: It remains unknown whether continuous or scheduled intermittent bolus local anesthetic administration is preferable for transversus abdominis plane (TAP) catheters. We therefore tested the hypothesis that when using TAP catheters, providing local anesthetic in repeated bolus doses increases the cephalad-caudad cutaneous effects compared with a basal-only infusion.

METHODS: Bilateral TAP catheters (posterior approach) were inserted in 24 healthy volunteers followed by ropivacaine 2 mg/mL administration for a total of 6 hours. The right side was randomly assigned to either a basal infusion (8 mL/h) or bolus doses (24 mL administered every 3 hours for a total of 2 bolus doses) in a double-masked manner. The left side received the alternate treatment. The primary end point was the extent of sensory deficit as measured by cool roller along the axillary line at hour 6 (6 hours after the local anesthetic administration was initiated). Secondary end points included the extent of sensory deficit as measured by cool roller and Von Frey filaments along the axillary line and along a transverse line at the level of the anterior superior iliac spine at hours 0 to 6.

RESULTS: Although there were statistically significant differences between treatments within the earlier part of the administration period, by hour 6 the difference in extent of sensory deficit to cold failed to reach statistical significance along the axillary line (mean = 0.9 cm; SD = 6.8; 95% confidence interval –2.0 to 3.8; $P = .515$) and transverse line (mean = 2.5 cm; SD = 10.1; 95% confidence interval –1.8 to 6.8; $P = .244$). Although the difference between treatments was statistically significant at various early time points for the horizontal, vertical, and estimated area measurements of both cold and mechanical pressure sensory deficits, no comparison remained statistically significant by hour 6.

CONCLUSIONS: No evidence was found in this study involving healthy volunteers to support the hypothesis that changing the local anesthetic administration technique (continuous basal versus hourly bolus) when using ropivacaine 0.2% and TAP catheters at 8 mL/h and 24 mL every 3 hours significantly influences the cutaneous effects after 6 hours of administration. Additional research is required to determine whether changing variables (eg, local anesthetic concentration, basal infusion rate, bolus dose volume, and/or interval) would provide different results. (Anesth Analg 2017;124:1298–303)

Single-injection transversus abdominis plane (TAP) blocks provide effective postoperative analgesia for a variety of surgeries involving the abdominal wall.[1] To extend the duration of analgesia beyond the 8 to 12 hours provided with a bolus of ropivacaine or bupivacaine,[2] investigators have reported perineural catheter insertion to allow for subsequent local anesthetic administration.[3–10] Indeed, retrospective studies suggest there may be benefits

*Department of Anesthesiology, University of California, San Diego, La Jolla, California; †School of Medicine, University of California San Diego, La Jolla, California; ‡Department of Neurology, Keck School of Medicine, University of Southern California, Los Angeles, California; and §Outcomes Research Consortium.

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Address correspondence to Brian M. Ilfeld, MD, MS, Department of Anesthesiology, University of California, San Diego, 200 West Arbor Dr, MC 8770, San Diego, CA 92103. Address e-mail to bilfeld@ucsd.edu.

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to using this technique.[11,12] Unfortunately, the only randomized, placebo-controlled study involving surgical subjects revealed no differences in pain scores between a basal infusion of ropivacaine 0.2% (10 mL/h, no bolus) and normal saline, although it was underpowered.[13]

In contrast, the only other published randomized trial involving TAP catheters and surgical subjects suggested effective analgesia delivery given that no differences were detected between the TAP treatment group and controls with a potent epidural infusion.[14] One major difference between this study and the negative randomized, placebo-controlled trial was that it involved repeated, large-volume bolus doses administered every 8 hours instead of a continuous basal infusion. Although it remains unknown if the varying administration techniques were at least partially responsible for the apparent differing results of these 2 studies, there are at least theoretical reasons to believe that repeated bolus doses may be a superior strategy for TAP catheters. TAP blocks target multiple nerves that are somewhat distant from each other, yet lie within the same fascial plane.[15] Therefore, a large bolus of local anesthetic theoretically spreads further from the injection point relative to a smaller volume, consequently affecting a higher number of nerves and increasing the area of analgesia/anesthesia.[16]

The superiority of repeated bolus doses over a continuous basal infusion has been demonstrated in some studies for various catheter locations,[17–20] yet not others.[21–23] As with other aspects of continuous peripheral nerve blocks, effects often vary depending upon the anatomy of the catheter location.[24] The relationship between administration strategy and ensuing effects remains unexamined for TAP catheters.[25] There is real potential for analgesic benefits if intermittent bolus doses improved spread for TAP catheters compared with a basal infusion, as suggested by one trial involving healthy volunteers that found only a 1.5-dermatome distribution after 24 hours of a basal ropivacaine 0.2% infusion (5 mL/h).[26]

The investigators therefore executed this randomized, triple-masked, controlled trial to determine whether delivering local anesthetic as a repeated bolus dose results in improved local anesthetic spread/effects compared with a continuous basal infusion for TAP catheters. The primary hypothesis was that for TAP catheters, providing local anesthetic in repeated bolus doses increases the extent of sensory deficit compared with a continuous basal infusion involving an identical local anesthetic dose/mass. The primary end point was the distance of sensory deficit to cold along the midaxillary line at hour 6 (6 hours after initiation of local anesthetic administration).

METHODS

Enrollment

This study followed good clinical practice and was conducted within the ethical guidelines outlined in the Declaration of Helsinki. The trial was prospectively registered at clinicaltrials.gov (NCT02662023). The University of California, San Diego, Institutional Review Board (San Diego, CA) approved all study procedures and provided oversight of the data and safety issues for the duration of the trial. Written, informed consent was obtained from all participating subjects.

Healthy adult male and female volunteers (18 years and older, weighing more than 45 kg) were recruited using an established University of California, San Diego, Investigational Review Board–approved volunteer database. Exclusion criteria encompassed any known neuromuscular deficit of the abdominal wall, a body mass index greater than 40 kg/m^2, regular opioid use within the previous 2 months, allergy to study medications, known renal insufficiency (creatinine > 1.5 mg/dL), pregnancy, or incarceration. The study was conducted at the University of California, San Diego, Clinical and Translational Research Institute (San Diego, CA).

Catheter Insertion

Following written, informed consent, bilateral TAP catheters (FlexBlock, Teleflex Medical, Reading, PA) were inserted using a standardized ultrasound-guided posterior approach technique described previously.[13] Subjects were placed in a lateral decubitus position with the side to be blocked up. A rolled blanket was placed under the dependent side to extend the space between the nondependent iliac crest and costal margin. Standard American Society of Anesthesiologists monitors and oxygen by nasal cannula at 3 L/min were applied. When sedation was given, intravenous midazolam (1 mg) and/or fentanyl (50 μg) were administered for patient comfort. The skin surrounding the insertion site was prepared with chlorhexidine gluconate/isopropyl alcohol solution and a fenestrated sterile drape applied.

The TAP was visualized with a 13 to 6 MHz 38-mm linear array transducer (M-Turbo, SonoSite, Bothell, WA) in a sterile sheath that was placed at the midaxillary line in a transverse orientation. The external oblique, internal oblique, and transversus abdominis muscles were identified with ultrasound. After the skin was anesthetized with 1% lidocaine, a 17-gauge Tuohy needle was introduced posterior to the transducer and advanced in-plane in an anterior direction. The final needle tip position was in the plane between the internal oblique and transversus abdominis muscles. Normal saline was injected under direct visualization to confirm proper positioning of the needle tip and the volume of normal saline was recorded. A flexible 19-gauge, single-orifice catheter (FlexBlock, Teleflex Medical, Research Triangle Park, NC) was advanced 3 cm beyond the needle tip. The needle was withdrawn over the catheter.

To check the perineural catheter placement accuracy, 5 mL of normal saline was administered via the catheter under ultrasound guidance to confirm an increase in fluid volume within the TAP (the plane between the transversus abdominis muscle and internal oblique muscle). The skin entry site was covered with a sterile clear occlusive dressing with care taken to not cover the skin along any areas that would be subsequently tested. The catheter was secured with an anchoring device and additional sterile occlusive dressings. If the amount of normal saline administered on one side was less than the other, additional normal saline was administered via the catheter to ensure equivalent volumes of saline on both sides.

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Treatment Group Assignment

The Investigational Drug Service created a computer-generated randomization table in blocks of 4, with a 1:1 ratio, stratified by sex. Each subject's right catheter was randomly assigned to 1 of 2 possible local anesthetic (ropivacaine 0.2%) administration techniques: a basal infusion (8 mL/h) or bolus doses (24 mL administered every 3 hours for a total of 2 bolus doses). The left catheter received the other possible treatment. This split-body study design enabled subjects to act as their own controls. Although the basal rate and bolus volume differed for each treatment group, the total dose/mass of local anesthetic was the same for each (24 mg every 3 hours, Table 1).

Investigational Drug Service personnel prepared all ropivacaine reservoirs and infusion pumps. The electronic infusion pumps (Nimbus Ambulatory Pump, InfuTronix, Natick, MA) are capable of providing automated bolus doses as well as a continuous basal infusion. An infusion pump with ropivacaine 0.2% was attached to each of the perineural catheters. For each subject, the tubing from the pumps to the subjects was gently wound at least 5 rotations and covered with opaque tape, masking treatment allocation to investigators and subjects. Following catheter connection to the subject, both infusion pumps were activated and local anesthetic administration was initiated at hour 0. For the infusion pump administering bolus doses, the 24-mL bolus dose was administered at hours 0 and 3. After 6 hours of administration, medical personnel removed the perineural catheters.

Outcome Measures

Outcome measurements were evaluated with the patient in the supine position with the head of the bed elevated at 45° on the right side first, followed by the left side at each hour for a total of 7 time points: hour 0 (before local anesthetic administration), hour 1, hour 2, hour 3 (immediately before the scheduled hour 3 local anesthetic bolus), hour 4, hour 5, and hour 6.

The sensory deficit was measured using 2 methods: cool roller (cold deficit)[2] and 5.46 Von Frey filaments (mechanical pressure deficit).[27] The sensory deficit was measured along 2 separate anatomical lines at each time point: the midaxillary "vertical" line (measuring cephalad-caudad effects) and a transverse "horizontal" line (measuring anterior-posterior effects) passing through the anterior superior iliac spine. A post hoc analysis was also performed multiplying the vertical and horizontal distances for each side of each subject to produce an estimated area of both cold and pressure sensory deficits.

The primary end point was determined before enrollment and defined as the distance of sensory deficit to cold measured in centimeters along the vertical midaxillary line at hour 6 (after 6 hours of continuous infusion and 3 hours after the final of 2 bolus doses). This measurement approximated the number of dermatomes (and thus the number of nerves traversing the transversus abdominis plane) that were affected by each treatment modality: a continuous basal infusion versus repeated bolus doses.

Statistical Analysis

The basal-bolus difference at each time point was assessed with paired *t* tests (ie, 1-sample *t* tests of basal-bolus differences for each subject). The primary hypothesis pertains to the 6-hour time point with significance level 5%. Analyses of all other time points are considered as post hoc and we applied no adjustment for multiplicity. Significant findings in secondary outcomes should be viewed as suggestive, requiring confirmation in a future trial before considering them as definitive.[28]

Sample Size Calculations

Sample size calculations were based on the primary aim of detecting differences in sensory effects between the 2 treatment techniques at hour 6. With n = 20 subjects, we had 95% power at the 5% significance level to detect the superiority of the administration of local anesthetic as repeated bolus doses as compared with a continuous basal infusion at hour 6. Using an expected SD of 7 cm for the primary end point,[2] and given a 2-sided type I error protection of 5%, n = 20 subjects provide 95% power to detect a mean difference between treatment techniques of 6 cm.[16] This was a split-body crossover design in which each subject had one of each treatment on opposite sides of the body. We chose 6 cm as a detectable treatment difference because a 3-cm distance is approximately equivalent to the width of 1 dermatome,[29] and we considered a 2-dermatome difference clinically significant. To allow for larger-than-anticipated SDs, smaller-than-anticipated difference between treatment means, dropout subjects, or failed catheters, we chose to enroll a total of 24 subjects.

RESULTS

Twenty-four subjects were enrolled, and all had bilateral TAP catheters placed per protocol (Table 1). For each subject, the right-sided TAP catheter was randomly assigned to receive hourly boluses (n = 12) or a continuous infusion (n = 12) and the left-sided TAP catheter received the alternate treatment.

For the primary end point after 6 hours of treatment, mean difference in sensory deficit to cold (bolus minus basal) was 0.9 cm (SD = 6.8; 95% confidence interval [CI] –2.0 to 3.8; $P = .515$). Although the difference between treatments was statistically significant at various early time points for the horizontal, vertical, and estimated area measurements of both cold and mechanical pressure sensory deficits, no comparison remained statistically significant by hour 6 (Figures 1–3).

DISCUSSION

This randomized, double-masked, crossover, split-body volunteer trial provided no evidence that administering

Table 1. Local Anesthetic Administration for Each Treatment Group: Ropivacaine 0.2%

Treatment	Basal Rate (mL/h)	Basal Dose (mg/h)	Bolus Volume (mL/3 h)	Bolus Dose (mg)	Total Dose (mg/3 h)
Basal infusion	8	16	0	0	48
Bolus doses	0	0	24	48	48

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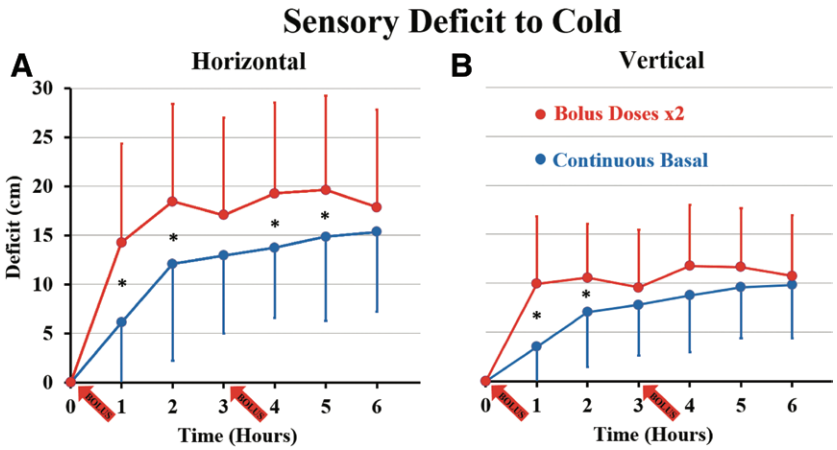

Figure 1. Effects of local anesthetic administered via transversus abdominis plane catheters on cutaneous deficits to cold as measured with a cool roller. A, Mean (standard error) sensory deficit measured along the vertical midaxillary line from ropivacaine 0.2% delivered as either a 6-h continuous basal infusion (8 mL/h) or 2 boluses (24 mL each) delivered automatically at hours 0 and 3. Time points for which $P < .05$ denoted with an asterisk (*). B, Mean (standard error) sensory deficit measured along the horizontal transverse line passing through the anterior superior iliac spine from ropivacaine 0.2% delivered as either a 6-h continuous basal infusion (8 mL/h) or 2 boluses (24 mL each) delivered automatically at hours 0 and 3. Time points for which $P < .05$ denoted with an asterisk (*).

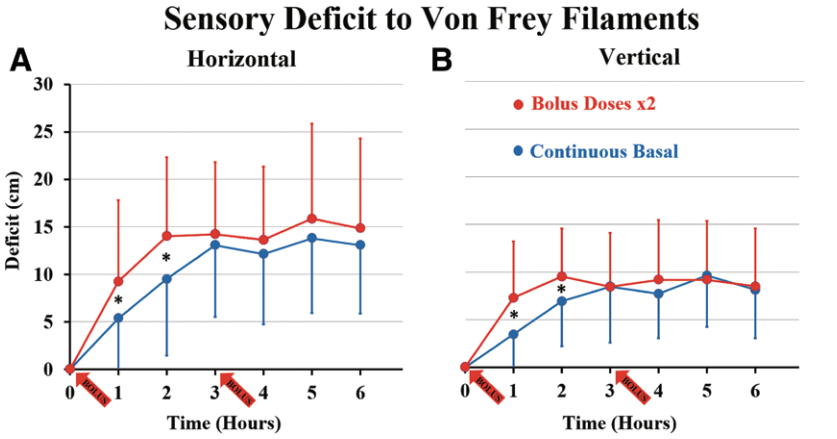

Figure 2. Effects of local anesthetic administered via transversus abdominis plane catheters on cutaneous deficits to mechanical pressure as measured with Von Frey filaments. A, Mean (standard error) sensory deficit measured along the vertical midaxillary line from ropivacaine 0.2% delivered as either a 6-h continuous basal infusion (8 mL/h) or 2 boluses (24 mL each) delivered automatically at hours 0 and 3. Time points for which $P < .05$ denoted with an asterisk (*). B, Mean (standard error) sensory deficit measured along the horizontal transverse line passing through the anterior superior iliac spine from ropivacaine 0.2% delivered as either a 6-h continuous basal infusion (8 mL/h) or 2 boluses (24 mL each) delivered automatically at hours 0 and 3. Time points for which $P < .05$ denoted with an asterisk (*).

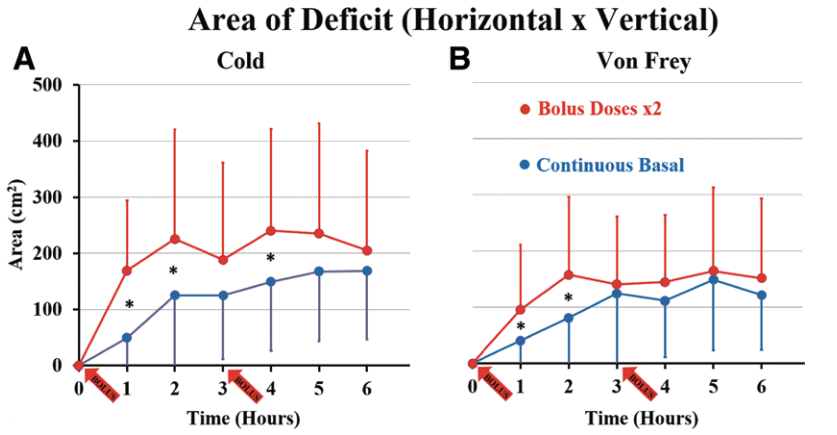

Figure 3. Effects of local anesthetic administered via transversus abdominis plane catheters on cutaneous sensory deficit estimated by multiplying the horizontal and vertical measurements for each side of each subject. A, Mean (standard error) cutaneous deficits to cold as measured with a cool roller. Time points for which $P < .05$ denoted with an asterisk (*). B, Mean (standard error) cutaneous mechanical pressure deficits as measured with Von Frey filaments. Time points for which $P < .05$ denoted with an asterisk (*).

Table 2. Subject Characteristics

	Male (n = 14)	Female (n = 10)	Combined (n = 24)
Age (y)	32 (10)	39 (14)	35 (12)
Height (cm)	176 (5)	166 (9)	172 (9)
Weight (kg)	86 (22)	65 (7)	77 (20)
Body mass index (kg/m^2)	28 (9)	24 (2)	26 (7)

Values are reported as mean (SD).

ropivacaine 0.2% as repeated bolus doses increases the cephalad-caudad cutaneous effects compared with a basal-only infusion following 6 hours of administration via TAP catheters. This result is disappointing given that for local anesthetic administered through a needle, a large bolus injected into the TAP will result in spread to a greater number of cutaneous nerves compared with a smaller volume of injectate.[16] Why the current study had a negative result remains unknown, although we will speculate on various possibilities.

First, it may be that medication dose/mass is the primary determinant of administration effects, as has been reported for interscalene,[30] femoral,[31] posterior lumbar plexus (psoas compartment),[31] and popliteal perineural catheters.[32] This would explain why a previous study reported a larger cephalad-caudad cutaneous effect with the use of a 0.6

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mL/kg bolus of levobupivacaine 0.125% compared with a bolus of half this volume—it was not the higher volume but rather the higher dose responsible for the differing results.[16] Although the current investigation did compare repeated large (24 mL) bolus volumes with a steady basal infusion of 8 mL/h, the mass of ropivacaine administered was equivalent at hours 3 and 6. Supporting this theory are 3 negative studies comparing a basal infusion and repeated bolus doses of equivalent local anesthetic mass for interscalene,[22] femoral,[21] and adductor canal[23] catheters.

Second, the basal rate, bolus volume, interval duration, local anesthetic concentration, and catheter insertion site specified for the current study may be inadequate to detect a difference between treatment modalities (basal versus bolus).[33] Supporting this theory is that a positive study demonstrating a benefit of intermittent boluses versus a basal infusion for ultrasound-guided perineural catheters involved the adductor canal location: ropivacaine 0.5% delivered as 15-mL boluses every 6 hours or a 2.5 mL/h basal.[19] However, considering there is evidence that adductor canal infusions require a relatively high basal rate to provide adequate analgesia,[34,35] this study might reflect an inadequate basal infusion rate rather than a clinically relevant benefit of repeated bolus doses. An additional positive study involving ultrasound-guided femoral catheters was nominally positive (intermittent bolus over continuous basal)[20]; yet, while the differences between treatments reached statistical significance for some variables—without any correction for multiple comparisons—they failed to reach clinical significance.[36,37]

Third, local anesthetic within the TAP at the level of catheter insertion used in the present study may be anatomically limited.[33] The theory that has been proposed—along with supporting data—is that there is a maximum degree of cephalad spread with a traditional TAP block.[33] If accurate, the bolus volume and basal rate of the current study may have reached this maximum cephalad level. This would not invalidate the results of the study, but rather suggest that alternative bolus and basal settings might produce different results (or, that the intermittent technique is not beneficial for TAP catheters).

Study Limitations

The most significant limitation is the lack of surgical pain in the healthy volunteer subjects of this study. The main goal of postoperative perineural local anesthetic infusion is to provide postsurgical analgesia, and since the subjects of this study were healthy pain-free volunteers, we used cutaneous cold and pressure deficits as surrogate outcome measures. Whether cutaneous sensation correlates well with postoperative pain following various abdominal procedures remains unknown, making extrapolation to clinical practice more difficult.

In addition, because there is no published information on the minimally important clinical effect size for TAP infusions, we had to extrapolate from similar literature.[16] We chose 6 cm as the minimum clinically meaningful treatment difference because a 3-cm distance is approximately equivalent to the width of 1 dermatome,[29] and we considered a 2-dermatome difference clinically significant. Our study does not rule out the possibility of smaller treatment differences (ie, within our 95% CI –2.0 to 3.8 cm for the primary end point) which some practitioners might consider to be clinically meaningful.

Finally, the period of local anesthetic administration and cutaneous testing was limited to 6 hours. The initial 24-mL bolus doses did result in a statistically significant difference from the basal-only group for the first 2 hours; but, by the end of the third hour, when the 2 treatments had administered an equivalent dose of local anesthetic, no differences remained (Figures 1–3). This pattern recurred to a far lesser degree for the subsequent 3-hour period of administration, so that by the time point of the primary outcome measure—6 hours—there were no remaining statistically significant differences between treatments. Most importantly, the overall trajectory of the 2 treatments suggests minimal increases past 6 hours, especially for the intermittent bolus group that appeared to have reached a steady state after just 2 hours. Therefore, we believe that additional local anesthetic administration would not have altered the results of this study.

In summary, this study involving healthy volunteers found no evidence to support the hypothesis that bolus doses of ropivacaine given within the TAP increased the distance of sensory deficit as measured by cool roller along the midaxillary line at hour 6 compared with a continuous infusion. Further research is warranted investigating larger volumes of local anesthetic bolus doses in a postsurgical patient population.

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Name: Bahareh Khatibi, MD.
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Name: Jacklynn F. Sztain, MD.
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Name: Brian M. Ilfeld, MD, MS (Clinical Investigation).
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