

# Ultrasound-Guided Single-Injection Infraclavicular Block Versus Ultrasound-Guided Double-Injection Axillary Block: A Noninferiority Randomized Controlled Trial

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**BACKGROUND:** Single-injection ultrasound-guided infraclavicular block is a simple, reliable, and effective technique. A simplified double-injection ultrasound-guided axillary block technique with a high success rate recently has been described. It has the advantage of being performed in a superficial and compressible location, with a potentially improved safety profile. However, its effectiveness in comparison with single-injection infraclavicular block has not been established. We hypothesized that the double-injection ultrasound-guided axillary block would show rates of complete sensory block at 30 minutes noninferior to the single-injection ultrasound-guided infraclavicular block.

**METHODS:** After approval by our research ethics committee and written informed consent, adults undergoing distal upper arm surgery were randomized to either group I, ultrasound-guided single-injection infraclavicular block, or group A, ultrasound-guided double-injection axillary block. In group I, 30 mL of 1.5% mepivacaine was injected posterior to the axillary artery. In group A, 25 mL of 1.5% mepivacaine was injected posteromedial to the axillary artery, after which 5 mL was injected around the musculocutaneous nerve. Primary outcome was the rate of complete sensory block at 30 minutes. Secondary outcomes were the onset of sensory and motor blocks, surgical success rates, performance times, and incidence of complications. All outcomes were assessed by a blinded investigator. The noninferiority of the double-injection ultrasound-guided axillary block was considered if the limits of the 90% confidence intervals (CIs) were within a 10% margin of the rate of complete sensory block of the infraclavicular block.

**RESULTS:** At 30 minutes, the rate of complete sensory block was 79% in group A (90% CI, 71%–85%) compared with 91% in group I (90% CI, 85%–95%); the upper limit of CI of group A is thus included in the established noninferiority margin of 10%. The rate of complete sensory block was lower in group A (proportion difference of 12% [95% CI, 2–22];  $P = 0.0091$ ), as was surgical success rate (82% [95% CI, 74%–89%] vs 93% [95% CI, 86%–97%]; proportion difference of 11% [95% CI 1–20];  $P = 0.0153$ ). Sensory block onset also was slower in group A (log rank test  $P = 0.0020$ ). Performance times were faster in group I (231 seconds [95% CI, 213–250]) than in group A (358 seconds [95% CI, 332–387];  $P < 0.0001$ ). No statistically significant difference was observed for vascular puncture, paresthesia during block performance, or procedure-related pain. No neurologic complication was noted at follow-up.

**CONCLUSIONS:** We failed to demonstrate that the rate of complete sensory block of the double-injection axillary block is noninferior to the single-injection infraclavicular block. However, the rate of complete sensory block at 30 minutes is statistically significantly lower with the axillary block. The ultrasound-guided single-injection infraclavicular block thus seems to be the preferred technique over the axillary for upper arm anesthesia. (Anesth Analg 2015;XXX:00–00)

When considering a peripheral block, clinicians are looking for a reliable, safe, and easy-to-perform technique.<sup>1</sup> Although a brachial plexus block for

distal upper arm surgeries can be performed with different techniques, there is no clear consensus regarding which has the best reliability/safety profile. Recent studies have shown a better success rate with the ultrasound-guided infraclavicular approach compared with the supraclavicular one but comparable with the ultrasound-guided axillary block.<sup>2–4</sup>

However, because of the need for multiple injections with the axillary block, a longer procedural time, and greater number of needle passes, many clinicians favor the single-injection ultrasound-guided infraclavicular block over the multiple injection ultrasound-guided axillary block because of its reliability and ease of performance.<sup>5–7</sup> However, the ultrasound-guided infraclavicular block is technically challenging in the obese patient and is performed in a noncompressible location.

The widespread development of ultrasound guidance has improved axillary block success rates,<sup>8–10</sup> patient comfort,<sup>11</sup> and ease of execution.<sup>10–13</sup> Indeed, the double-injection

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ultrasound-guided axillary block technique, with a perivascular injection posterior to the axillary artery and an injection around the musculocutaneous nerve, has a comparable success rate with the multiple perivascular injection technique with faster procedural time and fewer needle passes.<sup>14,15</sup> Because it is performed in a superficial location, it also enables better needle visualization and may improve the safety profile in case of vascular puncture. However, the efficacy of this newer and simplified double-injection axillary block in comparison with single-injection infraclavicular block has not been established clearly. When one considers its safety profile, the double-injection axillary block could indeed become the block of choice for the upper limb surgery if shown to be noninferior to the single-injection infraclavicular block.

The objective of this study was to compare the rate of complete sensory block 30 minutes after ultrasound-guided single-injection infraclavicular block with a double-injection ultrasound-guided axillary block. We hypothesized that the double-injection ultrasound-guided axillary block would show rates of complete sensory block at 30 minutes noninferior to the single-injection ultrasound-guided infraclavicular block.

## METHODS

### Population

This prospective, randomized, single-blinded study was first approved by our institutional Research Ethics Committee (PEJ-666) and was conducted in 2 academic hospitals of the CHU de Québec (Hôpital de l'Enfant-Jésus and Hôpital du Saint-Sacrement). Written informed consent was obtained from each participant. This study was registered to ClinicalTrials.gov (NCT01761175). Patients aged 18 years or older with ASA physical status I to III, who previously agreed to a regional anesthesia technique for their surgery at or distal to the elbow, were considered for eligibility. Patients with a body mass index >40 kg/m<sup>2</sup>, weight <45 kg, who were allergic to any medication used in the study protocol, who had contraindications to regional anesthesia, who had previous neurologic deficit in the operated arm, who had severe renal or hepatic failure, were pregnant, or were breast-feeding were excluded.

### Intervention

An IV line and standard monitoring were installed on all patients. Premedication was administered up to 2 mg midazolam if deemed necessary. The randomization sequence in either group A (axillary block) or group I (infraclavicular block) was generated by a third party not involved in the study by the use of a computer-generated random sequence ([www.randomizer.org](http://www.randomizer.org)), then sealed in prenumbered opaque envelopes. All blocks were performed by a certified anesthesiologist or a senior resident in their regional anesthesia rotation under direct supervision by one of the investigators with specific expertise in regional anesthesia. All blocks were performed using a L10-5 linear probe (Model z.one SmartCart, ZONARE, Mountain View, CA).

### Ultrasound-Guided Infraclavicular Block

Patients were in a supine position with their arm adducted. The ultrasound probe was positioned under the clavicle,

medial to the coracoid process, in a parasagittal plane. After a local anesthetic skin wheal, with the use of an in-plane technique, a 20-gauge 8.89-cm Tuohy needle was advanced to the posterior side of the axillary artery (6-o'clock position) until a fascial click was perceived, then 30 mL of 1.5% mepivacaine was injected, with the goal of a crescent-shaped distribution around the artery.<sup>5</sup>

### Ultrasound-Guided Axillary Block

Patients were in a supine position with their arm abducted to 90°. The ultrasound probe was placed to obtain a transverse image of the axillary artery at the level of the conjoint tendon of the latissimus dorsi and teres major muscles. After a local anesthetic skin wheal, with an in-plane technique, a 20-gauge 8.89-cm Tuohy needle was advanced to the posterior side of the axillary artery, where 25 mL of 1.5% mepivacaine was injected to obtain a posteromedial spread of the solution around the artery, then 5 mL of the same solution was injected around the musculocutaneous nerve. If the musculocutaneous nerve was not distinctly visualized, all the 30 mL was injected posteromedial to the artery.

### Block Assessment

One investigator blinded to the technique evaluated the block every 5 minutes after completion and up to 30 minutes. Sensations in the ulnar (palmar surface of the fifth finger), median (palmar surface of the second finger), radial (dorsum of the hand between the thumb and the index finger), musculocutaneous (lateral aspect of the forearm), medial cutaneous nerve of the forearm (medial aspect of the forearm), and medial cutaneous nerve of the arm (medial aspect of the arm) dermatomes were evaluated with ice and scaled from 0 to 2: 0 = normal sensation to cold, 1 = reduced sensation to cold compared with the opposite arm, and 2 = no sensation to cold. A complete sensory block was defined as a score of 2 in the ulnar, median, radial, and musculocutaneous nerve territories. Medial cutaneous nerves of the arm and forearm were evaluated but not considered for our primary outcome. Motor block was evaluated by contraction against resistance for the ulnar (finger abduction), median (second and third fingers flexion), radial (fingers extension), and musculocutaneous (elbow flexion) nerves. Motor block was quantified as 0 = normal strength, 1 = paresis, and 2 = paralysis. A complete motor block was defined as a score of 2 in all 4 nerves territories.

In the operating room, sedation could be administered (midazolam 0–5 mg or sufentanil 0–10 µg) for anxiety or for pain outside the operating field. No other medication was allowed for sedation. Surgical block success was defined by a nerve block that allowed surgery without a rescue block, an infiltration of local anesthetics, administration of analgesics for pain in the surgical field, or general anesthesia.

### Data Collection

Preoperatively, the following data were collected: age, sex, weight, height, ASA physical status, and medical, surgical, and anesthesia history. During bloc performance, imaging time (the time elapsed from the moment the probe is in contact with the patient to the insertion of the Tuohy needle), needling time (from the insertion of the needle to its complete removal),

and performance time (sum of imaging and needling time) were collected. The amount of midazolam received, any aspiration of blood or paresthesia, and procedure-related pain on a visual analog pain scale were recorded. During surgery, the type and length of surgery, tourniquet use and its duration, administration of sedatives or analgesia, infiltration of local anesthetics, or general anesthesia were collected. Any potential complication related to the regional anesthesia technique (i.e., local anesthetic toxicity, pneumothorax, local anesthetic allergy, hematoma at the puncture site, neurologic injury, infection, or abscess at the puncture site) was sought.

### Follow-Up

Patients were contacted at 24 hours and 1 month after their surgery by an investigator blinded to the technique. Standardized questions were asked about patient's satisfaction and potential complications (Table 1, Supplemental Digital Content 1, <http://links.lww.com/AA/B254>).

### Sample Size Calculation

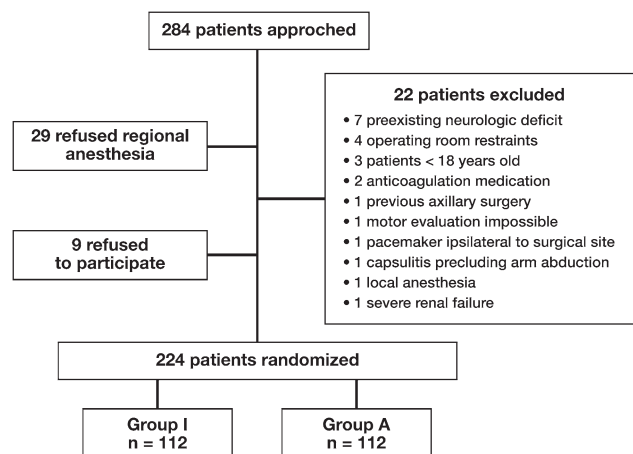
Considering a rate of complete sensory block of 90% for the infraclavicular and the axillary blocks,<sup>5–14</sup> and a noninferiority margin of 10%, a sample size of 224 patients was needed to evaluate the noninferiority of the axillary block in comparison with the infraclavicular block at 30 minutes, with a power of 80% and an  $\alpha$ -error of 5% (1-sided hypothesis). The margin of noninferiority was determined by consensus by a panel of clinical experts in regional anesthesia from our institution. A 10% difference in sensory block rate was considered a clinically significant difference.

### Statistical Analysis

Statistical analyses were conducted according to the intention-to-treat principle. For the primary outcome, the noninferiority of the double-injection ultrasound-guided axillary block was considered if the limits of the 90% confidence intervals (CIs) were within a 10% margin of the rate of complete sensory block of the infraclavicular block.<sup>16</sup> Sensitivity analyses on the primary outcome measures were performed a posteriori to evaluate the robustness of the findings. Secondary outcomes were expressed as 95% CIs based on a 2-sided hypothesis. Newcombe-Wilson score CIs with continuity correction were used for single proportion and difference of proportions.<sup>17</sup> Proportions were analyzed with the  $\chi^2$  or Fisher exact tests, and continuous variables were analyzed with the Wilcoxon test. Imaging, needling, and performance times were log-transformed, and CIs were generated by the Cox method<sup>18</sup> and were analyzed with the Student *t* test. The installation of the block over time was analyzed with the log rank test on KaplanMeier survival curves. Analyses were performed with the Statistical Analysis System (version 9.4, SAS Institute, Cary, NC).

### RESULTS

Among the 284 patients screened between September 2012 through February 2013, 224 patients were assigned randomly to either group I (112 patients) or group A (112 patients; Fig. 1). Patient characteristics were comparable between groups (Table 1). One patient in group I had an anatomic variation precluding the successful performance of the block at 30 minutes. After unsuccessful attempts, the



**Figure 1.** Flow diagram of participants.

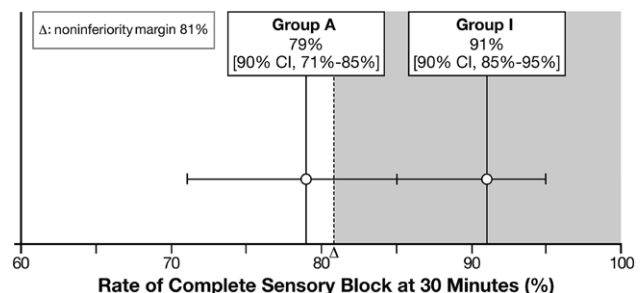
**Table 1. Patient Demographics and Surgery Characteristics**

	Group I (n = 112)	Group A (n = 112)
Age, y <sup>a</sup>	52 ± 16	48 ± 19
Male/female, n	73/39	72/40
BMI, kg/m <sup>2</sup> <sup>a</sup>	25.3 ± 3.8	26.4 ± 4.1
Diabetes, n	9	4
ASA I/II/III, n	73/37/2	60/45/7
Surgery of hand/wrist/forearm/elbow, n	80/23/4/5	79/25/2/6
Duration of surgery, min <sup>b</sup>	40 (20–55)	31 (15–55)
Tourniquet use, n	84	85
Duration, min <sup>b</sup>	37 (27–49)	31 (18–50)

BMI = body mass index; ASA = American Society of Anesthesiologists preoperative classification.

<sup>a</sup>Values are mean ± SD.

<sup>b</sup>Values expressed as median and the 25%–75% interquartile range.



**Figure 2.** Difference of sensory block rates at 30 min between groups. The dashed line at 81% indicates the noninferiority margin of 10%. The gray zone indicates the zone of noninferiority. Adapted from Piaggio et al.<sup>16</sup> CI = confidence interval.

patient was then out of protocol and the anesthetic plan was left to the attending anesthesiologist, who performed an axillary block. One patient assigned to group I inadvertently had an axillary block performed. The first patient was considered a failure for the primary outcome measure; data from the second patient were analyzed in group I, as per the intention-to-treat analysis.

At 30 minutes, the rate of complete sensory block was 91% (90% CI, 85%–95%) in group I compared with 79% (90% CI, 71%–85%) in group A (Fig. 2). The upper limit of the CI of group A is thus included in the established 10%

margin of noninferiority. However, the rate of complete sensory block was statistically significantly greater in group I compared with group A ( $P = 0.0091$ ). Other block characteristics are presented in Table 2. The onset of complete sensory and motor block was faster in group I (Fig. 3; Fig. 1, Supplemental Digital Content 2, <http://links.lww.com/AA/B255>). The data for the sensory and motor block installation for major nerves are available in supplemental digital content (Figs. 2–9, Supplemental Digital Content 3–10, <http://links.lww.com/AA/B256>, <http://links.lww.com/AA/B257>, <http://links.lww.com/AA/B258>, <http://links.lww.com/AA/B259>, <http://links.lww.com/AA/B260>, <http://links.lww.com/AA/B261>, <http://links.lww.com/AA/B262>, <http://links.lww.com/AA/B263>). Nine of the 11 rescue blocks in group A were performed on the median nerve. In 10 patients in group A, the musculocutaneous nerve could not be visualized; 30 mL of local anesthetics were injected posterior to the axillary artery.

One patient in group A showed mild signs of local anesthetic toxicity (tinnitus, dizziness, and tongue numbness), which subsided with the administration of midazolam. One patient in group I had a mild hematoma at the puncture site after block completion, which subsided progressively within 3 weeks. No neurologic sequelae related to the block performance were noted. Patient satisfaction did not differ between the 2 groups.

### Per-Protocol Analyses

We conducted a per-protocol analysis in which data from the patient in group I having had the wrong block performed were considered in group A for the analysis. This analysis showed a comparable rate of complete sensory

block of (101/111) 91% (90% CI, 85%–95%) in group I compared with (89/113) 79% (90% CI, 71%–85%) in group A at 30 minutes (proportion difference of 12% [95% CI, 2%–22%];  $P = 0.0108$ ).

### DISCUSSION

On the basis of our predefined 10% margin of noninferiority, we cannot exclude that the ultrasound-guided double-injection axillary block is “noninferior” to the ultrasound-guided single-injection infraclavicular block. However, we observed a statistically significant lower rate of complete sensory block at 30 minutes after the double-injection ultrasound-guided axillary block. We also observed a greater surgical success rate and faster performance times with the infraclavicular block.

Previous studies on ultrasound-guided upper limb blocks were designed as superiority studies.<sup>2–4</sup> Block rates obtained were then considered comparable between the axillary and the infraclavicular blocks in one of them.<sup>4</sup> However, these studies were not designed to evaluate the noninferiority between the techniques, but whether one technique was superior to another. On the contrary, we considered a noninferiority design as being appropriate to evaluate the potential clinical use of the axillary technique in the context where no technique is likely to have a clinically significant greater success rate than the ultrasound-guided infraclavicular block. We believe that the benefit of the axillary block over the infraclavicular block was in its potentially superior safety profile. To lead to practice changes in the field, the success of the axillary block then had to be showed noninferior to the infraclavicular block.

**Table 2. Characteristics of the Blocks**

	Group I (n = 112)	Group A (n = 112)	P
Complete sensory block at 30 min, % (90% CI)	91 (85–95)	79 (71–85)	0.0091 <sup>a</sup>
Complete motor block at 30 min, % (95% CI)	71 (61–79)	54 (44–63)	0.0089 <sup>a</sup>
Surgical success, % (95% CI)	93 (86–97)	82 (74–89)	0.0153 <sup>a</sup>
Operator, expert <sup>b</sup> /anesthesiologist/resident, n	30/38/44	34/32/46	0.6674 <sup>a</sup>
Number of takeovers <sup>c</sup> , n	1	3	0.6216 <sup>d</sup>
Imaging time, s <sup>e</sup>	68 (62–75)	117 (104–130)	<0.0001 <sup>f</sup>
Needling time, s <sup>e</sup>	161 (147–177)	241 (222–261)	<0.0001 <sup>f</sup>
Performance time, s <sup>e</sup>	231 (213–250)	358 (332–387)	<0.0001 <sup>f</sup>
Paresthesia, n	11	16	0.3166 <sup>a</sup>
Vascular puncture, n	2	1	0.6216 <sup>e</sup>
Block-related pain, VAS 0 to 10 <sup>g</sup>	2 (1–4)	2 (1–4)	0.3340 <sup>h</sup>
Dose of midazolam before the block, mg <sup>g</sup>	2 (1.5–2)	2 (1.5–2)	0.1047 <sup>h</sup>
Perioperative midazolam			
No. of patients, n	34	37	0.7002 <sup>a</sup>
Median dose, mg <sup>g</sup>	2 (1–2)	2 (1–2)	0.5442 <sup>h</sup>
Perioperative sufentanil			
No. of patients, n	8	13	0.2606 <sup>a</sup>
Median dose, µg <sup>g</sup>	5 (5–6)	10 (5–10)	0.0551 <sup>h</sup>
No. of patients for pain in the surgical field, n	3	9	0.2031 <sup>e</sup>

Categorical variables are expressed as count and/or percentage.

CI = confidence interval; VAS = visual analog pain scale.

<sup>a</sup>χ<sup>2</sup> test.

<sup>b</sup>Defined as one of the investigators (ND, SL, M-JN) with specific expertise in regional anesthesia.

<sup>c</sup>Number of blocks during which the supervising anesthesiologist had to take over.

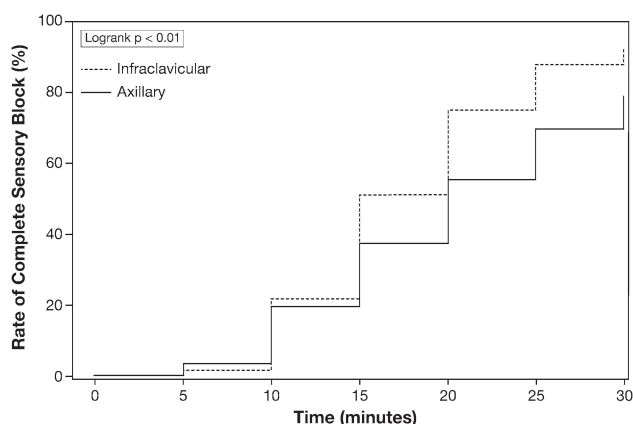
<sup>d</sup>Fisher exact test.

<sup>e</sup>Values are expressed as mean and 95% CIs generated by the Cox method.

<sup>f</sup>Student t test.

<sup>g</sup>Values are expressed as median and the 25%–75% interquartile range.

<sup>h</sup>Wilcoxon test.



**Figure 3.** Complete sensory block installation over time.

Although we observed, as a secondary analysis, that the difference between sensory block rates was statistically significant, the upper limit of the 90% CI of the sensory block rate of the axillary block was included in the 10% noninferiority margin defined a priori. Thus, we cannot exclude that the true difference between the sensory block rates of the 2 techniques is  $<10\%$ , and then decide on the rejection or not of the null hypothesis (not noninferiority).<sup>16</sup> According to a landmark review article on noninferiority studies,<sup>16</sup> our results are inconclusive, which means that it is still possible that the true sensory block rate of the axillary block at 30 minutes could be lower than the margin of noninferiority. However, the success rate of the axillary block is statistically worse than that of the infraclavicular block.

The rate of complete sensory block for the double-injection ultrasound-guided axillary technique found in the present study is comparable with those observed in previous trials.<sup>13,14</sup> Although the surgical success rate for the axillary block observed in our study is comparable with the one observed in a previous study,<sup>15</sup> it is inferior to what was previously found by other investigators.<sup>13,14</sup> The discrepancies in success rates could result from different injection end points between their technique and our own. Also, a mean number of needle passes of 4 and 3.5 were recorded in the previous studies.<sup>13,14</sup> For both block techniques, once the needle was in the right position, we could not move or redirect the needle to do a strict single- or double-injection technique to seek for the simplest technique possible.

For the axillary block, our high failure rate in the median nerve territory could be explained by the inability of the local anesthetic solution to spread to the lateral upper quadrant of the artery. A previous study<sup>14</sup> found that with the double-injection axillary block, the rate of sensory block of the median nerve was lower at 10 and 15 minutes compared with quadruple-injection techniques; however, this difference did not persist beyond this point.

Our study has limitations. First, any anesthesiologist in our center could perform the blocks, as well as any resident in his/her regional anesthesia rotation. However, this limitation was deliberate to mimic real-life conditions and increase the external validity of our study. Another limitation of this study is that the attending anesthesiologist was not always blinded to the block performed because of operational and feasibility

reasons. This may have therefore influenced the administration of sedation and surgical success but not the assessment of the primary outcome of complete sensory block at 30 minutes, which was evaluated before any analgesia or additional sedation was administered. Furthermore, administration of sedation or analgesia and the reasons of administration were tightly controlled to limit this bias. The main strength of our study is the use of a strict and thorough methodology compared with previous published trial on this topic. All blocks were also directly supervised by 3 of the authors to insure standardized techniques.

In summary, we failed to demonstrate that the rate of complete sensory block at 30 minutes with the double-injection ultrasound-guided axillary block is noninferior to the single-injection ultrasound-guided infraclavicular block. A statistically and clinically significant lower rate of complete sensory block was observed with the axillary block. Thus, when seeking a reliable, easily performed, and successful block, the single-injection ultrasound-guided infraclavicular block must still be considered. However, the axillary block remains a suitable alternative technique. Finally, we designed a noninferiority study based on the assumption that the axillary block could have a potentially improved safety profile, given its compressible location. However, our trial did not show any difference with regard to adverse events, although it was neither designed nor powered to demonstrate a difference in such a rare outcome. ■■

## DISCLOSURES

**Name:** Ariane Boivin, MD.

**Contribution:** This author helped in study design, conducting the study, data collection, data analysis, and manuscript preparation.

**Attestation:** Ariane Boivin approved the final manuscript and attests to the integrity of the original data and the analysis reported in this manuscript.

**Name:** Marie-Josée Nadeau, MD.

**Contribution:** This author helped in study design, conducting the study, data collection, manuscript preparation.

**Attestation:** Marie-Josée Nadeau approved the final manuscript and attests to the integrity of the original data and the analysis reported in this manuscript. Dr. Nadeau is the archival author.

**Name:** Nicolas Dion, MD.

**Contribution:** This author helped in study design, conducting the study, and data collection.

**Attestation:** Nicolas Dion approved the final manuscript and attests to the integrity of the original data and the analysis reported in this manuscript.

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**Contribution:** This author helped in study design, conducting the study, and data collection.

**Attestation:** Simon Lévesque approved the final manuscript and attests to the integrity of the original data and the analysis reported in this manuscript.

**Name:** Pierre C. Nicole, MD.

**Contribution:** This author helped in study design.

**Attestation:** Pierre C. Nicole approved the final manuscript.

**Name:** Alexis F. Turgeon, MD, MSc.

**Contribution:** This author helped in study design, data analysis, and manuscript preparation.

**Attestation:** Alexis F. Turgeon approved the final manuscript and attests to the integrity of the analysis reported in this manuscript.

**This manuscript was handled by:** Terese T. Horlocker, MD.

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