Single-operator real-time ultrasound-guided spinal injection using SonixGPSTM: a case series

Injection rachidienne échoguidée en temps réel par un opérateur unique avec le SonixGPSTM: une série de cas

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Abstract

Purpose The SonixGPSTM is a novel needle tracking system that has recently been approved in Canada for ultrasound-guided needle interventions. It allows optimization of needle-beam alignment by providing a real-time display of current and predicted needle tip position. Currently, there is limited evidence on the effectiveness of this technique for performance of real-time spinal anesthesia. This case series reports performance of the SonixGPS system for real-time ultrasound-guided spinal anesthesia in elective patients scheduled for joint arthroplasty.

Methods In this single-centre case series, 20 American Society of Anesthesiologists' class I-II patients scheduled for lower limb joint arthroplasty were recruited to undergo real-time ultrasound-guided spinal anesthesia with the SonixGPS after written informed consent. The primary outcome for this clinical cases series was the success rate of spinal anesthesia, and the main secondary outcome was time required to perform spinal anesthesia.

Results Successful spinal anesthesia for joint arthroplasty was achieved in 18/20 patients, and 17 of these required only a single skin puncture. In 7/20 (35%)

patients, dural puncture was achieved on the first needle pass, and in 11/20 (55%) patients, dural puncture was achieved with two or three needle redirections. Median (range) time taken to perform the block was 8 (5–14) min. The study procedure was aborted in two cases because our clinical protocol dictated using a standard approach if spinal anesthesia was unsuccessful after three ultrasound-guided insertion attempts. These two cases were classified as failures. No complications, including paresthesia, were observed during the procedure. All patients with successful spinal anesthesia found the technique acceptable and were willing to undergo a repeat procedure if deemed necessary.

Conclusions This case series shows that real-time ultrasound-guided spinal anesthesia with the SonixGPS system is possible within an acceptable time frame. It proved effective with a low rate of failure and a low rate of complications. Our clinical experience suggests that a randomized trial is warranted to compare the SonixGPS with a standard block technique.

Résumé

Objectif Le SonixGPSTM est un système innovant de suivi de l'aiguille récemment approuvé au Canada pour les interventions échoguidées réalisées avec une aiguille. Cet appareil optimise l'alignement entre l'aiguille et le faisceau grâce à un affichage en temps réel du positionnement actuel et prévu de la pointe de l'aiguille. À l'heure actuelle, les données probantes concernant l'efficacité de cette technique pour réaliser une rachianesthésie en temps réel sont limitées. Cette série de cas porte sur la performance du système SonixGPS pour réaliser une rachianesthésie échoguidée en temps réel chez des patients devant subir une chirurgie non urgente d'arthroplastie.

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Méthode Dans cette série de cas réalisée dans un seul centre, vingt patients de classe I-II selon la classification de l'American Society of Anesthesiologists et devant subir une arthroplastie au niveau des membres inférieurs ont été recrutés afin de subir une rachianesthésie échoguidée en temps réel avec le SonixGPS après avoir obtenu leur consentement écrit. Le critère d'évaluation principal de cette série de cas cliniques était le taux de réussite de la rachianesthésie, et le critère d'évaluation secondaire le plus important le temps nécessaire à la réalisation de la rachianesthésie.

Résultats La rachianesthésie pour l'arthroplastie a réussi chez 18/20 patients, et 17 patients n'ont nécessité qu'une seule ponction de la peau. Chez 7/20 (35 %) patients, la ponction durale a réussi lors du premier passage de l'aiguille, et chez 11/20 (55 %) patients, la ponction durale a réussi après deux ou trois repositionnements de l'aiguille. Le temps médian (intervalle) nécessaire pour réaliser le bloc était de 8 (5-14) min. La technique à l'étude a été abandonnée dans deux cas parce que notre protocole clinique dictait l'utilisation d'une approche standard si la rachianesthésie ne réussissait pas après trois tentatives d'insertion échoguidées. Ces deux cas ont été classés comme des échecs. Aucune complication, y compris la paresthésie, n'a été observée pendant l'intervention. Tous les patients dont la rachianesthésie a réussi ont jugé la technique comme étant acceptable et consentiraient, si cela s'avérait nécessaire, à subir à nouveau l'intervention.

Conclusion Cette série de cas montre que la rachianesthésie échoguidée en temps réel avec le système SonixGPS est possible dans un intervalle de temps acceptable. Ce dispositif s'est avéré efficace, offrant un faible taux d'échec et un faible taux de complications. Notre expérience clinique suggère qu'une étude randomisée serait nécessaire pour comparer le SonixGPS à une technique de bloc standard.

Although ultrasound (US)-guided regional anesthesia is well established, ultrasonography has been relatively underutilized in neuraxial anesthesia.^{1,2} This may be due in part to the fact that the vast majority of anesthesiologists master the conventional surface landmark-based techniques for spinal anesthesia with success rates approaching 96%.³ In addition, there is less familiarity and greater perceived difficulty of spinal sonoanatomy compared with sonoanatomy for other blocks.^{4,5} Recently, a novel SonixGPSTM electromagnetic needle tracking system (Ultrasonix, Richmond, BC, Canada) that provides a real-time display of current and projected needle tip positions has been approved by Health Canada for US-guided needle interventions. Cadaver trials

and one case report suggest that needle tip visibility down to the ligamentum flavum may be possible with the SonixGPS system.^{6,7} Since there is limited clinical evidence regarding the effectiveness of this technique, we performed a prospective case series to evaluate the SonixGPS for real-time US-guided spinal anesthesia in patients undergoing elective lower limb arthroplasty.

Methods

After receiving institutional ethics approval and written informed consent, 20 patients scheduled for elective knee or hip arthroplasty under the University of British Columbia Centre for Surgical Innovation (UBC- CSI) Arthroplasty Program at UBC Hospital were recruited. The UBC Hospital was chosen as the primary site to recruit patients due to the high volume of joint arthroplasty cases, the vast majority of whom receive spinal anesthetics (> 95%). Eligibility criteria for the UBC-CSI joint arthroplasty program include American Society of Anesthesiologists' (ASA) class I or II, < 80 yr of age, body mass index (BMI) < 40 kg·m⁻², and scheduled for uncomplicated primary joint arthroplasty. Study exclusion criteria included previous spinal surgery, contraindication to spinal anesthesia (e.g., coagulation defects or infection at the site of injection), anatomical abnormality of the spine, neurological disease, and allergy to study medications (ultrasound gel or local anesthetics). We excluded patients with a BMI > 35 kg·m⁻² because there is limited information on the utility of SonixGPS in this patient subgroup. All eligible patients scheduled for joint arthroplasty surgery on days that the clinical evaluation was conducted were approached for participation. Patients were positioned sitting and draped as usual for spinal anesthesia and routine monitors (electrocardiogram, pulse oximetry, and noninvasive blood pressure) were applied. All spinal injections were performed by a staff anesthesiologist or fellow, each experienced with the SonixGPS system and having performed more than 30 US-guided neuraxial procedures. Adjunctive sedation was provided with midazolam (0.01-0.03 mg·kg⁻¹ iv).

After standard aseptic skin preparation and draping, a 2-5 MHz convex transducer was covered with a sterile sheath, and sterile gel was used for transducer-skin contact. The SonixGPS electromagnetic transmitter arm was placed close to the patient's back to obtain an optimal signal and ultrasound image (Fig. 1). The L3/4 and L4/5 levels were identified and a sonographic image of the laminae and neuraxial structures (Fig. 2) was obtained in the left paramedian oblique sagittal plane with the probe angled medially (Fig. 3). The left paramedian approach was chosen because all right-handed operators in this study preferred to hold the needle with their dominant hand.

Sterile gauzes were used to wipe the needle insertion site immediately medial to the transducer until the area was free of gel, and then the intended needle path was infiltrated with 1% lidocaine. An out-of-plane US-guided needle insertion to the ligamentum flavum was performed with a sterile disposable proprietary 8-cm 19G SonixGPS needle (Fig. 1) using a previously described technique in cadavers.⁶ Once the needle tip was inserted to the ligamentum flavum, the inner stylet containing the electromagnetic sensor was removed and a 127-mm 22G Quincke tip spinal needle was inserted through the proprietary needle using a needle-through-needle technique. The spinal needle was then advanced to the subarachnoid space as evidenced by return of clear cerebrospinal fluid (CSF) from the spinal needle hub.

We defined return of CSF as a criterion for correctly locating the intrathecal needle tip. Plain 0.5% bupivacaine (10–15 mg), with or without fentanyl (15 µg), was administered via the spinal needle. Subsequently, the patient was placed in the supine or lateral position and managed in a standard manner for the remainder of the surgery by a separate anesthesiologist. Propofol 25–100 µg·kg⁻¹·min⁻¹ was used for intraoperative sedation, and supplemental oxygen was administered to all patients. Postoperatively, all patients completed a questionnaire to assess their satisfaction with the technique.

The primary outcome was the success rate of spinal anesthesia. Secondary outcomes recorded were: time taken to perform the block (time from transducer contacting the patient to completion of intrathecal injection), number of levels attempted, depth to the ligamentum flavum, number of skin punctures, number of spinal needle redirections,

Fig. 1 SonixGPS™ electromagnetic sensor arm with SonixGPS needle with sensor filament

Fig. 2 Ultrasound image showing out-of-plane needle path towards the lamina. PD/LF = posterior dura/ligamentum flavum complex; PLL/VB = posterior longitudinal ligament/vertebral body complex. Probe footprint and needle orientation are shown on the bottom right hand corner

Fig. 3 The ultrasound transducer is shown in the left parasagittal plane angled medially, and the SonixGPS™ needle is inserted just medial to the transducer edge. The pink plane represents the plane of the ultrasound beam, and the purple plane matches the actual direction on the needle. These planes are similar but not identical, and they intersect distal to the laminae. This “parallax effect” shows why it is possible to encounter a bony obstruction even when the SonixGPS system predicts a clear path to the ligamentum flavum

operator assessment of landmarks (1 = impossible; 2 = difficult; 3 = moderate; and 4 = easy), and quality of the ultrasound images (1 = poor; 2 = fair; 3 = good; 4 = excellent). Skin punctures were limited to a maximum of three, following which the procedure was converted to a landmark-based spinal technique without ultrasound; these attempts were deemed as failures. A needle redirection was defined as the need to reposition the 8-cm 19G needle after

initial US-guided placement. The following complications were recorded: pain during insertion, paresthesia, accidental vascular or dural puncture, and inadequate or failed spinal block. We also recorded patients' assessment of the acceptability of the procedure (yes/no) and their willingness to undergo real-time US-guided spinal puncture (yes/no) at another time.

A convenience sample of 20 patients was enrolled in order to represent a typical population presenting for elective spinal anesthesia prior to hip or knee arthroplasty. All data were entered into a spreadsheet program (Microsoft® Excel, Microsoft Corp, Seattle, WA, USA) and analysed with SPSS® software (IBM Corporation, Armonk, NY, USA). Normality was tested with the Schapiro-Wilk test. Normal data are presented as means (standard deviation, SD), and non-normal data are summarized as medians (range) or as actual counts.

Results

Twenty ASA class I-II patients (seven male, 13 female) were studied, and mean (SD) patient characteristics were: height, 166 (11) cm; weight, 75 (15) kg; and BMI 27 (2.9) $\text{kg}\cdot\text{m}^{-2}$. Three patients had a BMI > 30 (30.8, 30.5, and 32.6 $\text{kg}\cdot\text{m}^{-2}$), but their image quality was comparable with patients with a lower BMI. Primary and secondary outcomes are summarized in the Table.

Clear CSF acquisition was followed by successful spinal anesthesia and surgery in 18/20 (90%) patients using real-time US-guidance in accordance with our predefined criterion of successful intrathecal needle tip location. Acquisition of CSF occurred without needle redirection in seven of these cases. One patient required one needle redirection for acquisition of CSF, four patients required

two needle redirections, and six patients required three needle redirections.

In the remaining two patients, real-time US-guided spinal anesthesia was converted to a standard percutaneous approach in accordance with our protocol; these attempts were classified as failures. The standard spinal anesthetic technique was successful in one of these patients, and the other patient required general anesthesia because multiple further attempts at spinal anesthesia were also unsuccessful. In all cases, only one spinal level was accessed for spinal insertion. In 17/20 (85%) cases only one skin puncture was required, and one case required two skin punctures. The median (range) time taken to perform the block was 8 (5–14) min, and the median (range) depth to the ligamentum flavum was 4.6 (3.8–5.5) cm.

The quality of the ultrasound image was rated as good to excellent in 95% of cases despite landmarks being assessed as difficult or impossible to feel in 6/20 (30%) cases. Overall, the landmarks were assessed as moderate to easy in 14/20 (70%) patients. In three patients with a BMI of 30.5, 30.8, and 32.6 $\text{kg}\cdot\text{m}^{-2}$, the landmarks were assessed as 3, 1, and 4 and ultrasound images were assessed as 3, 3, and 4, respectively.

No complications were observed, including paresthesia, accidental dural puncture, post-dural puncture headaches, or spinal hematomas. Successful US-guided spinal anesthesia for joint arthroplasty was achieved in 18/20 (90%) patients. One patient was converted to a standard spinal anesthetic technique and one required general anesthesia.

All patients found the technique to be acceptable. The 19 patients who received a spinal anesthetic stated that they would elect to have an US-guided neuraxial technique again if it were an option.

Discussion

This case series evaluated the performance of the SonixGPS for real-time US-guided spinal anesthesia in elective patients scheduled for routine spinal anesthesia. The results suggest that 1) a reasonable success rate can be anticipated with this technique, and 2) the procedural time, image quality, number of skin punctures, and number of needle redirects for successful acquisition of CSF are comparable with those reported with other techniques.

Some important factors to consider with any US-guided spinal technique include the number of spinal levels required, the success rate on the first skin puncture, the number of needle redirects required, image quality, and procedural time. In our study, only one spinal level was required and scanning of other levels was not necessary. The success rate of spinal anesthesia with first skin puncture was 17/20 (85%) compared with the 65% rate

Table Primary and secondary outcomes

# of levels attempted (1/2/3)	20/0/0
# of skin punctures (1/2/3)	17/1/2
# needle redirects (0/1/2/3/4)	7/1/4/6/2
Depth to ligamentum (cm) Mean (SD)	4.6 (0.4)
Operator assessment of landmarks (1/2/3/4)*	1/5/7/7
Operator assessment of ultrasound images (1/2/3/4)**	0/1/10/9
Patient acceptability (yes/no)	20/0
Willingness to have repeat procedure (yes/no)	19/1

Values are expressed as number *n* or mean (SD)

*Operator assessment of landmarks (1 = impossible; 2 = difficult; 3 = moderate; 4 = easy)

**Operator assessment of ultrasound images (1 = poor; 2 = fair; 3 = good; 4 = excellent)

SD = standard deviation

reported with US-guided real-time spinal puncture without needle guidance.⁸ The success rate with first puncture was also 65% with pre-procedural ultrasound, albeit this population had poorly defined landmarks.⁵ Since multiple skin punctures and needle redirects are associated with an increased risk of complications, such as spinal hematoma, post-dural puncture headache, and neural injury, it is important for any novel technique to have a high success rate with the first skin puncture.^{5,9,10} Interestingly, successful dural puncture occurred in 7/20 (35%) cases with the first needle pass, which is better than the 27% success rate that Chin *et al.*⁵ reported with pre-procedure ultrasound and the 30% success rate that Conroy *et al.*⁸ reported with conventional ultrasound. On the other hand, 18/20 (90%) dural punctures were achieved within our study definition of three or fewer skin punctures. The latter results are better than the 50% and 27% success rates within five needle passes reported with pre-procedure ultrasound and with landmark methods, respectively.⁵ In Conroy's study of real-time US-guided spinal anesthesia, the median (range) number of needle passes was 3 (1-18).⁸ Our failure rate of 2/20 (10%) was higher, partly due to a lower pre-defined threshold of three needle punctures before conversion to a standard spinal technique, and in one patient, spinal anesthesia could not be achieved despite multiple attempts by two experienced anesthesiologists. If this patient were excluded, the failure rate using the needle guidance system would be 1/19 (5%). This is comparable with the reported 3% failure rate with real-time US-guided spinal anesthesia without needle guidance⁸ and a failure rate of 1.6% with pre-procedural US-guided spinal anesthesia.⁵ In two studies on real-time US-guided spinal-epidural anesthesia, the reported failure rates were 22% and 14%.^{11,12}

Spinal sonoanatomy is technically more challenging than other ultrasound imaging procedures because bony structures contribute to acoustic artifacts.¹² In addition, needle tip visibility to the ligamentum flavum and dura cannot be assured due to steep needle angles. The SonixGPS provides a display of needle location and projected path that overcomes some of these issues. In addition, one of the recognized difficulties of real-time US-guided spinal anesthesia techniques is the awkward angle that is often required under the transducer for in-plane approaches. We have presented a novel out-of-plane approach that reduces this problem. Thus, needle advancement to the dura can be performed with greater ease and confidence compared with the traditional ultrasound approach. The operator assessment of ultrasound image quality was rated as fair in 1/20 (5%) patients, good in 10/20 (50%), and excellent in 9/20 (45%), for a mean (SD) overall score of 3.4

(0.59). These results may partly reflect the demographic characteristics of our patients: mean (SD) BMI of 27 (2.9) kg·m⁻² and depth to the ligamentum flavum of 4.6 (0.4) cm. It would be interesting to study the performance of the SonixGPS and image quality in patients with a higher BMI and greater depth to the ligamentum flavum.⁵

The time to perform a real-time US-guided spinal technique needs to be reasonably short for it to be implemented widely in routine cases. The median (range) time taken to perform the spinal block with our SonixGPS needle-through-needle technique was 8 (5-14) min. Our times compare favourably with the 12-min procedure time for US-guided spinals reported by Chin *et al.*,⁵ and the eight minutes with real-time ultrasound spinals reported by Conroy *et al.*⁹ All of these times are reasonable and unlikely to impact overall operating room turnover times, and they may actually contribute to efficiency because procedural times with landmark-based techniques can range from 5-21 min.⁵ Patient satisfaction with our technique was high, all patients found the technique acceptable, and 19/20 (95%) patients expressed a willingness to undergo a repeat procedure. There were no adverse events as a result of the study protocol.

There are some limitations with respect to this case series. First, our patients had modestly high BMIs, but severely obese patients (BMI ≥ 35) were excluded and only 30% of our population had poorly palpable landmarks. Our study is a prospective case series, and it is not powered to detect the rate of adverse events that are uncommonly seen with spinal anesthesia. We did not encounter any major equipment-related problems or adverse events. Furthermore, this series allowed us to gain insight into issues related to real-time US-guided spinal anesthesia with the SonixGPS that can lay the groundwork for future controlled comparative studies.

In conclusion, this case series supports the use of the SonixGPS needle tracking system to perform real-time US-guided spinal anesthesia in patients scheduled for elective spinal anesthesia.

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Conflicts of interests None declared.

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