Basivertebral Nerve Radiofrequency Ablation (Intracept)

Procedural Technique

David Stolzenberg, DO, Tariq Z. Issa, BA,* Jeffrey Boyd, DO,* Michael J. Boctor, MD,† David Tran, MD,‡ Paul M. Kitei, MD,* and Gregory D. Schroeder, MD**

Abstract: Intraosseous basivertebral nerve ablation is indicated for the treatment of chronic vertebrogenic low back pain with failure of at least 6 months of conservative treatment. This article details patient positioning and setup, step-by-step instructions for the procedure, and postoperative management. Pearls and pitfalls are also discussed. In addition, an instructional procedure video accompanies this paper and can be found online (at https://vimeo.com/791578426/de0e90cfbe).

Key Words: basivertebral nerve ablation, nonoperative, discogenic back pain, low back pain, Modic changes, intracept

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INDICATIONS

Intraosseous basivertebral nerve ablation (BVNA) is indicated for the treatment of chronic, axial low back pain attributed to pathologically degenerated vertebral endplates evidenced by Modic changes on magnetic resonance imaging (MRI) between L3 and S1 (Fig. 1).[1–3] BVNA is a validated treatment option for low back pain clinically consistent with anterior column pain lasting >6 months despite at least 6 months of conservative treatment.[1] Two multicenter randomized controlled trials showed statistically and clinically significant improvement in pain and function in patients who underwent BVNA as compared with sham and standard care.[4,5] With regard to the durability of these improvements, Smuck et al[4] demonstrated that at 3 years post-BVNA, 72.6% of patients experienced at least a 50% reduction in numeric pain scores, and 85.3% of patients experienced at least a 15-point reduction in Oswestry Disability Index. Fischgrund et al[5] published 5-year results that were similar, with 66% of patients reporting at least 50% pain reduction and 75% reporting a reduction in the Oswestry Disability Index by at least 15 points. Moreover, aggregate data from these studies further supports these positive clinical outcomes.[6] This novel procedure has received published support from the International Society for the Advancement of Spine Surgery, American Society of Pain and Neuroscience, and North American Spine Society.[3,7,8]

CONTRAINDICATIONS

BVNA is contraindicated in patients with severe cardiac or pulmonary compromise, active implantable pulse generators (eg, pacemakers, defibrillators), targeted ablation zone(s) <10 mm away from a sensitive structure not intended to be ablated such as the vertebral foramen, active systemic infection or local infection in treatment area, and those who are pregnant or skeletally immature.[9]

PATIENT POSITIONING AND SETUP

Preoperative planning is recommended utilizing lumbar x-ray and MRI review to establish per-level entry side, angle of entry, wig-wag direction needed if scoliosis is present, and any specific anatomical variants (i.e., long, narrow, and/or sagittal pedicles). Computed tomography (CT) can be helpful if thinner slices are required. When considering the optimal side of entry, pedicle width asymmetry, facet hypertrophy asymmetry, and vertebral body rotation should be taken into account. Angles of entry are measured on axial MRI images in the plane of the discs (Fig. 2). One line is drawn from the deepest part of the groove between the transverse process (TP) and superior articular process (SAP) through the center/medial portion of the pedicle and into the vertebral body. A second sagittal line is drawn from the spinous process through the midline of the vertebral body where it will intersect with the first line. This angle can be approximated by obliquing the C-arm until the facet joint is 50% across the superior endplate (SEP); however, this does not take into account individual anatomic factors, such as facet joint size, pedicle width, length, orientation, and other impediments to access. For S1, factors, such as iliac crest height, space between iliac crest and S1 pedicle, and size of the S1 SAP, can all help determine the preferred side of entry. Starting with left-

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From the *Department of Orthopaedic Surgery, Rothman Institute, Thomas Jefferson University, Philadelphia, PA; †Department of Plastic Surgery, Loma Linda University, Loma Linda, CA; and ‡Axion Spine and Neurosurgery, Alpharetta, GA.
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Reprints: David Stolzenberg, DO, Rothman Orthopaedic Institute, Thomas Jefferson University, 925 Chestnut Street, 5th Floor, Philadelphia, PA 19107 (e-mail: david.stolzenberg@rothmanortho.com).
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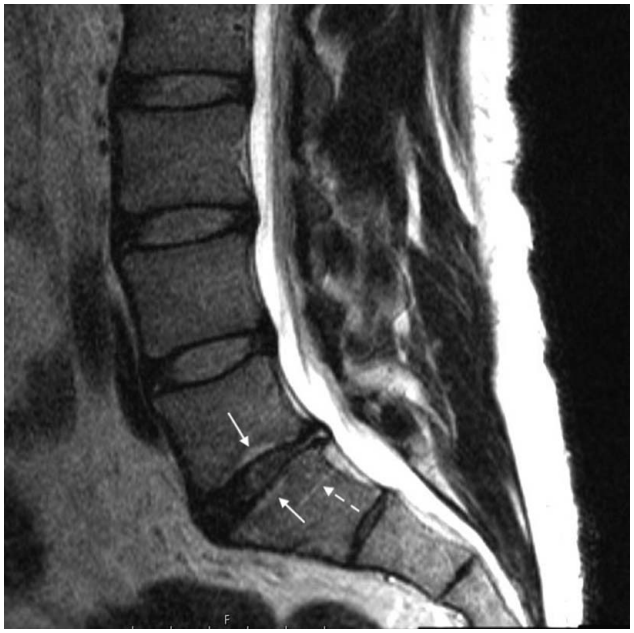

FIGURE 1. Sagittal T2 magnetic resonance imaging (MRI) demonstrating Modic I endplate changes at L5–S1 and the location of the S1 basivertebral nerve.

sided access for the first treated level, followed by the right side, and then alternating can be helpful in simplifying C-arm movements during the procedure. Having the instruments on the right can make repeated movements of the C-arm between anterior-posterior (AP) and lateral more cumbersome. The location of the basivertebral nerve along with the accompanying vein can generally be confirmed on MRI (Fig. 1). This is particularly important at S1, as there may be some variability in its location cephalocaudally, and this allows for optimal targeting. In addition, any narrow pedicles should be measured to confirm they will accommodate the 4 mm cannula. During preoperative planning, it should also be noted if a spinous process is abnormally angled in relation to the rotation of the vertebral body, as centering an angled spinous process can erroneously identify the midpoint location on AP. In these cases, achieving an AP view with symmetric-appearing pedicle rings may better indicate a true AP view. For obese patients, the incision may initially be more medial or lateral depending on patient-specific body habitus. However, this will still be set from the point predetermined by measuring the angle of approach on MRI and positioning the C-arm as described for any patient, overlying the targeted bony anatomy.

The final target for the BVNA probe at the lumbar vertebral bodies is the midpoint of the superior and inferior endplates, 30%–50% anterior from the posterior vertebral body, and midpoint on AP. At S1, the target is 40% inferior from the SEP, 50% anterior from the posterior vertebral body (with 40%–60% being acceptable), and midpoint on AP. For safety, the probe must be at least 10 mm ventral to the posterior vertebral body.

Routine preoperative intravenous antibiotics are given. The patient is positioned prone on a radiolucent procedure table. At least one firm pillow is placed under the abdomen to fully minimize the lumbar lordosis. The skin is sterilized in a standard manner, and a sterile drape with an opening in the middle is placed. A sterilely draped C-arm is then brought over to the patient for fluoroscopic visualization. General anesthesia or monitored anesthesia care is most commonly used, but intraveneous conscious sedation may be acceptable.

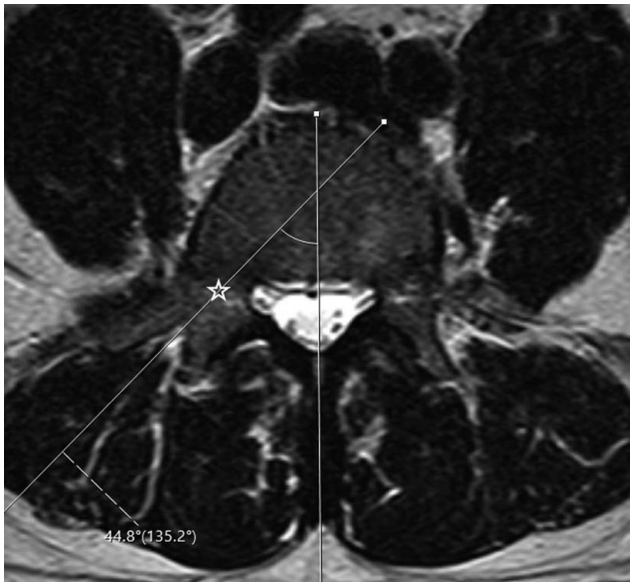

FIGURE 2. Axial MRI view at L5 demonstrating preoperative planning with angle measurements.

STEP-BY-STEP INSTRUCTIONS

A detailed procedural technique video (https://vimeo.com/791578426/de0e90cfbe) has been designed to accompany and reinforce the information in this paper (Supplemental Video 1, Supplemental Digital Content 1, http://links.lww.com/CLINSPINE/A329).

An initial fluoroscopic image is taken to localize and center the first targeted lumbar vertebral body: L5 in this example. Adjustments are made to obtain a true AP view with the spinous process equidistant from the pedicles. It is recommended to rotate the table to obtain a true AP view at each level, rather than obliquing the C-arm, to ensure that the lateral will be a true lateral view for respective vertebral levels. The C-arm intensifier is then tilted until the SEP is squared and then obliqued to the predetermined angle and side. The pedicle should be in the upper one-third of the vertebral body. If the pedicle is too high, the angle of entry will not be optimal. A sterile radiopaque marker is placed on the patient's skin overlying the target at the midpoint of the lateral pedicle border (Fig. 3A). Classically, the superolateral corner of the pedicle is targeted; however, this will result in a cephalocaudal angle

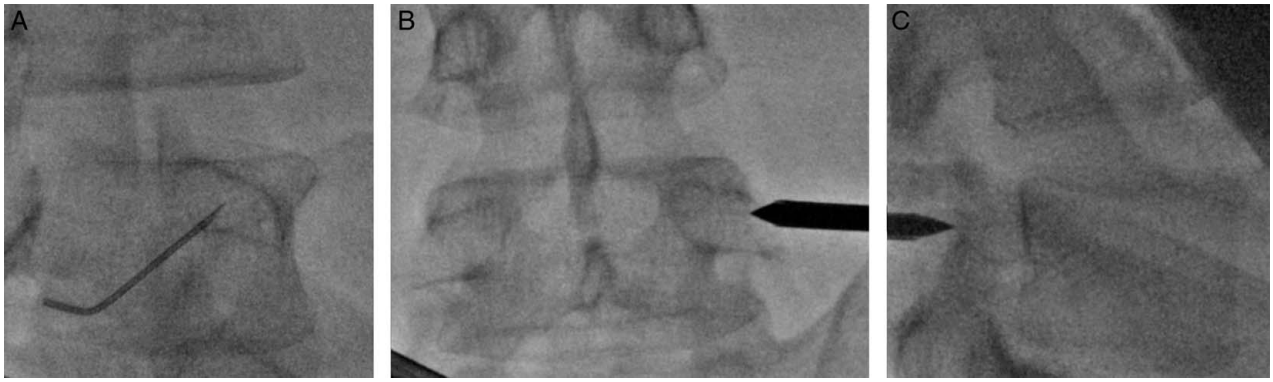

FIGURE 3. A, Oblique x-ray view with a radiopaque marker overlying the starting point on the lateral aspect of the right L5 pedicle. B, Anterior-posterior (AP) x-ray with introducer cannula assembly (ICA) showing stylet tip on the starting point on lateral pedicle. C, Lateral x-ray view showing the starting point on posterior pedicle.

of entry, whereas entering at the 3 o'clock or 9 o'clock position will allow entry more parallel to the basivertebral nerve and eliminate one plane that needs to be accounted for when advancing towards the target. A 22-gauge 5-inch Quincke needle is then inserted and advanced down to the pedicle to anesthetize the periosteum and entire soft tissue tract as it is removed. Optionally, AP and lateral images can be obtained when this needle is in place to confirm the planned trajectory. The skin incision is then made with a #10 or #11-blade scalpel in the same medial-lateral trajectory. Horizontal orientation of the blade will allow for better approximation at closure. The incision is made as a stab incision through the skin and just through the fascia.

The diamond-tip stylet with a red cap is then loaded into the introducer cannula with the blue handle, creating the introducer cannula assembly (ICA). Before inserting the ICA, it can be helpful to remove ~10 degrees of obliquity on the C-arm, as otherwise, the handle of the introducer cannula will obscure the distal tip and target the pedicle if advancing in a true coaxial manner. The ICA is inserted through the skin incision and advanced through the punctured fascia. It is then held with a clamp under the handle with the dominant hand to allow precise control while keeping hands out of the x-ray beam. The nondominant hand holds the ICA at the skin to advance it. The ICA is guided to contact bone at the lateral pedicle target. It can be walked medial slightly inside the pedicle border until the deepest part of the groove between SAP and TP is reached and may be felt to abut the base of the SAP. Once it is in the deepest part of the groove, it can also be walked cephalad and caudad to find a relatively flat entry point to prevent skiving during initial malleting. An AP image is obtained to confirm proper position (Fig. 3B), followed by a lateral image to confirm proper depth consistent with the posterior pedicle (Fig. 3C). At this point, wig-wag on the C-arm is utilized as needed to obtain a true lateral view and confirm that the pedicles are overlapping at the vertebral level being accessed. If the ICA appears superficial, it is likely too medial and on the facet joint. If it appears deep, it has likely slid over the TP and is lateral to the pedicle. If any adjustments for starting depth are made under the lateral view, another AP or oblique view should be obtained to confirm the proper starting point on the lateral pedicle. A lateral view also allows optimization of the cephalocaudal trajectory of the ICA before bone entry. Changing and optimizing the angle of entry with the ICA will be much more reliable than attempting to adjust the trajectory while inside the pedicle or vertebral body.

The ICA is advanced into the bone with gentle taps with a 1– 3 lb mallet to obtain purchase and is then advanced under lateral view with the mallet until the midpoint of the pedicle is reached. If the bone feels abnormally hard, it may be on the facet joint if superficial or at the medial pedicle border if deep; this will need to be confirmed and adjusted as needed under AP/oblique views. Once at the midpoint of the pedicle under lateral view, an AP view is obtained to confirm that the mid-pedicle has also been reached in the medial-lateral plane. The depth of the ICA on the lateral view should mirror the medial-lateral position on the AP view. If the stylet tip is more than slightly too medial or lateral at this time, adjustment of the ICA angle is made by gently pulling the cannula at the level of the skin, as opposed to at the handle. Forceful pulling at the handle can potentially bend the ICA or fracture the pedicle. Additional malleting is performed and checked on the AP and lateral views to confirm an optimal trajectory in the pedicle.

If still too medial in the pedicle on AP radiographs without being concordantly deep on lateral or too deep on lateral without being medial enough, one should switch to the bevel-tip stylet (Fig. 4). Because the tip of the bevel is on the side as opposed to in the middle on the diamond stylet, it will back up the cannula slightly when inserted. Therefore, ensure that the ICA is near mid-pedicle on lateral view before switching stylets to avoid completely dislodging the ICA from the bone. The tip of the bevel stylet, combined with pulling the ICA at the skin as needed, will allow maximal direction changes. If too medial on AP view, the bevel-tip should be turned laterally and advanced to confirm the breach of the medial pedicle

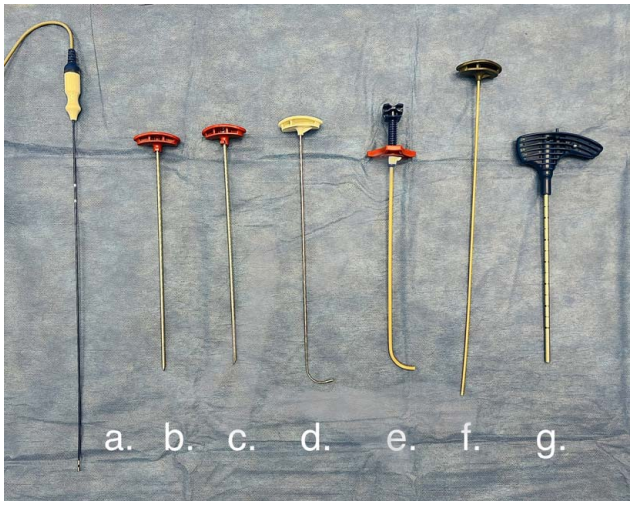

FIGURE 4. Intracept Equipment ("a" bipolar radiofrequency probe, "b" diamond-tip stylet, "c" bevel-tip stylet, "d" J-stylet, "e" curved cannula, "f" straight stylet, and "g" introducer cannula). full color online

will not occur, and vice-versa if starting too laterally.

Advancement continues under lateral view until approaching the cortex of the vertebral body. One more AP view is critical to confirm the medial cortex of the pedicle will not be breached before advancing the ICA into the vertebral body. The ICA is then advanced under lateral view until the entire tip of the stylet and leading edge of the cannula is within the vertebral body, at which time the stylet is removed (Fig. 5). If any angle adjustments of the ICA were needed during advancement through the pedicle, once the tip of the stylet is within the cortex of the vertebral body, further optimization of the angle can be made until the leading edge of the cannula is through the cortex. If using the bevel tip and the ICA had turned laterally in the pedicle, the ICA can be turned medially once in the vertebral body, as there is no longer a risk of medial pedicle breach and nerve root injury.

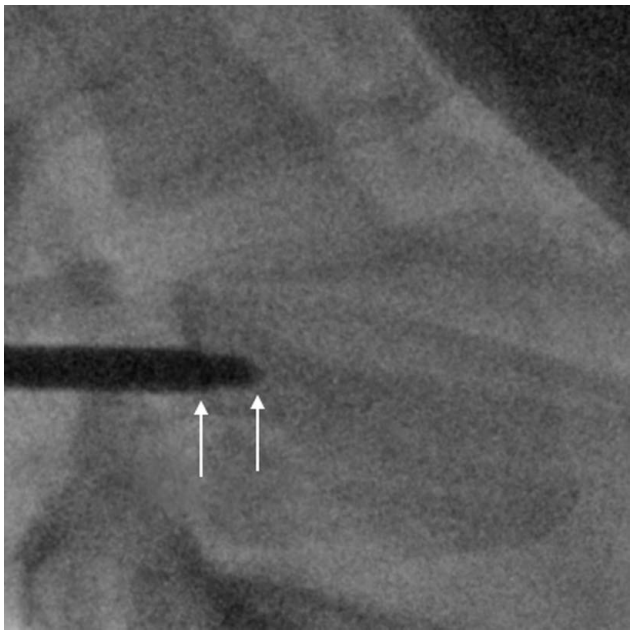

FIGURE 5. Lateral x-ray at L5 showing the endpoint of the ICA with the tip of the stylet and leading edge of the cannula in the vertebral body.

The straight stylet is then loaded into the curved cannula, made of polyetheretherketone (PEEK), creating the curved cannula assembly (CCA). The straight stylet is utilized to more easily load the curved cannula into the introducer cannula and is subsequently exchanged for the J-stylet, which is made of nitinol. Once the J-stylet is loaded into the introducer cannula with arrows on both devices aligned and pointing midline, the red wingnut is spun counterclockwise to the highest point. A lateral image is obtained to assess for any undesired curvatures in the J-stylet before deployment with malleting (Fig. 6A). The blue handle of the CCA can be spun to achieve the optimal trajectory of the J-stylet, which in this case is minor caudal curvature. It is important that the path of the J-stylet is optimized early on, as adjustments can be difficult once further into the vertebral body. Angle adjustments should be slight, otherwise overcorrections will occur. The mallet is used to gently and slowly advance the J-stylet, one 2 mm thread at a time, allowing it to heat up and curve towards the midline in the vertebral body. If the J-stylet is advanced quickly, either by harder or faster malleting, it will drive the tip straight/ventral instead of curving medially. Additional adjustments in trajectory are made by slightly rotating the blue handle of the CCA between malleting as needed and are possible up to ~1.5 cm of deployment. As the J-stylet curves towards the midline, its tip will begin to look smaller in the lateral view, which is known as foreshortening (Fig. 6B). A true AP view is obtained and advancement of the J-stylet continues until it is just past midline.

If the mid-vertebral body on AP is not reached with the J-stylet once all threads are exhausted (Fig. 6C), care should be taken to avoid further malleting as this can sheer off the tip of the PEEK cannula inside the vertebral body. The white indicator box on the handle will also show that "overdrive" is approaching once the black line becomes visible. Instead, the J-stylet should be exchanged for the straight stylet, which is then advanced past midline in AP by pinching the stylet above the handle while malleting to avoid kinking the straight stylet. Plunge in and out with the straight stylet before removal to clear the tract for the bipolar electrode. No directionality is available with the straight stylet, so one must make certain that the final trajectory is as desired before use.

The bipolar probe is then inserted until the distal white line on the probe is flush with the top of the blue hub on the CCA. Next, the red wingnut is spun clockwise to retract the PEEK sheath of the curved cannula off the electrodes at the distal tip of the bipolar probe, confirmed with the proximal white line being flush with the CCA

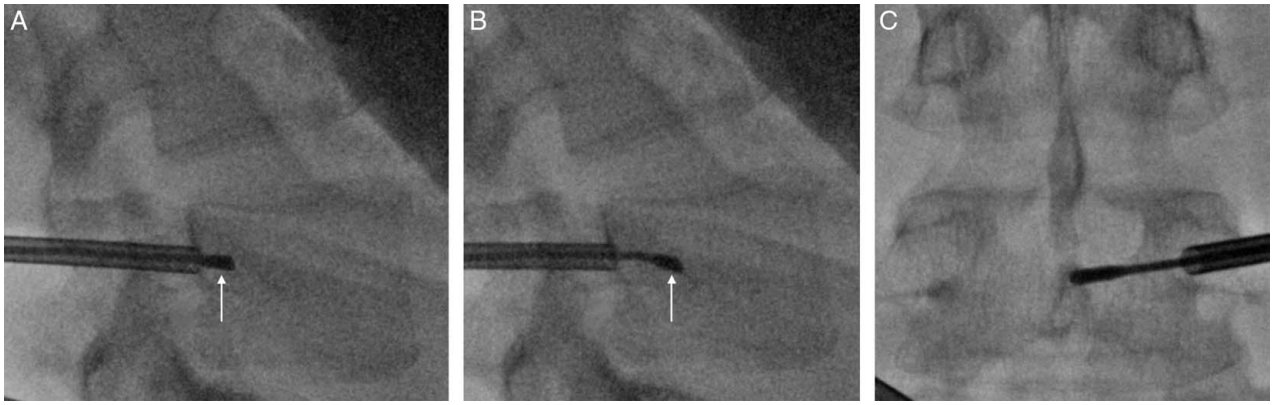

FIGURE 6. A, Lateral x-ray with the J-stylet of the curved cannula assembly beginning to exit the introducer cannula into the vertebral body at L5. B, Lateral x-ray view with J-stylet starting to curve medially, known as foreshortening. C, AP x-ray with the J-stylet approaching midline at L5.

hub. Probe placement is verified in a true AP view to make certain the bipolar electrodes are midline (usually when the electrodes straddle the spinous process) and lateral view to confirm proper depth (Fig. 7). The radiofrequency generator is then turned on to create the thermal lesion. Two ablation protocols are available based on placement accuracy and desired lesion size: 75 °C for 7 minutes (5 mm ablation zone radius) or 85 °C for 15 minutes (6 mm ablation zone radius). While the first lesion is being created, a second ICA is advanced through the skin and soft tissues on the contralateral side for the next lesion in the same manner as mentioned previously, again considering level-specific anatomical factors.

The S1 level has several unique access characteristics compared with the typical lumbar level. The target entry point is visualized over the midpoint of the lateral S1 pedicle with a squared S1 SEP (Ferguson view), typically obtained with substantial cephalad tilt on the C-arm (Fig. 8). As the lateral border of the S1 pedicle is sometimes poorly visualized in an oblique view, as compared with the distinct medial border, it can be targeted directly inferior to the junction of the S1 SAP and sacral ala. The oblique angle and trajectory are as determined on preoperative MRI and x-ray review; however, even if a very oblique angle is possible with the iliac crest location, one should not start beyond ~30 degrees obliquity. Without preoperative planning, the C-arm is obliqued from the Ferguson view until just before the medial iliac crest overlies the target on the pedicle. However, if this level is accessed in the same manner as a lumbar level, which is often 35–45 degrees of obliquity, placement will likely be too posterior preventing one from reaching the S1 target of 50% from posterior to

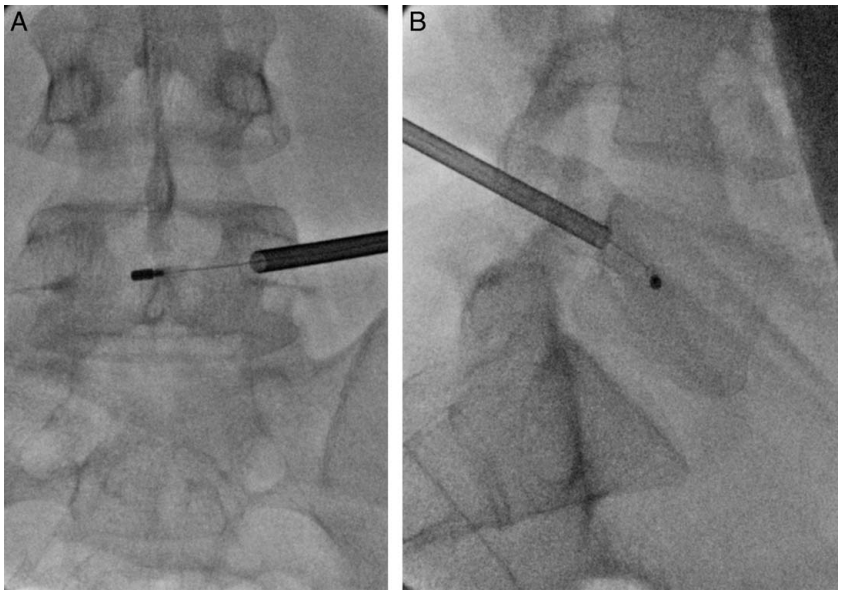

FIGURE 7. A, AP x-ray demonstrating final midline position of the electrode at L5. B, Lateral x-ray with final position of the electrode between 30% and 50% from the posterior vertebral body and 50% from the superior and inferior endplates.

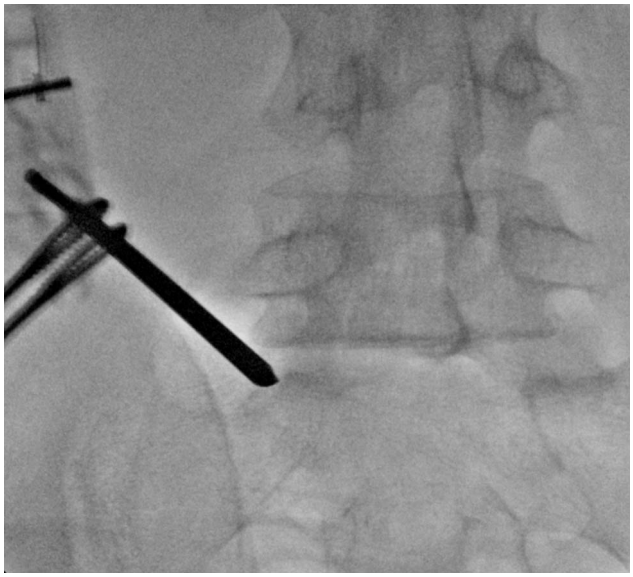

FIGURE 8. Oblique x-ray at S1 showing the tip of the ICA at the lateral pedicle starting point.

anterior cortex without additional adjustments. Conversely, if the iliac crests are very high/medial and the angle of entry approaches ≤ 15 degrees, the bevel-tip stylet can be used for access to allow for medial advancement once bone is contacted, in combination with pulling the cannula at the skin to accentuate the angle as needed once in bone. A steeper cephalocaudal tilt can also be used to be able to obtain more of an oblique starting angle when needed. If this is perfomed, the J-stylet will need to be directed cephalad to compensate. In this case, the initial deployment of the CCA was too posterior in the vertebral body, so the ICA advanced further into the vertebral body than normal before redeploying the CCA to the target (Fig. 9). This will be discussed further in the pearls and pitfalls section.

Once each lesion is completed, the entire equipment assembly with a probe is removed together. Do not remove the probe first, as this may result in shearing of the probe. Occasionally, probe removal is needed due to high impedances that cannot be overcome with automatic adjustments by the generator. The probe should be removed very slowly to clean off any coagulated blood on the tip. A few plunges of the straight stylet before replacing the probe will usually eliminate a subsequent impedance spike. Hemostasis is achieved and closure is accomplished by applying a skin adhesive or steri-strip to each incision with an overlying dressing or adhesive bandage.

POSTPROCEDURE MANAGEMENT

To aid with postoperative pain management and mitigate any transient radiculitis, which occurs at a rate of ~5%, intraoperative intraveneous steroids (Solu-Medrol 125 mg) are recommended unless the patient has poorly controlled or labile diabetes. The dressing can be removed on postoperative day 1, at which time the patient may shower. Any steri-strips are left in place until they fall off or are removed at the 2-week follow-up appointment. Patients should use ice and oral analgesics as needed for 1 to 4 days. Postprocedure pain typically diminishes significantly from day to day. Radiculitis may have a delayed onset but is transient and often responsive to oral steroids. Patients are not permitted to submerge underwater for 2 weeks and should avoid repetitive bending, twisting, and lifting greater than ~15 lbs for 2 weeks. Gradual resumption of normal activities as tolerated may follow. Maximal pain relief from the procedure varies between several days to up to three months postoperative and should be durable for at least 5 years, if not permanent.

PEARLS AND PITFALLS

Throughout this manuscript, pearls and pitfalls have been included in an interspersed manner with their applicable portions of the procedure. Additional pearls and pitfalls are discussed in detail in this section.

Often one will encounter an entry angle that is less than optimal for the treated level to allow for posterior placement of the CCA at L3–L5 and midline placement at S1. This may be due to narrow and/or sagittal pedicles at L3–L5 or medial iliac crests at S1. In this setting, the "retraction" method may be used. Access to the vertebral body is obtained in the usual manner, with the stylet and leading edge of the cannula. Once the CCA is in place, the J-stylet is held in place with one hand, while the other hand gently rotates and retracts the cannula 0.5–1 cm out of the vertebral body and into the pedicle. The CCA with J-stylet is slowly malleted to catch bone and starts turning medially more posteriorly in the vertebral body than it otherwise would. This can be accentuated by pulling the cannula laterally at the skin, taking care not to break a narrow or osteoporotic pedicle.

The opposite problem can also occur, where standard access with the CCA curves medially too soon, risking thermal injury to the spinal canal if < 1 cm away from the cortex or being inefficacious if too posterior from the S1 target. Adequate clearance from the posterior vertebral is confirmed if the entire 9 mm tip of the J-stylet is visualized fully beyond the cortex of the posterior vertebral body before foreshortening (Fig. 6A). There are 2 ways to manage being too posterior. If the J-stylet is noted to start foreshortening too posteriorly, switching to the straight stylet is advised. This must be done when the J-stylet is starting to go partially medial, not fully foreshortened, to allow for a ventral/medial trajectory. If this does not result in a satisfactory correction, the CCA can be removed, the diamond stylet reinserted, and the ICA can be driven further into the vertebral body before redeploying the CCA. This is essentially the opposite of the retraction method. This can be repeated if necessary to get even more anterior, often with the bevel tip, if a final placement is very challenging at S1 and the angle of entry at the skin is wide enough to allow for it.

Care should be taken to avoid being too anterior, as once that tract is created, it is generally very challenging to create a new tract to obtain more posterior placement in the vertebral body. Before aborting the side and restarting access

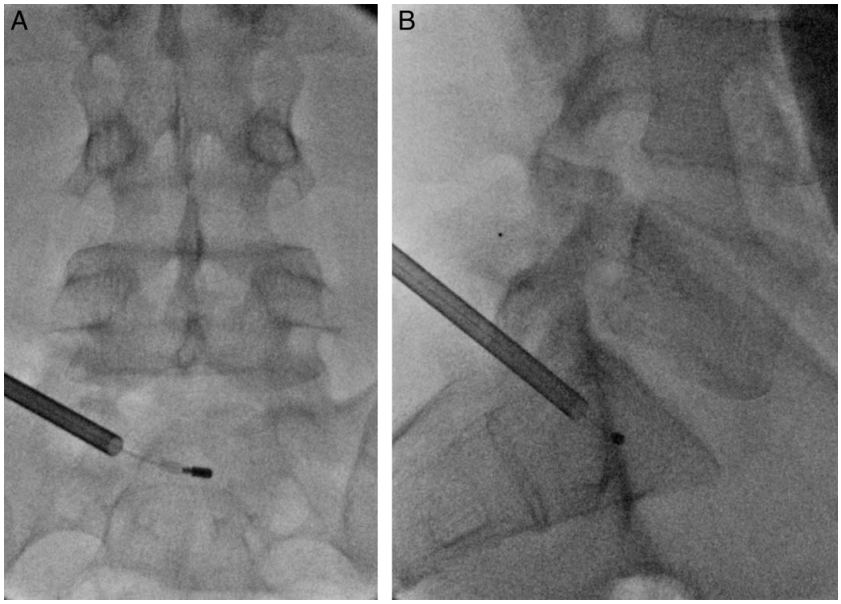

FIGURE 9. A, AP x-ray demonstrating final midline position of the electrode at S1. B, Lateral x-ray with final position of the electrode between 50% from the anterior and posterior vertebral body and 40% from the superior endplate.

on the contralateral pedicle, one can try retracting the ICA slightly and aggressively turning the J-stylet cephalad or caudad to try to create a brand new tract in the vertebral body.

If hard bone is encountered while advancing the ICA through the pedicle and before the vertebral body is reached, one must first make certain they are not at the medial pedicle border to avoid a pedicle breach and possible nerve injury by checking an AP or oblique view. Beyond this point, the ICA will typically be at the pedicle-vertebral body junction. Using a heavier mallet and harder strikes will usually suffice, but a hand drill may be necessary to breach the cortex of the vertebral body. The stylet is removed and replaced with the hand drill. Light pressure and slow rotations are used to advance just through the density. The stylet, preferably the diamond, can then be replaced, and malleting resumed.

With regard to preoperative planning, in cases where there is no clear transpedicular path due to very narrow or sagittal pedicles, very lateral superior articular process in relation to the pedicles, or obstruction by pedicle screws, an extrapedicular approach may be an option. The details of this off-label technique are beyond the scope of this manuscript.

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