Basivertebral Nerve Ablation

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Abstract

Low back pain is one of the most prevalent musculoskeletal ailments in the United States. Intraosseous radiofrequency ablation of the basivertebral nerve is an effective and durable therapy for low back pain and can be offered to patients who have chronic low back pain of greater than 6 months of duration, failure to respond to noninvasive therapies for 6 months, with either Modic Type I or Type II changes at L3–S1. This article reviews the anatomy and physiology, patient selection, technique, and evidence regarding basivertebral nerve ablation.

Keywords

- interventional radiology
- pain management
- basivertebral nerve
- nerve ablation

Low back pain (LBP) is one of the most common musculoskeletal ailments and the leading cause of years lived with disability in the world.[1] It is also the most expensive occupational disorder in the United States with around 30 million people currently suffering from LBP,[2] resulting in nearly 50 million physician visits annually.[3] Conservative management is typically the first-line intervention for patients with LBP with treatment strategy including avoidance of aggravating factors, physical therapy, exercise programs, massage therapy, low-impact aerobic exercise, and pharmacologic pain management (i.e. nonsteroidal anti-inflammatory drugs, nonnarcotic analgesics).[2] Invasive therapies are often utilized only in chronic or refractory cases of LBP. These include local regional therapies such as epidural steroid injections, facet injections, rhizotomy, and surgical decompression. These therapies can bring about transient or sometimes durable relief but outcomes are variable and inconsistent.[4] Epidural injections have the potential to cause several adverse outcomes such as impaired glucose control, insomnia, and hypertension or periprocedural complications including vasovagal reactions, nausea, and increased back or leg pain.[5] More serious complications such as infection, hematoma, central or peripheral nerve injury, and hypersensitivity reactions may also occur. Recently, intraosseous ablation of the basivertebral nerve has been introduced as an effective treatment for LBP in select patients and the International Society for the Advancement of Spine Surgery (ISASS) has integrated this treatment modality into their LBP management guidelines in 2019.[6]

Anatomy and Pathophysiology

The source of chronic LBP has been an evolving area of research. Initially thought to be related to the intervertebral disc, the discogenic pain theory was revised when studies demonstrated that it was, in fact, pain receptors within the vertebral end plates, transmitted via the basivertebral nerves (►**Fig. 1**) that are damaged in degenerative disease.[7,8] Basivertebral nerves (BVNs) are postulated to be responsible for transmission of pain signals from the endplate as evidenced by the presence of nociceptive neurotransmitters as well as increased presence in areas of discogenic disease corresponding with LBP.[7–10]

Modic Type I and Type II changes on magnetic resonance imaging (MRI) are associated with discogenic disease and LBP (►**Fig. 2**). Degenerative disease will lead to release of inflammatory markers leading to the development of Modic changes (MCs) as it has been shown that an increased

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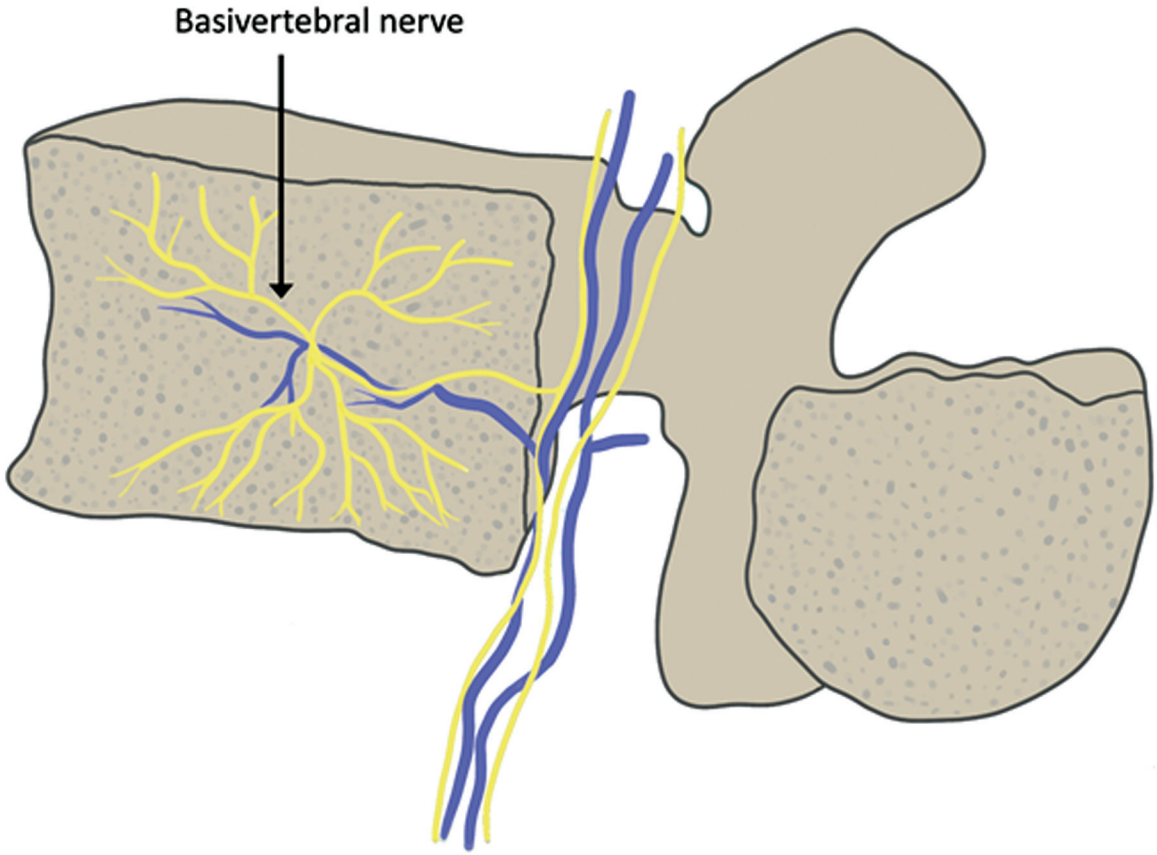

Fig. 1 Diagram of basivertebral nerve (yellow) as it travels alongside the basivertebral vessels (blue).

expression of toll-like receptors (TLRs), and activation of TLRs in marrow and disc cells leading to increased transcription of NF-κB genes.[11] The enzymatic process releases catabolites and damage-associated molecular patterns which may enable the formation of MC, as chronic activation of TLRs may generate adipose tissue and instigate adipocyte hypertrophy.[12] Discs neighboring MC produce increased cytokines and osteoclastic factors than discs with a similar degree of degeneration without nearby MC.[13] In fact, Modic Type I and II changes are required (along with chronic LBP for 6 months of duration and failure to respond to at least of 6 months of nonsurgical management) to consider basivertebral nerve ablation according to the International Society for the Advancement of Spine Surgery (ISASS).

Fig. 2 Preoperative lumbar spine MR for patient undergoing basivertebral ablation. Sagittal T2-weighted (**a**) and T1-weighted (**b**) MR of the lumbar spine demonstrating endplate degenerative changes with increased T1 and T2 signals in L3 and L4 consistent with Modic Type II changes.

Basivertebral Ablation Indications and Technique

The indications and contraindications of basivertebral ablations are presented in ►**Table 1**. The procedure can be performed under general anesthesia or moderate sedation per institutional protocol, physician, and patient preference. Currently, the only FDA-approved system for basivertebral ablation (BVA) is the Intracept system by Relievant (Intracept System, Relievant Medsystems, Sunnyvale, CA), although radiofrequency ablation of the basivertebral nerve can be achieved using other systems as well in Europe.

Patient Positioning and Periprocedural Considerations

A representative from Relievant is also typically present for these procedures to provide technical support. The patient is placed in the prone position on the angiography table. A bump or pillow can be placed underneath the patient to achieve optimal levels of lumbar extension. Arms should be

Table 1 Indications and contraindications of basivertebral ablation

Indication	Contraindications
Chronic axial low back pain >6 mo refractory to conservative therapy for >6 mo *and* Modic Type 1 or 2 changes on MRI in L3–S1 at one or more levels	Active systemic or local infection
	Skeletal immaturity
	Pregnancy
	Pacemakers, defibrillators or other electronic implants
	Severe cardiac or pulmonary compromise
	Ablation zone is <10 mm from spinal canal

positioned at the head, especially if using a bi-plane, with careful attention to avoid brachial plexus injury.

The prep should include the thoracolumbar region with iodine-based solution. Once prepped, the area is draped in sterile fashion using a drape. Following this, a surgical timeout is called to confirm the procedure and patient and preprocedural antibiotic is administered, typically 2 g of cefazolin IV.

Intracept Procedure Technique

The first step in the procedure is to square the pedicles and vertebral bodies in anteroposterior and lateral. The needle insertion site and periosteum are anesthetized by lidocaine injection via a 20-gauge needle. The intended vertebral body is accessed via a transpedicular approach with the Intracept (R) trocar with a non-beveled introducer needle. Once the trocar approximates the posterior border of the vertebral body, the introducer needle is removed and a J-Stylet and the introducer are advanced into appropriate position within the posterior one-third of the vertebral body, with tip just across midline. The radiofrequency probe is then inserted into position under direct fluoroscopic guidance. Radiofrequency ablation is typically performed for 15 minutes at 85 °C. Following ablation, the probe and needles are removed. A Syvek (Marine Polymer Technologies, Inc., Danvers MA) patch is placed over the skin puncture sites and manual compression is held for 5 minutes or until hemostasis is ensured. Several intraprocedural fluoroscopic images may be viewed in ►**Fig. 3**. A postprocedural lumbar spine MR

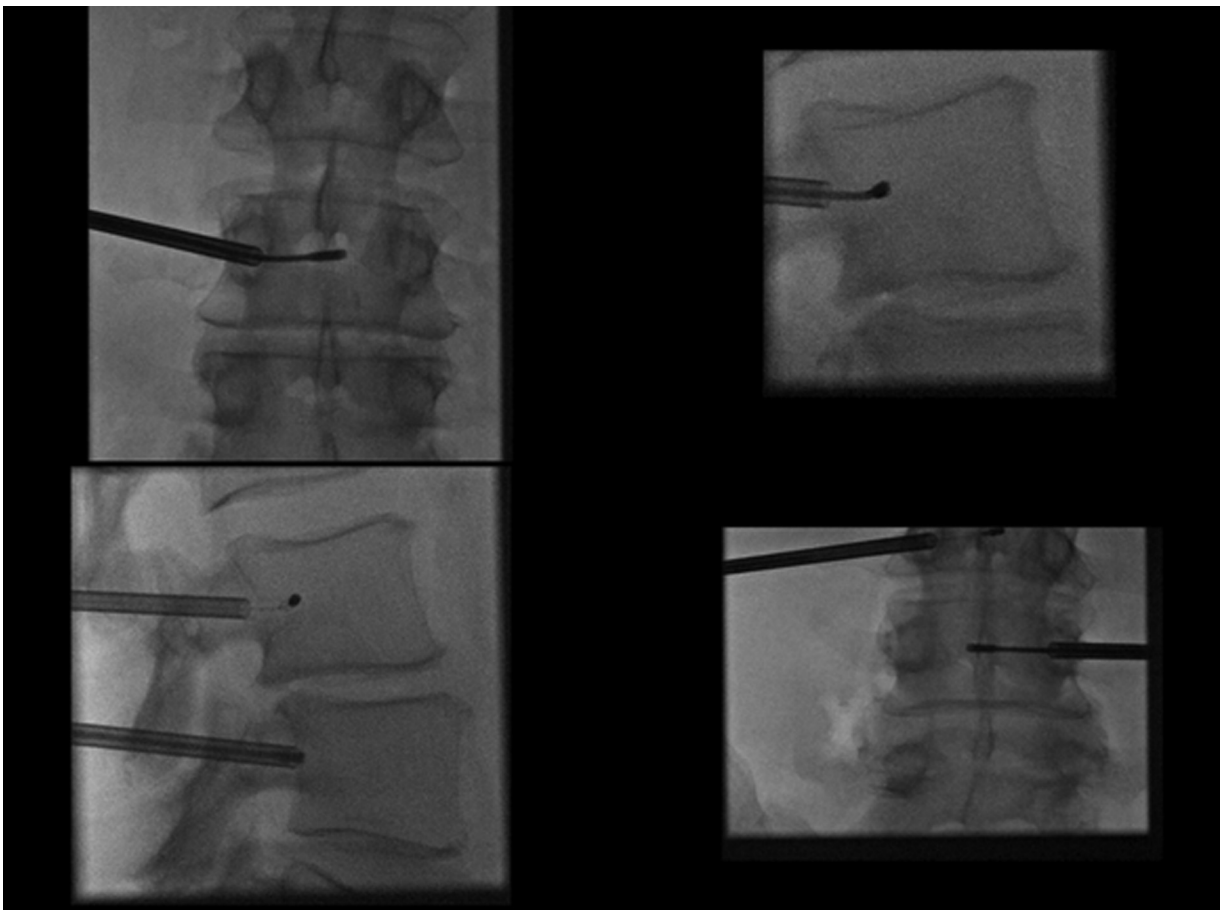

Fig. 3 Intraprocedural images of L3 and L4 basivertebral nerves.

obtained approximately 5 months following BVA is presented in ►**Fig. 4**.

Discussion

BVA is an emerging, novel technique aimed at treating LBP. Becker et al conducted the pilot study to determine the safety and efficacy of this modality in treating chronic LBP.[14] This study enrolled 17 patients (mean age of 48) with chronic LBP and either MC 1 (bone marrow edema and inflammation) or MC 2 (conversion of normal red hematopoietic bone marrow into yellow fatty marrow) changes on MRI.[2] Sixteen of the 17 patients were successfully treated using BVA, as evaluated via the Oswestry Disability Index (ODI) and visual analog scale (VAS), which were calculated at the time of and 3 months after the procedure with statistically significant improvement in ODI from 52 to 23 (0–100, the lower the better) and VAS from 61 to 45 (0–100, the lower the better).

Fig. 4 Postoperative lumbar spine MR in patient who underwent basivertebral ablation 5 months prior. Sagittal T2-weighted (**a**) and T1-weighted (**b**) images; T1/T2 signal hyperintensity in the intervened upon L3 and L4 vertebral bodies (arrows).

Following the pilot study, the INTRACEPT study is a prospective randomized control trial comparing intraosseous radiofrequency ablation to standard-of-care treatment in chronic LBP.[15] A total of 104 patients with a mean age of 50 and chronic LBP of at least 6 months of duration with Type I or II MC between L3 and S1 were included in the study. At 3-month follow-up, BVN outperformed the standard of care: ODI decreased by 25 points compared with 4 in the standard-of-care group; and BAS decreased by 3.5 compared with 1 in the standard-of-care group. The significance was so profound that the planned interim analysis at 3 months resulted in the third-party data management committee to recommend halting the study in favor of offering crossover to the control group.

Subsequently, the SMART study enrolled 225 patients (mean age of 47 years) with chronic LBP with MC1 or MC2 changes in vertebral bodies L3 to S1 to evaluate the safety and efficacy of radiofrequency ablation of the basivertebral nerve.[16] Seventy-eight patients were designated to the control group (simulated radiofrequency ablation) and 147 patients in the treatment group. The primary endpoint for efficacy was change in ODI scores from baseline to 3 months postprocedure, and the primary endpoint for safety was musculoskeletal and neurologic adverse events at 12 months. At 3 months, there was statistically significant decrease in ODI, and no device or procedure-related adverse events through 12 months in patients treated with radiofrequency ablation. At 24 months, the patients of the SMART trial were reevaluated, BVA was offered to the patients in the control group, and 73% elected to cross.[16] Improvements in the ODI, Short Form-36, and VAS were found to significantly improve at 3, 6, 9, 12, 18, and 24 months. At 5 years, 85% of the treatment arm was retained and demonstrated sustained ODI decrease in 61% of patients as well as sustained VAS decrease in 65% of patients.[17]

Conclusion

Overall, several studies have demonstrated the safety and effectiveness of BVA in treating chronic LBP, specifically patients with MC I and II involving L3–S1. Within this setting, BVA has shown a clinically meaningful reduction in validated pain outcomes in patients with chronic LBP. Further study should be performed to further validate the vertebrogenic model of LBP and to further refine the technical aspects of the procedure.

Conflict of Interest
None declared.

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